Court File No.: CV-12-9667-00CL

ONTARIO
SUPERIOR COURT OF JUSTICE

COMMERCIAL LIST

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, c. C-36, AS AMENDED, AND IN THE MATTER OF A PLAN OF COMPRISE OR ARRANGEMENT OF SINO-FOREST CORPORATION

Court File No. CV-11-431153-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

THE TRUSTEES OF THE LABOURERS' PENSION FUND OF CENTRAL AND EASTERN CANADA, THE TRUSTEES OF THE INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 793 PENSION PLAN FOR OPERATING ENGINEERS IN ONTARIO, SJUNDE AP-FONDEN, DAVID GRANT and ROBERT WONG

Plaintiffs

- and -

SINO-FOREST CORPORATION, ERNST & YOUNG LLP, BDO LIMITED (formerly known as BDO MCCABE LO LIMITED), ALLEN T.Y. CHAN, W. JUDSON MARTIN, KAI KIT POON, DAVID J. HORSLEY, WILLIAM E. ARDELL, JAMES P. BOWLAND, JAMES M.E. HYDE, EDMUND MAK, SIMON MURRAY, PETER WANG, GARRY J. WEST, PÖYRY (BEIJING) CONSULTING COMPANY LIMITED, CREDIT SUISSE SECURITIES (CANADA), INC., TD SECURITIES INC., DUNDEE SECURITIES CORPORATION, RBC DOMINION SECURITIES INC., SCOTIA CAPITAL INC., CIBC WORLD MARKETS INC., MERRILL LYNCH CANADA INC., CANACCORD FINANCIAL LTD., MAISON PLACEMENTS CANADA INC., CREDIT SUISSE SECURITIES (USA) LLC and MERRILL LYNCH, PIERCE, FENNER & SMITH INCORPORATED (successor by merger to Banc of America Securities LLC)

Defendants

Proceeding under the *Class Proceedings Act, 1992*

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(Motion for Fee Approval, returnable December 13, 2013)

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Court File No. CV-12-9667-00-CL

ONTARIO
SUPERIOR COURT OF JUSTICE
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IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, c. c-36, AS AMENDED

AND IN THE MATTER OF A PLAN OF COMPROMISE OR ARRANGEMENT OF SINO-FOREST CORPORATION

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TABLE OF CONTENTS

Case Name:

Baker Estate v. Sony BMG Music (Canada) Inc.

RE: The Estate of Chesney Henry "Chet" Baker et al., Plaintiffs/Moving Parties, and Sony BMG Music (Canada) Inc. et al., Defendants/Respondents

[2011] O.J. No. 5781

2011 ONSC 7105

98 C.P.R. (4th) 267

210 A.C.W.S. (3d) 586

31 C.P.C. (7th) 320

2011 CarswellOnt 15453

Court File No. CV-080036065100 CP

Ontario Superior Court of Justice

G.R. Strathy J.

Heard: November 22, 2011.
Judgment: November 30, 2011.

(97 paras.)

Civil litigation -- Civil procedure -- Parties -- Class or representative actions -- Class counsel -- Fees -- Retainer agreement -- Settlements -- Approval -- Application by class counsel for approval of their fees, taxes and disbursements allowed in part -- Action was settled and settlement was approved by court -- Retainer agreements between the representative plaintiffs and class counsel and fees sought by counsel were approved -- Counsel achieved excellent results in this complicated matter, which involved substantial risks for them, and their skill and competence was exceptional -- Request for compensation for representative plaintiffs was denied -- They substantially contributed to the settlement but this was not rare and exceptional case where payment was required.

Legal profession -- Barristers and solicitors -- Compensation -- Contingency agreements -- Fair and reasonable -- Measure of compensation -- Reasonable charges, reasonably performed -- Taxation or assessment of accounts -- Application by class counsel for approval of their fees, taxes and disbursements allowed in part -- Action was settled and settlement was approved by court -- Retainer agreements between the representative plaintiffs and class counsel and fees sought by counsel were approved -- Counsel achieved excellent results in this complicated matter, which involved substantial risks for them, and their skill and competence was exceptional -- Request for compensation for representative plaintiffs was denied -- They substantially contributed to the settlement but this was not rare and exceptional case where payment was required.

Professional responsibility -- Remuneration -- Fees -- Contingency fees -- Professions -- Legal -- Barristers and solicitors -- Application by class counsel for approval of their fees, taxes and disbursements allowed in part -- Action was settled and settlement was approved by court -- Retainer agreements between the representative plaintiffs and class counsel and fees sought by counsel were approved -- Counsel achieved excellent results in this complicated matter, which involved substantial risks for them, and their skill and competence was exceptional -- Request for compensation for representative plaintiffs was denied -- They substantially contributed to the settlement but this was not rare and exceptional case where payment was required.

Application by class counsel for approval of a request for payment of fees, taxes and disbursements in the amount of $7,647,583. The fee portion was $6,950,000, taxes were $610,805 and disbursements were $86,778. This class action was brought in 2008 on behalf of artists and rights holders who had not received full compensation for the use of their works. It was initially commenced by Carol Baker, who was the widow of an entertainer named Chet Baker. She was the initial representative plaintiff and an individual named Northey replaced her due to a dispute regarding the administration of her husband's estate. The Court approved the settlement that was reached in the amount $46,688,805. These funds were to be paid into a settlement trust for the benefit of the class. The defendants also agreed to pay $600,000 on account of the plaintiffs' costs. This reduced class counsel's claim to $7,047,583. Both representative plaintiffs executed contingent fee agreements that stipulated a maximum counsel fee of 30 per cent of the amount recovered. The fee portion represented 15 per cent of the settlement fund which was a significant discount of the fee that class counsel were contractually entitled to. The fee request was supported by the widow and by Northey. Some parties objected to the fee and the matter was adjourned to allow them to file additional materials. An interim payment of $2,200,000 plus taxes and disbursements was approved as a condition of the adjournment. All the objectors acknowledged that class counsel was entitled to a fee of at least this amount. Class counsel also sought honorariums for the two representative plaintiffs.

HELD: Application allowed in part. The retainer agreements between the representative plaintiffs and class counsel were approved. They met the requirements of the Class Proceedings Act. The fees of class counsel in the amount of $6,250,000 plus taxes was approved. Such was to be paid out of

the settlement trust. The results that were achieved were excellent, especially since the defendants had serious defences available to them. The gross recovery under the settlement was almost the full amount that was owed to class members. The net recovery after the deduction of fees was between 80 per cent and 85 per cent of the amount owed. This case involved significant factual and legal complexities. The settlement itself was extremely complicated. The skill and competence demonstrated by class counsel was exceptional. The risk undertaken by class counsel and the opportunity cost was sizeable. The action took four years to complete and during those years class counsel, who spent 6,000 hours on the file received no compensation. The approved fee was fair and reasonable. Class counsel were also entitled to render invoices on an hourly rate basis for any services rendered in the implementation of the settlement. The representative plaintiffs were not entitled to compensation. Even though the representative plaintiffs made a significant contribution to the settlement, this was not one of those rare and exceptional cases where such payment was required.

Statutes, Regulations and Rules Cited:

Class Proceedings Act, 1992, S.O. 1992, c. 6, s. 5, s. 32(2), s. 33

Copyright Act, R.S.C. 1985, c. C-42,

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ENDORSEMENT (CLASS COUNSEL
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1 G.R. STRATHY J.:--

I get along without you very well,
of course I do.
Except when soft rains fall
and drip from leaves, that I recall
the thrill of being sheltered in your arms.
Of course I do,
but I get along without you very well.

Chet Baker, I Get Along Without You Very Well (Except Sometimes)

Chet Baker was an American trumpeter and jazz singer. He was born in 1929 and died in Amsterdam in 1988 in tragic circumstances, after a troubled and turbulent life. He left behind an impressive, if occasionally melancholic, legacy of music.

2 Unfortunately, Mr. Baker and his heirs, like many musicians and their families, did not receive full compensation for the use of his works by others. This was the result of a royalty and licensing system in Canada that permitted third parties, such as the defendants, Sony BMG Music (Canada) Inc. ("Sony"), EMI Music Canada Inc. ("EMI"), Universal Music Canada Inc. ("Universal") and Warner Music Canada Co. ("Warner") (collectively, the "Record Labels"), to reproduce and distribute copyrighted musical works owned or controlled by musicians or their rights holders, without having a licence to do so or without paying the royalties due to the rights holders.

3 The issue was well known by the defendants Canadian Musical Reproduction Rights Agency Ltd. ("CMRRA") and Society for Reproduction Rights of Authors, Composers and Publisher (SODRAC) Inc. ("SODRAC"), (referred to as the "Collectives"). They had been aware of the problem for years and had apparently been unwilling or unable to resolve it. CMRRA represents the reproduction rights of the vast majority of music publishers whose repertoires are in use in Canada. SODRAC is a copyright collective that administers the reproduction rights in musical works and collects royalties on behalf of its clients. Due to a combination of factors, including the Collectives' lack of resources and the absence of motivation on the part of the Record Labels, nothing significant was done. The problem simply festered and grew worse - until this proceeding was commenced.

4 This class action was brought in 2008 on behalf of artists and rights holders who had not received full compensation for the use of their works. It was initially commenced by Mr. Baker's widow, Carol Baker. Mrs. Baker saw it through almost to completion before she was required to withdraw as a result of a dispute concerning the administration of her husband's estate. Craig Northey, a Canadian singer/songwriter, agreed to step into the role of representative plaintiff to complete the work commenced by Mrs. Baker, ultimately finalizing a settlement with the defendants and establishing a structure not only to resolve past injustices, but to establish a mechanism to ensure that they did not recur.

5 On May 30, 2011, I approved the settlement of this class proceeding. It will result in the payment of $46,688,805.91 into a settlement trust for the benefit of the class. In addition, the Record Labels will pay $600.000.00 as a contribution to the costs incurred by the Class.

6 Class Counsel subsequently moved for approval of a request for payment of fees, taxes and disbursements in the amount of $7,647,583.85. The fee portion is $6,950.000.00, taxes are $610,805.19 and disbursements are $86,778.66. After the deduction of the $600,000.00 paid by the Record Labels, the sum of $7,047,583.85 would be paid out of the settlement fund. The fee portion of the account of Class Counsel represents a payment of approximately 15% of the settlement fund.

7 On October 27, 2011, when this motion came on for hearing, some of the objecting parties requested an adjournment to consider the filing of additional material. As a condition of the adjournment, I approved an interim payment of $2,200,000.00 plus taxes and disbursements. All objectors acknowledged that Class Counsel was entitled to a fee of at least that amount.

8 Class Counsel also ask for permission to pay an honorarium of $3,000, to each of Mr. Northey and Mrs. Baker.

Background

9 This action was brought under the Class Proceedings Act, 1992, S.O. 1992, c. 6 ("C.P.A.") on behalf of owners of copyright in certain musical works in relation to a systemic practice by the Record Labels whereby musical works were exploited without securing the necessary licences and/or without payment of the applicable mechanical royalties. The representative plaintiffs alleged that these parties were liable for infringing copyright in musical works, by reproducing those works in sound recordings released or distributed in physical formats in Canada without securing licences from the owners of the copyright to reproduce those works and/or by failing to pay the required royalties. The claim made further allegations against the Collectives in their capacity as intermediaries between copyright owners and the Record Labels.

10 A brief description of the problem will be sufficient for the purposes of this motion.

11 Prior to 1988, the Copyright Act, R.S.C. 1985, c. C-42 contained a compulsory statutory licence for mechanical reproduction of musical works, which set royalties at two cents per playing surface. Because the licence was mandatory, and the royalty was fixed, the practice developed that record companies would release new records without applying for a licence in advance. This was an efficient method of operation, but it meant that the owner of the copyright in the work had to be located and paid. That was often a problem. The Record Labels began to develop what was referred to as the "Pending Lists", to record their use of musical works for which the owners of the copyright had not been paid.

12 The statutory licence was repealed in 1988. This meant that it was now necessary to negotiate a licence in the case of each musical work. It fell to CMRRA to negotiate the terms of the licences. Unfortunately, in practice, there were serious problems, largely administrative.

13 The practice of the record companies of "breach copyright now, pay later" continued under the new copyright regime, except that in some cases the "pay later" was not happening. Due to ongoing difficulties in identifying owners of copyright, and other administrative problems, the size and value of the items on the Pending Lists continued to grow. By the time this action was commenced, the list contained more than 250,000 items, with an estimated value in excess of $50,000,000.

14 CMRRA had attempted, over the years, to address the issue of the Pending Lists. Although some progress was made from time to time, it is my impression that both CMRRA and the Record

Labels had more pressing current issues to deal with and there were neither the resources, nor the will, to treat the Pending Lists as a priority.

This Action

15 This action was commenced on the instructions of Carol Baker in the name of the Estate of Chesney Henry "Chet" Baker Junior and Chet Baker Enterprises LLC, by Statement of Claim issued on August 14, 2008. It was brought against the Record Labels and the Collectives.

16 On September 3, 2008, a Fresh as Amended Statement of Claim was issued and October 6, 2008, an Amended Fresh as Amended Statement of Claim was filed. Class Counsel filed a Certification Motion Record on January 26, 2009.

17 The action was, in a sense, welcomed by the Collectives because it got the urgent attention of the Record Labels and it provided a potential framework for the resolution of the Pending Lists problem. On October 2, 2008, Class Counsel concluded a cooperation and settlement agreement with the Collectives. On March 31, 2009, Class Counsel moved for approval of the settlement agreement with the Collectives.

18 The decision by Class Counsel to sue the Collectives and to negotiate a settlement agreement with them provided to be a shrewd tactical move. It isolated the Record Labels and it took advantage of the expertise and resources of the Collectives in prosecuting the action against the Record Labels. There is no question that the assistance of the Collectives, and their Lawyers, has contributed to the successful resolution of this matter and the establishment of a workable system going forward.

19 The plaintiffs served a motion record for certification in January, 2009.

20 I was appointed to case manage this proceeding in the fall of 2009. I have presided over about ten in-person case conferences and an equal number of teleconferences with counsel. There have also been several court appearances. I will describe my observations concerning these attendances, and of the dynamics of the litigation, in due course.

21 Settlement discussions between the parties began in earnest in March of 2010. The parties attended before Justice Colin L. Campbell, acting as a mediator, over several dates. These discussions continued on a vigorous and adversarial basis until settlement agreements were reached with each of the Record Labels.

22 Settlement terms were reached fast with Sony, followed by Warner and then EMI in close succession in June 2010. Settlement documentation was executed with those labels throughout July and August of 2010. Minor amendments were made to the Sony settlement agreement and a final version was signed in December of 2010.

23 Negotiations with Universal did not initially bear fruit. A revised schedule for the certification motion against Universal was established through a series of case management conferences. Class Counsel, the Collectives, and Universal conducted cross-examinations of all witnesses who had sworn affidavits in connection with the certification motion, including Mrs. Baker, who was examined in the U.K. This examination involved no small expense and confirms my impression that Universal was prepared to take a serious run at contesting certification.

24 Settlement discussions continued with Universal concurrently with the certification schedule. Further mediation sessions were held with Justice Campbell. In or about December, 2010, settlement terms were finally reached with Universal and settlement documentation was executed shortly thereafter.

25 In January of 2011, the Collectives advised that they had identified certain "held royalties" which had been paid to the Collectives by the Record Labels but could not be distributed. They stated that they wished to contribute these to the settlement fund. A second amended settlement agreement was therefore executed with the Collectives on January 31, 2011.

26 On or about February 9, 2011, EMI advised that it would be submitting video royalty amounts into the settlement fund as contemplated by its settlement agreement. As a result, the parties agreed to a revised class definition reflecting EMI's participation in the video aspect of the settlement.

27 In February of 2011, the Record Labels advised Class Counsel and the Collectives of their position that a portion of the "held royalties" which had been paid to the Collectives by the Record Labels, and were proposed to be paid into the settlement trust, should be credited to the payments to be made by the Record Labels into the settlement trust. This reflects the ongoing adversarial nature of the proceedings.

28 All parties engaged in negotiations aimed at ascertaining the nature and veracity of the Record Labels claims to a credit in respect of those held royalties. Those negotiations culminated in an agreement whereby the Record Labels have been provided with a credit of $1.25 million against payments to be made by them into the settlement trust.

29 Prior to the execution of the agreement to provide a credit to the Record Labels in respect of "held royalties", correspondence was sent to the Court from Paul Baker, Chet Baker's son, challenging the authority of Carol Baker to act on behalf of the estate of Chet Baker in commencing this action and in pursuing the settlement.

30 Carol Baker and Class Counsel disagreed with the objections made by Paul Baker. Notwithstanding that view, the Record Labels continued to have concerns about the ability of Carol Baker and Chet Baker Enterprises LLC to act as Representative Plaintiffs. It was ultimately agreed by all parties, and approved by me, that it would be most expeditious, efficient and desirable for Mrs. Baker and Chet Baker Enterprises LLC to withdraw as the proposed representative plaintiffs in favour of an appropriate substitute.

31 Class Counsel were then retained by Craig Northey, an accomplished Canadian songwriter and musician, who has a claim for unpaid mechanical royalties on one of Record Label's pending lists. Mr. Northey was prepared to step into the role of representative plaintiff and to prosecute the action to a conclusion.

32 The settlement agreements reached between Carol Baker and the defendants were terminated and Mr. Northey executed new settlement agreements with each of the defendants on substantially the same terms as the agreements signed by Mrs. Baker. In addition, Mr. Northey executed a copy of the agreement providing the Record Labels with a credit with respect to the "held royalties".

33 As a result of the time and effort required to address the issue of the substitution of a new class representative, the Record Labels demanded a reduction to the costs payments provided for in each Label's settlement agreement in the aggregate amount of $150,000, to be divided as agreed amongst the Record Labels as a condition of entering into the new agreements with Mr. Northey. Once again, the Record Labels pressed for every concession they could get. The plaintiff agreed to this demand, recognizing, among other things, the desirability of concluding the settlement in a timely way.

34 It is likely that additional work will be required of Class Counsel in the administration of the settlement. Class Counsel request compensation for such work on an hourly rate basis out of the settlement fund.

The Settlement

35 Under the terms of the settlement, as ultimately implemented, a total of $46,688,805.91 is to be paid into a settlement trust for the benefit of Class members. After payment of Class Counsel's fees and other expenses, these funds will be administered and distributed by an entity ("CSI") jointly created by the Collectives. The Record Labels will contribute a total of $42,761,023.94 of this amount and CMRRA and SODRAC will pay $3,927,781.97 in "held royalties". The objective of the settlement administration will be to identify, and pay, the accrued royalties to as many rights holders as possible. It will be necessary to prioritize the efforts of the administration in both temporal and financial terms. Priority will be given to high value amounts (items on the Pending Lists with a value of $2,500 or more) and medium value amounts ($1,000-$2,500) which will be identified on a claims website which can be accessed by potential class members. Efforts will be made to locate rights holders in respect of low value items (less than $1,000).

36 As well, as part of the settlement, a system of licensing and royalty administration has been established, on a going-forward basis, to ensure that the problem does not recur. This is a very important feature of the settlement and a significant accomplishment.

37 After the administration period has been completed with respect to high value and medium value amounts, any residue will be distributed cy-pres to the universe of rights holders with market share in Canada, according to analysis that will be carried out by CSI. A similar distribution will be

made with respect to the low value items.

38 It is the stated goal of Class Counsel, and CSI to compensate rights holders to the greatest extent possible. As noted, Class counsel propose to remain involved, on a fee-for-service basis, in the administration of the settlement, as required.

Settlement Approval

39 On May 30, 2011, I approved the settlement, finding that it was fair, reasonable and in the best interests of the class. My reasons indicated that I was satisfied that this action meets the requirements of section 5 of the C.P.A.: there is an identifiable class, represented by a suitable and qualified plaintiff, with tenable causes of action under the Copyright Act and for unjust enrichment, which give rise to issues that can be resolved on a common basis. I found that certification, and the settlement it implements, would achieve the goals of the C.P.A. by giving access to justice to many individuals with relatively modest claims that could not, as a practical matter, have been economically pursued on an individual basis. I found that the action and the settlement achieved judicial economy by consolidating the claims of several thousand class members into one proceeding and achieved behaviour modification by resolving a long-standing problem in the music industry and by putting a process in place to address the problem going forward.

The Position of Class Counsel

40 As stated above, Class Counsel seeks approval of a fee of $6,950,000 plus taxes and disbursements.

41 Both representative plaintiffs executed contingent fee agreements that stipulated a maximum counsel fee of 30% of the amount recovered. The fee request made by Class Counsel is approximately 15% of the gross settlement value and therefore represents a significant discount of the fee to which Class Counsel is contractually entitled. The fee request is supported by both Mrs. Baker and Mr. Northey.

42 In summary, the submissions of Class Counsel are as follows:

(a) this was complex intellectual property litigation, involving multiple defendants and a seemingly intractable problem that has finally been resolved in a way that not only provides direct benefits to the Class, but also addresses the issue on an ongoing basis;
(b) the settlement was an extremely good one, resulting in a high rate of recovery of the unpaid amounts;
(c) Class Counsel carried all the disbursements in the litigation and agreed to indemnify the representative plaintiff against an adverse costs award - this avoided the need to seek assistance from the Class Proceedings Fund, which would have charged a 10% levy on any settlement or recovery;

(d) it has taken over four years to bring this matter to completion, during which time Class Counsel received no fees; and

(e) Class Counsel were at risk for a variety of reasons, including the risk that the action would not be certified or, if certified, would not ultimately be successful.

43 I will address other points made by Class Counsel in the course of my reasons.

Objections

44 There were no substantive objections to the settlement itself and there have been only two opt-outs. The fee request is opposed by the Collectives, by Universal and by Warner/Chappell Music Canada Ltd. ("WCMC"). I will review their objections.

The Objection of WCMC

45 WCMC takes the position that the fee is excessive in light of the services rendered by Class Counsel, when balanced against the complexity of the matter, the importance of the matter to the Class, the expectations of the Class and the effect that the fee will have on the recovery achieved by the Class. That being said, WCMC acknowledges the contribution made by Class Counsel to the successful resolution of this matter and asks that a fair fee be awarded, having regard to the time and expenses invested by Class Counsel. It submits that the fee should be based on the time actually spent and the hourly rates of Class Counsel.

46 WCMC submits that the litigation was not complex, liability was not seriously disputed and the action was settled at a relatively early stage. It says that Class members should be entitled to receive the royalties that are due to them, and should not be required to accept a discount in order to allow Class Counsel to benefit from a fee that far exceeds the time spent on the matter.

47 WCMC makes the point that songwriters rely on royalties to earn their livelihood and that without songwriters and their songs, the world would be decidedly bleak. Its letter of objection points out:

> Songwriters rely on royalties as their means of making a living. Take away a songwriter's income and a songwriter will be forced to pursue a different livelihood. The result will be detrimental to us all. Songs are used in television, movies, commercials and for personal enjoyment. Songs are used to tell stories, to create moods, to quiet the mind, generate enthusiasm, to energize the body, to uplift spirits. Music is used to celebrate and to mourn. Music can be educational and can be therapeutic. The world benefits from the fruits of the songwriter's labor.

48 This is a fair point, elegantly made. No sensible person would suggest, however, that a

songwriter should be compensated based on the time spent writing the song, which is the way in which WCMC submits Class Counsel should be compensated, in spite of the terms on which they took on the brief.

49 WCMC's letter continues:

> The songwriters and publishers were punished by the failure of the record Companies to pay royalties in the first instance. They are being punished a second time by being made to accept less than the full royalties they are entitled; and, will be punished a third time if Class Counsel is awarded the contingent fee requested, which will further reduce the royalties payable to the Class Members.

50 WCMC concludes by asking that the Court fix Class Counsel's fee in an amount that corresponds with the time actually spent, so that the royalties payable to class members will more closely correspond to the amounts actually owing to them.

The Objection of Universal

51 Universal is both a defendant and, through its publishing arm, is a member of the Class. It acknowledges that Class Counsel are entitled to fair compensation, but it says that the fee requested is excessive having regard to the nature of the dispute, the settlement and the expectations of the class. It also says that there was unnecessary duplication of work and over-lawyering by Class Counsel.

52 Universal's position is similar to the position of WCMC. It says that the issues in the action were straightforward, the problem was notorious and long-standing and the matter settled prior to certification and before significant time was expended in preparation for discovery and trial.

53 Universal also notes that the net amount that class members will receive will already be diluted by the 10% commission that will be paid to CSI for the administration of the settlement.

54 Finally, Universal says that a review of Class Counsel's docket summary suggests that the involvement of three counsel firms in the action resulted in duplication of effort and "over-lawyering." It refers to Andersen v. St. Jude Medical Inc., [2004] O.J. No. 3102 (S.C.J.) at para. 11, in which Cullity J. expressed concern about the risk of duplication of work and overhead when there are multiple counsel involved in the brief. As has been noted by Universal, that was a contested costs award and not a fee request. That distinction reflects the philosophy of costs awards that what may be reasonable billing as between a lawyer and his or her own client may not be within the reasonable expectations of the opposing party when it comes to a costs award. Universal submits, however, that the same principles should apply to shield class members from being required to pay excessive fee requests by Class Counsel.

The Objection of the Collectives

55 The Collectives say that the fees claimed are not fair and reasonable. They say that a "multiplier" approach should be used using a multiplier of 1.3, resulting in a Class Counsel fee of around $2,725,000.

56 The objections of the Collectives are essentially, that this was relatively risk-free litigation that was handed to Class Counsel on a platter, that liability was not seriously in issue, that most of the heavy lifting was done by the Collectives and that the resulting settlement, while decent, was not exceptional. They make the following submissions, in summary:

(a) after being named as defendants in this action, the Collectives and their lawyers made significant efforts to resolve the issues, thereby taking a considerable burden off the shoulders of Class Counsel - their lawyers spent a total of 2,200 billable hours on the matter, reflecting the time and effort involved;
(b) the Collectives, and their lawyers, have been significantly involved in moving the action forward, in fact, at times they were pressing Class Counsel to move the matter forward;
(c) the future licensing proposal was developed by the Collectives, which have also helped to develop the proposal and documentation for the resolution of the litigation;
(d) the Collectives were actively involved in pushing for settlement, participating in the mediation, negotiating with the Record Labels and developing the settlement documentation and protocols;
(e) the Collectives identified the existence of the held royalties, which were added to the settlement trust and this recovery was not the result of the efforts of Class Counsel;
(f) there was time and money wasted due to the issues surrounding the authority of Carol Baker to represent the Baker estate, ultimately resulting in a reduction of $150,000 of the amount paid by the Record Labels by way of costs - this issue could have been foreseen and avoided;
(g) the net benefit of the settlement is approximately $38.5 million, after deduction of the 10% commission that will be payable to the Collectives for the administration of the settlement and
(h) the held royalties were not contributed to the settlement by the Collectives as a result of any efforts made by Class Counsel and they should be excluded from the settlement fund for the purposes of calculating the fee.

Discussion

Approval of Class Counsel's Retainer

57 The first issue is the consideration of the agreement made between Class Counsel and the

representative plaintiffs with respect to fees and disbursements.

58 Section 33 of the C.P.A. recognizes that Class Counsel may enter into a contingent fee arrangement with the representative plaintiff. Section 32(2) provides that an agreement respecting fees and disbursements between Counsel and the Class representative is not enforceable unless approved by the Court. The agreement must be in writing, must state the terms under which the fees and disbursements are to be paid and must give an estimated fee. It must also state the method by which payment is to be made, whether by lump sum, salary or otherwise. Where the Court does not approve the agreement, it may nevertheless determine the amount of fees and disbursements owing to counsel.

59 As I have noted, the fee agreement between Class Counsel and the representative plaintiffs called for a contingent fee of 30%. Class Counsel voluntarily agreed to reduce their fee to approximately 15%.

60 I find that the fee agreements meet the requirements of the C.P.A. I turn now to the question of whether Class Counsel's fee request should be approved.

Fee Approval

61 My responsibility in this motion is to determine a fee that is "fair and reasonable" in all of the circumstances: Parsons v. Canadian Red Cross Society (2000), 49 O.R. (3d) 281 (S.C.J.) at paras. 13 and 56.

62 The factors to be considered in the application of this test are well-known and I will turn to them in a moment. I will begin with a few preliminary textual comments.

63 First, a contingent fee retainer in the range of 20% to 30% is very common in class proceedings, as it has been in other kinds of litigation in this province for some years. As Class Counsel has pointed out, there have been a number of instances in recent years in which this Court has approved fees that fall within that range. These include:

* Abdulrahim v. Air France,
  [2011] O.J. No. 326: 30%

* Ainslie v. Afexa Life Sciences Inc.,
  [2010] O.J. No. 3302: 19.4%

* Robertson v. ProQuest LLC,
  [2011] O.J. No. 2013: 24%

* Osmun v. Cadbury Adams Canada Inc., [2010] O.J. No. 2093: 25%

* Pichette v. Toronto Hydro, [2010] O.J. No. 3185: 28.5%

* Robertson v. Thompson Canada Ltd., [2009] O.J. No. 2650: 36%

* Cassano v. Toronto-Dominion Bank (2009), 98 O.R. (3d) 543: 20%

* Martin v. Barrett, [2008] O.J. No. 2105: 29%

64 There should be nothing shocking about a fee in this range. Personal injury litigation has been conducted in this province for years based on counsel receiving a contingent fee as high as 33%. In such litigation, it is generally considered to reflect a fair allocation of risk and reward as between lawyer and client. It serves as an inducement to the lawyer to maximize the recovery for the client and it is regarded as fair to the client because it is based upon the "no cure, no pay" principle. The profession and the public have for years recognized that the system works and that it is fair. It allows people with injury claims of all kinds to obtain access to justice without risking their life's savings. The contingent fee is recognized as fair because the client is usually concerned only with the result and the lawyer gets well paid for a good result.

65 My second observation reflects the reality of class action litigation. Defendants tend to be well-resourced and represented by larger law firms. This is a case in point. There were four defendants. EMI and Universal were represented by national and international law firms, each with over 500 lawyers. Sony and Warner were represented by a smaller litigation firm (about 50 lawyers) which focuses exclusively on complex litigation. The Collectives were represented by a 200 lawyer firm. These were some of the best law firms in the country, charging substantial hourly rates, with virtually unlimited resources and no incentive to roll over and play dead.

66 Due to the nature of the work, Class Counsel are frequently associated with smaller firms and are invariably engaged on a contingent basis. Without wanting to paint all with the same brush, defendants frequently employ a strategy of wearing down the opposition by motioning everything, appealing everything and settling nothing. If class proceedings are to realize the goal of access to

justice, Class Counsel must be liberally compensated to ensure that they take on challenging but difficult briefs such as this one.

67 There must be an economic incentive to encourage lawyers to take on litigation of this kind and this is a factor to be considered in assessing the reasonableness of a fee: Gagne v. Silcorp Ltd. (1998), 41 O.R. (3d) 417 (C.A.); Parsons v. Canadian Red Cross Society (2000), 49 O.R. (3d) 281 (S.C.J.); Vitapharm Canada Ltd. v. F. Hoffmann-La Roche Ltd., [2005] O.J. No. 1117 (S.C.J.) at paras. 59-61. If first-class lawyers cannot be assured that the Courts will support their reasonable fee requests, how can the Courts and the public expect them to take on risky and expensive litigation that can go for years before there is a resolution?

68 My third comment, which is not original, is that this is one area where the Court should free itself from the chains of the hourly rate. The result achieved for the class should generally be the most important test of the value of counsel's services.

69 Finally, flowing from this, it seems to me that one should consider the proposed fee from the perspective of the class member, both prospectively and retrospectively. Had it been possible for Class Counsel and the class members to discuss the issue from the outset, would the class have considered the fee arrangement reasonable? If so, in light of the ultimate resolution, does the fee remain reasonable? In the context of this case, if Class Counsel had proposed a fee of 15 cents per dollar of gross recovery, would that have appeared fair and reasonable at the outset? With the benefit of hindsight, does it appear fair and reasonable?

70 I now turn to the factors that have traditionally been considered in determining the fees of Class Counsel. In Vitapharm Canada Ltd. v. F. Hoffmann-La Roche Ltd., [2005] O.J. No. 1117 (Sup. Ct.) at para. 67, Cumming J. summarized those factors:

(a) the factual and legal complexities of the matters dealt with;
(b) the risk undertaken, including the risk that the matter might not be certified;
(c) the degree of responsibility assumed by Class Counsel;
(d) the monetary value of the matters in issue;
(e) the importance of the matter to the class;
(f) the degree of skill and competence demonstrated by Class Counsel;
(g) the results achieved;
(h) the ability of the class to pay;
(i) the expectations of the class as to the amount of fees; and
(j) the opportunity cost to Class Counsel in the expenditure of time in pursuit of the litigation and settlement.

See also: Endean v. Canadian Red Cross Society, [2000] B.C.J. No. 1254 (S.C.); Wamboldt v. Northstar Aerospace (Canada) [2009] O.J. No. 2583 (S.C.J.) at para. 33; Smith Estate v. National Money Mart Co., [2011] O.J. No. 1321, 2011 ONCA 233 (C.A.).

71 The weight to be given to a particular factor will vary from case to case, In Ainslie v. Afexa Life Sciences Inc., [2010] O.J. No. 3302, 2010 ONSC 4294, I observed that one of the most important factors on a fee approval motion must be the result achieved in relation to the amount at issue and the complexity of the case. Some assessment must be made of what the plaintiff was able to obtain, in relation to what the case was really "worth". Other important facts are the time spent and the risks incurred by the lawyers, the agreement between Class Counsel and the representative plaintiff and the level of fees awarded in other proceedings of a similar nature. I stated, at para. 44:

> After examining all these factors, it is important to ask whether the work of Class Counsel has fulfilled the goals of the C.P.A. by giving access to justice to claimants who might not otherwise obtain it and by promoting behaviour modification of wrongdoers. It is also important to recognize that the achievement of these goals demands that there is an available pool of experienced and skilled lawyers of high repute, who are prepared to take on the onerous and risky responsibility of Class Counsel. Where counsel achieve successful results, they render a service not just to the class but to the legal system itself, by providing access to justice and by achieving judicial economy. Their fees should not be assessed simply on the basis of quantum meruit - they should be enhanced in appropriate cases to recognize and reward successful performance and to serve as all incentive to counsel to take on class action litigation.

72 The results achieved in this case were, in my view, excellent. The Collectives and Universal agree that the result was a good one, although they point out that there has been no recovery of interest or statutory damages.

73 The gross recovery under the settlement is almost the full amount owing to class members. The net recovery, after the deduction of fees, will be in the range of 80% to 85% of the amount owing. It is true that substantial statutory damages were potentially recoverable under the Copyright Act, but the availability of such damages is not absolute and the entitlement to such damages was speculative in the circumstances. It is also true that the settlement does not include recovery of interest over the long period that payment was withheld, but a party will frequently agree to forebear a claim for interest in return for a settlement. The results achieved must also be considered in the context that there were serious defences available to the defendants, including, in particular, limitations defences.

74 While the defendants say that the percentage fee should not be applied to the commission of some $4 million payable to CSI for the administration of the settlement, that money is necessarily spent in order to put the settlement into the hands of the class in an equitable and expedited manner. It was obtained through the efforts of counsel. While the "held royalties" are somewhat in the nature of a windfall, we should not lose track of the fact that Class Counsel have actually agreed to reduce their fee to a percentage that is half as much as the amount to which they were entitled under their

retainer agreements.

75 The matter was important to the class. As the submission of WCMC points out, intellectual property rights and the entitlement to royalties for their use are vitally important to songwriters and musicians. The breach of those rights was real and long-standing. The recovery of wrongfully withheld past royalties, and the creation of a structure to ensure that the problem will not recur, must be regarded as an extremely important achievement for the benefit of the Class.

76 The monetary value of the matter was significant, some $50 million. This will be real cash in the hands of the Class - not coupons, discounts or forgiveness of debt having only notional value.

77 The degree of responsibility assumed by counsel was also significant, in light of the size of the Class and the amount at issue. It is fair to note that Class Counsel was assisted by the Collectives, but Class Counsel was ultimately responsible for, and accountable for, the prosecution of the litigation.

78 The factual and legal complexities of the matter were not at the highest end of the scale, but they were significant. The issues in the action were essentially unique and unprecedented and required thorough investigation. There were multiple parties. The settlement itself was extremely complicated, involved multiple parties and multiple documents and a complex structure for resolution.

79 In my view, the skill and competence demonstrated by Class Counsel was exceptional. They developed and executed an aggressive strategy designed to bring this action forward for certification and their determination to do so, and their credibility as counsel, brought the defendants, one by one, to the bargaining table and ultimately to settlement. The objectors do not take issue with the skill and competence of Counsel, other than to point out that the difficulties that arose with respect to Mrs. Baker resulted in increased costs and delayed the resolution. In my view, the unfortunate and possibly unmeritorious concerns raised by Paul Baker, at the eleventh hour, cannot be laid at the doorstep of Class Counsel. It was one of those things that can go wrong in litigation. Class Counsel responded to the challenge in a timely and practical manner.

80 The risk undertaken by Class Counsel, and the opportunity cost was sizeable. The action took four years to bring to conclusion. In comparison to some substantial class actions, this is commendable expedition. At the same time, during those years Class Counsel received not a penny for their efforts. They incurred and paid disbursements on behalf of the class, They spent some 6,000 hours on the file without compensation. Their docketed time has a face value of about $2.2 million. They bore the risk of an adverse costs award if the action was not successful. They, not the Class, were at risk.

81 The expectation of the class as to the amount of the fee and the ability of the class to pay would not detract from the fee proposed by Class Counsel. There has been minimal opposition to the fee request in spite of quite extensive notice of this hearing. The class members are clearly able

to pay the fee and it will not significantly dilute their recovery.

82 Turning to the dynamics of the litigation, having case managed this action for over two years, and having conducted a number of case conferences as this proceeding worked its way to resolution, it is my view that this was a difficult, hard-fought piece of litigation in which the outcome was by no means assured. While the plaintiffs were successful in securing the early cooperation of the Collectives, this itself was no small accomplishment. Nor were the initial settlements with Sony, Warner and EMI. Universal remained a tenacious hold-out and there were very serious questions as to whether a resolution would be achieved.

83 From my observations, the positions taken by Universal from time to time were highly adversarial and its position was aggressively and effectively advanced. I reject any suggestion that the settlement was a cake walk for Class Counsel. It was hard work and the risk of failure of the resolution strategy was always present. So was the risk that the action would not be certified for any one of the reasons advanced by Universal.

84 Class Counsel were insistent that if the matter was not resolved, they would proceed to a certification hearing and counsel for Universal was equally insistent that certification would be vigorously opposed and that there were flaws in the plaintiff's case that made it unsuitable for certification. This was not posturing. The very satisfactory result in the proceeding was due to the preparedness of Class Counsel to go to the wall if a satisfactory settlement could not be achieved. I am convinced that this resolve was demonstrated to the defendants throughout and it resulted in a better and more effective settlement for the class.

85 Having supervised the proceeding and having reviewed counsel's time records, it is my view that the assertion that this case was over-lawyered is unfair and erroneous. Class Counsel were a consortium consisting of Bates Barristers, Harrison Pensa and the Canadian Internet Policy and Public Interest Clinic, a legal clinic representing consumers and public interests in intellectual property and other matters. Most of the work was done by Mr. Bates, the more senior of the lawyers (1983 call), and by Mr. Foreman (2002 call). Mr. Foreman spent at least 1,670 hours on the file. Mr. Bates spent about 800 hours. The total time spent on the matter, by all personnel in the Class Counsel consortium, was around 6,000 hours, having a face value of $2.2 million. Although there were various juniors, paralegals and others involved in the file. I have no sense at all that this is a case in which everyone from the most senior partner to the most junior clerk was thrown at the file in order to pump up the fee. Nor do I have the sense, at all, that any of the lawyers involved was engaging in unnecessary or redundant work. On the contrary, my observation is that Class Counsel conducted themselves efficiently throughout.

86 I think one should resist the temptation to engage in armchair quarterbacking when assessing the value of Class Counsel's time. The objecting defendants and WCMC make the argument that this was an easy piece of litigation. I disagree. The problem festered for many years before Class Counsel got involved. None of the defendants was able to resolve it. It took over four years to

resolve once this action was commenced. Even after it had been resolved with some of the defendants, there were constant frictions and new problems cropped up, such as the "held royalties" and the substitution of a new class representative.

87 WCMC suggests that Class members are being "punished" by having to pay over a percentage of the royalties to which they are entitled in order to pay the lawyers. This submission overlooks the fact that Class members would likely still be waiting for their royalties had Class Counsel not agreed to invest their own blood, sweat and tears in the issue and to take on the Record Labels in what has proven to be an arduous battle.

88 In this case, the proposed fee is about 15% of the net settlement. Had Class Counsel proposed a fee of this size to the Class, as a condition of taking on a battle that had sat unresolved for years, there is no question in my mind that the vote would have been overwhelmingly positive. Looking back on the time and effort displayed by Class Counsel and considering the result and the other factors I have referred to, it seems to me that it was a fair bargain and the result is, in general, fair.

89 I would say that the "held royalties" do not stand on quite the same footing and there should be a modest reflection of the fee to reflect this. In all the circumstances, a fee of $6,250,000 would be fair and reasonable, plus taxes. In addition, Class Counsel shall be entitled to render invoices to CSI on an hourly rate basis, for any services rendered in the implementation of the settlement. All such invoices shall be approved by me or by the judge case-managing this proceeding in the future.

Compensation for Representative Plaintiffs

90 Class Counsel have requested payment of an "honorarium" of $3,000 to each of Mrs. Baker and Mr. Northey, out of the fees received by Class Counsel.

91 The retainer agreements signed by Mrs. Baker and Mr. Northey allowed for the possibility of a quantum meruit compensation of the class representative, if approved by the Court:

> If the action is successful, the consortium shall make a request to the Court for an award of compensation for the plaintiff on a quantum meruit basis for the time spent acting as a representative for the class. It is acknowledged that such compensation is entirely within the discretion of the court.

92 Mrs. Baker and Mr. Northey have sworn affidavits stating that, while they have no expectation of receiving such compensation, or honorarium, they would be grateful for any payment the Court may see fit to make. Their affidavits indicate that they were extensively involved in settlement discussions, correspondence, telephone conversations and meetings, and review of settlement documentation. Mrs. Baker, who lives in England, was required to travel from her home in Cornwall to London for cross-examination on her affidavits.

93 The payment of compensation to a representative plaintiff is exceptional and rarely done:

McCarthy v. Canadian Red Cross Society [2007] O.J. No. 2314 (S.C.J.) at para. 20; Windisman v. Toronto College Park Ltd., [1996] O.J. No. 2897 (Gen. Div.); Sutherland v. Boots Pharmaceutical plc, [2002] O.J. No. 1361 (S.C.J.); Bellaire v. Daya [2007] O.J. No. 4819 (S.C.J.) at para. 71. It should not be done as a matter of course. Any proposed payment should be closely examined because it will result in the representative plaintiff receiving an amount that is in excess of what will be received by any other member of the class he or she has been appointed to represent: McCutcheon v. Cash Store Inc. [2008] O.J. No. 5241 (S.C.J.) at para. 12. That said, where a representative plaintiff can show that he or she rendered active and necessary assistance in the preparation or presentation of the case and that such assistance resulted in monetary success for the class, it may be appropriate to award some compensation: Windisman v. Toronto College Park Ltd., [1996] O.J. No. 2897 (Gen. Div.) at para. 28.

94 The Court of Appeal has recently indicated in Smith Estate v. National Money Mart Co., 2011 ONCA 233, 106 O.R. (3d) 37 at paras. 134-135 that any compensation paid to the representative plaintiff should normally be paid out of the settlement fund and not out of Class Counsel's fee, to avoid concerns with respect to fee-splitting,

95 It is interesting to note that on certification motions, the Court is often concerned to ensure that the representative plaintiff is truly engaged in the litigation and is not a mere "bench-warmer" or a "straw man" recruited by Class Counsel. Courts have frequently commented on the need to have an active and involved plaintiff who will be familiar with the proceedings, instruct counsel, monitor settlement discussions and generally act as any private client would in supervising his or her own litigation. A private client will normally receive indirect compensation for such efforts out of the proceeds of settlement or judgment. A representative plaintiff normally will not. That being said, these are contributions the Court expects a representative plaintiff to make and I respectfully agree with the observation of Hoy J. in Bellaire v. Daya, above, at para. 71 that compensation should not be awarded simply because the representative plaintiff has done what is expected of him or her. It should be reserved for cases, like Garland v. Enbridge Gas Distribution Inc., [2006] O.J. No. 4907 (S.C.J.) where the contribution of the representative plaintiff has gone well above and beyond the call of duty,

96 I have decided that this is not one of those rare and exceptional cases that calls for payment of compensation to the class representative. I do not wish to minimize, in any way, the efforts of Mrs. Baker and Mr. Northey. They have acted as exemplary representatives. They can be proud of their contributions to the prosecution and resolution of this matter and they have earned the gratitude of the Class. The Court could ask no more of them. I hope they will appreciate that my decision not to award compensation is no reflection on their most commendable efforts on behalf of the Class.

Summary and Order

97 An order will therefore issue:

(a) approving the retainer agreements entered into between the representative

plaintiffs and Class Counsel;

(b) approving the fees of Class Counsel in the amount of $6,250,000 plus taxes and directing that such amount be paid out of the Settlement Trust; and

(c) providing that future services rendered by Class Counsel shall be invoiced on a time and hourly rate basis, subject to Court approval.

G.R. STRATHY J.

cp/s/qllxr/qlvxw/qlana/qlhcs/qljac

REPORT

ON

CLASS ACTIONS

ONTARIO LAW REFORM COMMISSION

VOLUME III

Ministry of the
Attorney
General

1982

The Ontario Law Reform Commission was established by the *Ontario Law Reform Commission Act* for the purpose of reforming the law, legal procedures, and legal institutions. The Commissioners are:

DEREK MENDES DA COSTA, Q.C., LL.B., LL.M., S.J.D., LL.D., *Chairman*

H. ALLAN LEAL, Q.C., LL.M., LL.D., *Vice Chairman*

HONOURABLE RICHARD A. BELL, P.C., Q.C.

WILLIAM R. POOLE, Q.C.

BARRY A. PERCIVAL, Q.C.

M. Patricia Richardson, M.A., LL.B., is Counsel to the Commission. The Secretary of the Commission is Miss A. F. Chute, and its offices are located on the Sixteenth Floor at 18 King Street East, Toronto, Ontario, Canada M5C 1C5.

During the course of the Class Actions Project, the Honourable G. A. Gale, C.C., Q.C., LL.D., retired as Vice Chairman of the Commission because of ill health. While the Commission benefited greatly from Mr. Gale's knowledge and experience and acknowledges its indebtedness to him, we wish to state that he did not agree with all the recommendations contained in this Report, particularly those relating to costs.

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review and set aside the agreements where they would require the payment of unreasonable fees.[112]

In the usual case – where a class lawyer does not have an agreement with any class member, except perhaps the representative plaintiff – the basis for a claim for remuneration will be either a statutory fee provision or the common fund or substantial benefit doctrine. If the class action terminates by a settlement that creates a fund for the class or culminates in a judgment that the class is entitled to monetary relief, the class lawyer, under the common fund doctrine, will apply to the court for fees to compensate him for his services that benefited class members with whom he has no contractual relations. If the class action obtains an injunction or a declaration, application to the court will be made under any applicable statutory fee provision or the substantial benefit doctrine.

Consequently, in such cases, a class lawyer's right to remuneration for his efforts on behalf of the class, although not based on a contingent fee agreement, nevertheless is contingent, because it depends on a favourable resolution of the action, either by an adjudication or by a settlement. If the action fails, no compensation for such efforts will be forthcoming, notwithstanding the lawyer's expenditure of time and effort.

(ii) Fee Assessment

a. Calculation of Attorneys' Fees

Once the entitlement of the class lawyer to remuneration is established, it becomes the task of the trial judge to assess the appropriate attorney's fee. The fact that the court has a discretion to determine fees does not distinguish class actions from individual actions. Where the exceptions to the American rule apply in individual actions, courts calculate the fee to be awarded. Cases in which attorneys' fees have been determined in individual actions constitute the background for fee assessment in class actions.

When assessing fees, courts are obliged to follow a standard of "reasonableness with reference to the particular facts of the case".[113] Although undoubtedly a sensible exhortation, this directive affords little guidance as to how fees should be calculated in particular cases. Consequently, there have been attempts by the courts[114] and by the American Bar Association[115] to give content to the concept of reasonableness by devising lists of factors that should be considered. Many of these efforts, however, have been directed to

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[112] *Dunn v. H.K. Porter Co.*, 602 F.2d 1105 (3d Cir. 1979). For commentary, see Note, "*Dunn v. Porter*: Guidelines for Federal Courts in Exercising Their Authority to Review and Set Aside Contingent Fee Agreements", [1979] Det. Coll. L. Rev. 765.

[113] *Angoff v. Goldfine*, 270 F.2d 185 (1st Cir. 1959), at 188.

[114] See, for example, *In re Osofsky*, 50 F.2d 925 (S.D.N.Y. 1931), at 927, and *Angoff v. Goldfine*, *supra*, note 113, at 189.

[115] See American Bar Association, *Code of Professional Responsibility*, Disciplinary Rule DR 2-106(B).

judicial fee assessment generally, and have not specifically addressed the issue in the context of class action litigation.[116] The guidelines respecting the exercise of judicial discretion have been criticized as lacking the requisite clarity and precision because they fail to explain what weight should be given to the various factors.[117] They are considered little more than hortatory enjoinders to assess a reasonable fee. The inadequacy of these guidelines has been demonstrated by the practice of some courts of stating simply that due consideration had been given to them, without explaining how the factors affected the amount of the fee that was ultimately awarded. Courts have often appeared to review the criteria as a *pro forma* exercise, unrelated to the factual circumstances of the particular case.[118]

Turning to a consideration of how courts have calculated the amount of attorneys' fees in class actions, it may be observed that the courts have altered their general approach over the years. Formerly, courts sought to assess the value of lawyers' services by examining a number of factors, but emphasizing the amount of the monetary recovery or the value of the benefit conferred on the class; the usual result was the application of a percentage formula to the class recovery.[119] The new trend, which is becoming the dominant approach, has been to calculate fees by reference to various factors designed to measure the value of the services performed, with particular attention being given to the time expended by the lawyer.[120] It has been suggested that the transition from an emphasis on the amount of the recovery to an emphasis on the time expended may have been precipitated by criticism of the size of fee awards by certain courts and commentators.[121]

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[116] See, however, Federal Judicial Center, Board of Editors, *Manual for Complex Litigation* (1978) (Clark Boardman), §1.47, at 96-96.1, *n.* 127 (hereinafter referred to as "Manual"), where the editors suggest that, in class actions, the following factors, among others, should be considered: "(1) that in seeking and accepting employment as counsel for a judicially determined class an element of public service is involved; (2) the representation of the class by counsel is not a result of private enterprise but results from provisions of an opportunity to represent the class by a judicial determination; and (3) the policy of the law in class actions, including antitrust actions, is to provide a motive to private counsel to represent consumers and to enforce the laws".

[117] In *City of Detroit v. Grinnell Corp.*, 495 F.2d 448 (2d Cir. 1974), at 470, the Court of Appeals for the Second Circuit stated that "more is needed than a mere listing of factors. Such a list, standing alone, can never provide meaningful guidance." One commentator has referred to the lists of factors as "essentially meaningless litanies": see Dawson II, *supra*, note 87, at 927.

[118] See Mowrey, *supra*, note 93, at 304-06; Note, "Computing Attorney's Fees in Class Actions: Recent Judicial Guidelines" (1975), 16 B.C. Ind. & Com. L. Rev. 630, at 632-33 (hereinafter referred to as "Recent Judicial Guidelines"); Smith, "Standards for Judicial Approval of Attorneys' Fees in Class Action and Complex Litigation" (1977), 20 How. L.J. 20, at 28-29; and Note, "Attorneys' Fees - Conflicts Created by the Simultaneous Negotiation and Settlement of Damages and Statutorily Authorized Attorneys' Fees in a Title VII Class Action" (1978), 51 Temple L.Q. 799, at 807-08.

[119] The earlier approach is described in Mowrey, *supra*, note 93, at 334-38.

[120] See Miller, *Attorneys' Fees in Class Actions* (1980), at 60-62.

[121] In *City of Detroit v. Grinnell Corp.*, *supra*, note 117, at 469, the Court stated that, "[f]or the sake of their own integrity, the integrity of the legal profession, and the integrity of Rule 23, it is important that the courts should avoid awarding 'windfall fees' and that they should likewise avoid every appearance of having done so".

Crucial to this development were two decisions of the Court of Appeals for the Third Circuit in *Lindy Brothers Builders, Inc. v. American Radiator & Standard Sanitary Corp.*[122] These decisions and others[123] sought to bring a coherent method to the judicial assessment of attorneys' fees in class action litigation. In view of the impact of the so-called "*Lindy* approach", it is necessary to describe it in some detail.

The *Lindy* case was an antitrust class action that terminated with the creation of a settlement fund from which the class lawyers, relying on the common fund doctrine, sought fees for efforts on behalf of class members with whom they had no contingent fee agreements. In an express effort to rationalize fee determination, the Third Circuit Court of Appeals devised a method intended to achieve the fundamental objective of fee determination in class actions – "to compensate the attorney for the reasonable value of services benefiting the unrepresented claimant".[124] Briefly, the prescribed method of fee assessment first requires the court to calculate the number of compensable hours spent by the lawyer in activities on behalf of the class. The amount of time is then multiplied by its value, that is, the lawyer's "normal billing rate",[125] which conceivably may vary for different activities. After the resulting product, which the Court termed the "lodestar", is calculated, it is adjusted to take account of two factors: the quality of work demonstrated by the lawyer in the conduct of the case, and the fact that payment of the lawyer is contingent on success.[126] After the reasonable value of the lawyer's services

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[122] 341 F. Supp. 1077 (E.D. Pa. 1972), vacated and remanded 487 F.2d 161 (3d Cir. 1973) (the latter hereinafter referred to as "*Lindy I*"), on remand 382 F. Supp. 999 (E.D. Pa. 1974), and 540 F.2d 102 (3d Cir. 1976) (*en banc*) (the latter hereinafter referred to as "*Lindy II*"). The evolution of the *Lindy* standards is described in *Barrett v. Kalinowski*, 458 F. Supp. 689 (M.D. Pa. 1978), at 701-03. For a description of the newer approach, see Manual, *supra*, note 116, §1.47, at 97-106; Mowrey, *supra*, note 93, at 338-40; and Harvard Developments, *supra*, note 111, at 1611-13.

[123] See *City of Detroit v. Grinnell Corp.*, *supra*, note 117, which presented a similar analysis. Another influential appellate court decision was *Johnson v. Georgia Highway Express, Inc.*, 488 F.2d 714 (5th Cir. 1974), which established twelve factors that should be examined by a court in assessing lawyers' fees but, unlike *Lindy*, did not set out a step-by-step method of computation.

[124] *Lindy I*, *supra*, note 122, at 167.

[125] See Mowrey, *supra*, note 93, at 323-25; Recent Judicial Guidelines, *supra*, note 118, at 647; and Harvard Developments, *supra*, note 111, at 1613, *n.* 150.

> There has been some controversy whether hourly rates can be assigned to the work performed by class lawyers. Hourly rates are given in respect of services that are not performed on a contingent basis and, therefore, lend themselves to the establishment of standard fees. Class litigation in the United States, however, is almost invariably undertaken by lawyers on a contingent basis. For example, Wright and Miller, *supra*, note 77, Vol. 7A (Curr. Supp. 1981), §1803, observed as follows (at 228):
>
> > [T]he notion that there are fixed hourly rates that can be attributed to all lawyers and used as objective markers of the worth of their services is somewhat of an illusion. These rates have never existed for contingent fee lawyers, since time and hourly rates are irrelevant for their type of practice.
>
> See, also, Mowrey, *supra*, note 93, at 324, and Newberg, *supra*, note 83, Vol. 3, §6924d, at 1148.

[126] *Lindy I*, *supra*, note 122, at 166-69.

on behalf of the entire class is determined, the unrepresented class members pay a percentage of that amount equal to their percentage recovery from the fund.[127] In *Lindy II*, the Third Circuit Court of Appeals refined the analytical process by providing a fuller explanation of the contingency and quality of work factors.[128]

As indicated above, the intention of the *Lindy* decisions was to rationalize the method of fee assessment by putting it on a more objective basis than was hitherto evident in the use of a percentage formula. While, by comparison to the earlier method of fee assessment, the *Lindy* approach does systematize the method of fee assessment, it remains a subjective exercise in which the court, at each stage of the analysis, must make judgments about matters incapable of precise quantification.

Even the starting point, the determination of the time spent by the lawyer, obliges the court to render subjective judgments. The court must ascertain whether the lawyer's activities in respect of which time is claimed did, in fact, enure to the benefit of the class.[129] In determining the amount of compensable time, courts seek to ensure that lawyers do not engage in unnecessary preparation and duplication of effort in order to inflate their fees.[130] The nature of the inquiry demanded by the emphasis on time spent on behalf of the class requires lawyers to submit, and therefore to maintain, comprehensive information about their activities. A further incentive to keep precise records has been created by the practice of some courts of disregarding unrecorded time, unless it can be substantiated by other means.[131]

As we have indicated, the *Lindy* decisions require courts to multiply the hours spent on behalf of the class by the "normal billing rate". In fulfilling this directive, courts appear to have adopted different approaches. While some decisions appear to take a subjective approach, relying on the lawyer's statement of his hourly rate, others prefer to assign a rate based on a consideration of more objective standards.[132]

As we have explained, the "lodestar" – which is the product of the time spent on behalf of the class multiplied by the "normal billing rate" – may be increased to reflect the influence of two factors, namely, the quality of the

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[127] See text accompanying note 124, *supra*.

[128] *Lindy II*, *supra*, note 122, at 116-18.

[129] See Newberg, *supra*, note 83, Vol. 3, §6925, at 1153-56, and Mowrey, *supra*, note 93, at 319-20.

[130] See Note, "Computing Attorney's Fees in Individual and Class Action Antitrust Litigation" (1972), 60 Calif. L. Rev. 1656, at 1667; Dawson II, *supra*, note 87, at 927-28; Mowrey, *supra*, note 93, at 322-23; Smith, *supra*, note 118, at 64-66; Recent Judicial Guidelines, *supra*, note 118, at 644; Harvard Developments, *supra*, note 111, at 1617; and Wright and Miller, *supra*, note 77, Vol. 7A (Curr. Supp. 1981), §1803, at 228-29.

[131] See Manual, *supra*, note 116, §1.47, at 105; Smith, *supra*, note 118, at 39-41; and Newberg, *supra*, note 83, Vol. 3, §6125, at 1153-54.

[132] For example, in *City of Detroit v. Grinnell Corp.*, *supra*, note 117, at 471, the Court referred to "the hourly amount to which attorneys of like skill in the area would typically be entitled for a given type of work".

lawyer's work and the contingent nature of success. In assessing the former, a court is interested in the quality of work demonstrated in the course of the particular litigation, rather than in an evaluation of the lawyer's ability in a general sense.[133] This inquiry will include an examination of the lawyer's performance in court, conduct of negotiations, and administration of the class action. If the quality shown is unusually high or unusually low, the compensation is adjusted accordingly.

In evaluating the quality of services rendered, a factor inevitably cited is the nature of the issues involved in the class action. Not surprisingly, novel or complex issues are thought to demand greater ingenuity and industry in order to bring the suit to a successful conclusion.[134] Whether the litigation will be judged to have this character may depend on whether the position of the class has been assisted by the existence of legal precedent or antecedent government proceedings, either of which likely will ease the task of the class lawyer.[135] The quality of work also will be assessed having regard to the result achieved.[136] For example, a larger recovery realized in a relatively short period of time normally demonstrates the exercise of superior skill by the class lawyer.

The contingent nature of success is a factor that is to be considered independently of the quality of work factor. Increasing the "lodestar" amount and, hence, the fee award, to reflect this factor is intended to take account of the economic realities of class litigation – or, more specifically, the financial risk undertaken by a class lawyer.[137]

In class litigation, compensation will be forthcoming only after the investment of a substantial amount of time and effort by the lawyer. While not receiving any remuneration for his or her work, the usual expenses of running an office are being incurred. Moreover, substantial advances may be made on behalf of the client to pay for the enormous expenses incurred in the action, which would augment significantly the financial risk assumed by the class lawyer.

In conducting litigation on this basis, the position of a class lawyer

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[133] In *Lindy II*, *supra*, note 122, at 117, Aldisert J., who gave the opinion of the Court (Gibbons and Seitz JJ. concurring in part and dissenting in part), stated that "counsel who possess or who are reputed to possess more experience, knowledge and legal talent generally command hourly rates superior to those who are less endowed. Thus, the quality of an attorney's work *in general* is a component of the reasonable hourly rate; this aspect of 'quality' is reflected in the 'lodestar' and should not be utilized to augment or diminish the basic award under the rubric of 'the quality of an attorney's work'" (emphasis in original). See, also, Mowrey, *supra*, note 93, at 307-11, and Newberg, *supra*, note 83, Vol. 3, §6931, at 1198-99.

[134] See Newberg, *supra*, note 83, §6933, at 1200-02; Smith, *supra*, note 118; and Wright and Miller, *supra*, note 77, Vol. 7A (Curr. Supp. 1981), §1803, at 231-32, *n.* 62.12.

[135] See Newberg, *supra*, note 83, Vol. 3, §6933, at 1200.

[136] See Mowrey, *supra*, note 93, at 311-18.

[137] For a discussion of the economics of class litigation, see Note, "Developments – Attorney Fee Awards in Antitrust and Securities Class Actions" (1980), 6 C.A.R. 84, at 132-33, and Newberg, *supra*, note 83, Vol. 3, §6926a, at 1166-67.

compares unfavourably with that of a lawyer who performs non-contingent work compensable on a certain or hourly basis. If a class lawyer were not compensated in a manner that reflected the risk of failure, in addition to being reimbursed for his investment of time and resources, it is argued that lawyers would prefer to undertake other kinds of work for which payment was certain.

A court's examination of the contingency factor at the termination of a class action is an *ex post facto* assessment of the probability of success. The court engages in a retrospective inquiry in which the risk of failure is evaluated from the perspective of the time the action was initiated. In considering the contingency factor, courts have identified certain elements that, in their view, bear upon the probability of success. These elements have been summarized as follows:[138]

> At the outset it is helpful to outline the various elements of the contingency factor. Analysis of these elements will focus on their positive or negative effects on certainty of success. The risk of success or failure requires consideration, for example, of the presence or absence of prior governmental proceedings or prior legal precedent. These two elements are often cited as affecting the contingency factor, but their importance can only be assessed in light of the specific facts of each controversy.[139] For this reason, the likelihood of obtaining a favorable liability judgment, and the risks involved in proving damages even after liability is shown, are particularly important. The risk that the damages proved will be disproportionate to the litigation efforts expended, thus resulting in inadequate compensation is also present. The contingencies in obtaining class certification present another large hurdle. The decision to commit a lawyer's time, money and personnel to resolution of the class action issues represents a unique risk borne by the attorney, though the class representative remains personally responsible for costs should the case be dismissed. Additionally, the vigor and capabilities of the defense may increase the difficulties, and the risk of litigating the counsel fee petition remains.

Although the *Lindy* approach was developed in the context of an application for fees from a settlement fund, its impact has extended beyond that context. Courts have held that this approach is to be followed where the defendant has agreed to pay reasonable attorney's fees in addition to a settlement fund.[140] Where fees are assessed pursuant to statutory fee provisions, the *Lindy* approach also has influenced the method of fee calculation.[141]

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[138] Newberg, *supra*, note 83, Vol. 3, §6926, at 1165.

[139] The effect of prior government proceedings appears to be uncertain. It has been suggested that, from the perspective of the class lawyer, the risk of failure will be reduced where there has been a criminal conviction or where "substantial investigations undertaken by the government indicate that a private party can prove guilt in a separate trial". Short of a guilty plea or a guilty verdict after trial, there will not be a substantial reduction in the contingency factor. However, in the course of a particular proceeding, evidence supporting the class may be generated, which would attenuate the risk. The absence of any governmental proceeding accentuates the complexity and novelty of the action, thereby increasing the risk of failure assumed by counsel: see Newberg, *supra*, note 83, Vol. 3, §6926b, at 1179, and §6926i, at 1180.

[140] *Merola v. Atlantic Richfield Co.*, 493 F.2d 292 (3d Cir. 1974), and *Merola v. Atlantic Richfield Co.*, 515 F.2d 165 (3d Cir. 1975).

[141] *Hughes v. Repko*, 578 F.2d 483 (3d Cir. 1978); *Northcross v. Board of Education of Memphis City Schools*, 611 F.2d 624 (6th Cir. 1979), *cert.* denied 100 S. Ct. 2999 (1980); and *Copeland v. Marshall*, 641 F.2d 880 (D.C. Cir. 1980).

While there has been some criticism of the *Lindy* approach,[142] a recent study of attorneys' fees in class actions, commissioned by the Federal Judicial Center,[143] reveals its importance. The study confirms that there is a growing trend to emphasize the time and labour expended by the lawyer. But it also demonstrates that the method of fee assessment is not yet sufficiently consistent to warrant a conclusion that there is a firmly established practice. Variations exist among the eleven federal court circuits and among the courts within each circuit. However, while the *Lindy* approach has not been rigidly followed by all courts, it has been generally accepted in preference to the earlier approach that emphasized the amount of the recovery.

b. Procedure

In the United States, attorneys' fees in class actions are determined by the court at a hearing, upon the application of the class lawyer. Where a suit terminates by settlement, usually the hearing is scheduled simultaneously with the hearing for the approval of the settlement.[144] As indicated, the fees that are the subject of the lawyer's application are intended to compensate him for services on behalf of class members with whom he has no contractual relations.[145]

With his application to the court for fees, a class lawyer must submit supporting affidavits and memoranda outlining the basis of his claim. The lawyer must provide a detailed description of the nature and progress of the class action, his efforts on behalf of the class, and their results.

An application for fees may be opposed by class members, either individually or in a group, by the defendant, or by other lawyers who have participated in the action.[146] To a great extent, the source of payment will

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[142] See Newberg, *supra*, note 83, Vol. 3, §6924d, at 1148-50, and §6935, at 1205-06. See, also, Leubsdorf, "The Contingency Factor in Attorney Fee Awards" (1981), 90 Yale L.J. 473, and Herzel and Hagan, "Plaintiffs' Attorneys' Fees in Derivative and Class Actions" (1981), 2 Litigation 25.

[143] See Miller, *supra*, note 120.

[144] See *infra*, ch. 20.

[145] Some class lawyers have applied for attorneys' fees from the shares of class members who have retained their own lawyers. These attempts have met with mixed results. Certain courts, concerned with the assessment of "double fees", have refused to award fees in respect of represented class members, while others, adhering strictly to the common fund doctrine, have ordered that fees be paid: see Newberg, *supra*, note 83, Vol. 3, §§6980-6980g, at 1277-90.

[146] Lawyers, other than the lawyer retained by the representative plaintiff, may be participating in the class action as counsel for other representative plaintiffs or intervenors. Where the class action has produced a fund, either as a result of a settlement or an adjudication, these lawyers may apply for fees, challenging the fee application of the class lawyer, on the basis that their efforts have contributed to the creation of the fund, and that their services should be compensated accordingly.

Competition for fees obliges the court to deal with certain allocational and distributional questions. Where the lawyers and the defendant settle by agreement both the amount of the fee and to whom it is to be distributed, the approval of the court still is necessary. In the absence of agreement, the court will have to determine how a global

determine who will challenge it. For example, in a settlement agreement, if the defendant has arranged to pay a fee over and above the settlement fund, or if the defendant is liable to pay attorneys' fees under a statutory provision, he will have an interest in attempting to persuade the court to assess a lower fee than that requested by the lawyer. If the fee is to be deducted from a settlement fund otherwise payable to the class, class members will have an economic interest in arguing that it is excessive because it will reduce their shares. In view of this interest, notice of an impending fee hearing is sent to them.

A controversial procedural issue has concerned whether the fee assessment should be a hearing involving *viva voce* testimony, the presentation of documentary evidence, cross-examination, and pre-hearing discovery.[147] The alternative to such a formal proceeding is a court determination relying exclusively on documentary material. It seems that the former type of hearing is mandatory where it appears from the fee application that facts are in dispute, even where there has been no formal challenge to the lawyer's claims, or where one or more objecting class members wish to present evidence.[148]

After the court has determined the fee, it must consider how the burden is to be borne by members of the class. The general rule is that class members bear the burden on a *pro rata* basis. Until resolved by a recent decision of the United States Supreme Court, there was an issue whether class members who have not claimed their shares should be required to contribute to attorneys' fees on a *pro rata* basis. In *The Boeing Company v. Van Gemert*,[149] Mr. Justice Powell, who delivered the opinion of the Court, stated that, since "[t]he right to share the harvest of the lawsuit, upon proof of their identity, whether or not they exercise it, is a benefit in the fund created by the efforts of the class representatives and their counsel",[150] class members who do not claim their shares should nonetheless be obliged to contribute on a *pro rata* basis to the award of attorneys' fees.

Once the amount of the fee is settled, it is a simple matter to secure payment. Before individual shares of the recovery are distributed to class members, the fees are deducted from the fund and the amount of the individual shares is reduced accordingly.[151]

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amount is to be divided among lawyers claiming fees. If there is no agreement as to the total amount of the fees, the court will determine the individual fee applications of the various lawyers, rather than assess a global sum. In cases where the theoretical basis of the award of the attorney's fee is to reward services that have benefited the class members with whom the lawyers have no contractual relationship, the inquiry necessarily will focus first on the question of whether the activities of the particular lawyer benefited the class.

[147] See Mowrey, *supra*, note 93, at 292-94.

[148] *Lindy I*, *supra*, note 122, at 169; *City of Detroit v. Grinnell Corp.*, *supra*, note 117, at 468; and *Piambino v. Bailey*, 610 F.2d 1306 (5th Cir. 1980), at 1328.

[149] *Supra*, note 81. For a discussion of this case, see *supra*, ch. 14, sec. 3(b)(i).

[150] *The Boeing Company v. Van Gemert*, *supra*, note 81, at 750.

[151] See Newberg, *supra*, note 83, Vol. 3, §6970a, at 1256-57.

Case Name:

Labourers' Pension Fund of Central and Eastern Canada (Trustees of) v. Sino-Forest Corp.

Between

The Trustees of the Labourers' Pension Fund of Central and Eastern Canada, the Trustees of the International Union of Operating Engineers Local 793 Pension Plan for Operating Engineers in Ontario, Sjuunde Ap-Fonden, David Grant and Robert Wong, Plaintiffs, and

Sino-Forest Corporation, Ernst & Young LLP, BDO Limited (formerly known as BDO McCabe Lo Limited), Allen T.Y. Chan, W. Judson Martin, Kai Kit Poon, David J. Horsley, William E. Ardell, James P. Bowland James M.E. Hyde, Edmund Mak, Simon Murray, Peter Wang, Garry J. West, Pöyry (Beijing) Consulting Company Limited, Credit Suisse Securities (Canada), Inc., TD Securities Inc., Dundee Securities Corporation, RBC Dominion Securities Inc., Scotia Capital Inc., CIBC World Markets Inc., Merrill Lynch Canada, Inc., Canaccord Financial Ltd., Maison Placements Canada Inc., Credit Suisse Securities (USA) LLC and Banc of America Securities LLC, Defendants

PROCEEDING UNDER the Class Proceedings Act, 1992

[2012] O.J. No. 1331

2012 ONSC 1924

110 O.R. (3d) 173

Court File No. 11-CV-431153CP

Ontario Superior Court of Justice

P.M. Perell J.

Heard: March 22, 2012.
Judgment: March 26, 2012.

(94 paras.)

Civil litigation -- Civil procedure -- Parties -- Class or certification actions -- Certification -- Procedure -- Pleadings -- The defence -- Time for filing -- Applications and motions -- Conduct of hearing -- Adjournments -- Motion by plaintiffs to require defendants to file defences and hear certification and leave motions together allowed in part -- Plaintiffs claimed defendants made misrepresentations in primary and secondary markets and committed oppression, negligence, negligent misrepresentation, conspiracy and unjust enrichment -- Defendants could not be ordered to plead secondary market defences until leave granted -- However, defendants who delivered affidavits under Securities Act were required to file defences -- Delivery of Statements of Defence without prejudice to seeking summary dismissal or challenging certification -- Leave and certification heard together for efficiency -- Adjournment granted to BDO to plead limitations defence.

Securities regulation -- Civil liability -- Secondary market disclosure -- Defences -- Motion by plaintiffs to require defendants to file defences and hear certification and leave motions together allowed in part -- Plaintiffs claimed defendants made misrepresentations in primary and secondary markets and committed oppression, negligence, negligent misrepresentation, conspiracy and unjust enrichment -- Defendants could not be ordered to plead secondary market defences until leave granted -- However, defendants who delivered affidavits under Securities Act were required to file defences -- Delivery of Statements of Defence without prejudice to seeking summary dismissal or challenging certification -- Leave and certification heard together for efficiency -- Adjournment granted to BDO to plead limitations defence.

Motion by the plaintiffs for an order requiring the defendants to deliver their Statements of Defence and to have the certification and leave motions heard together. The plaintiffs were a union and pension funds that claimed the defendants made misrepresentations in primary and secondary markets. The plaintiffs also claimed oppression, negligence, negligent misrepresentation, conspiracy and unjust enrichment against some defendants. None of the defendants had served Statements of Defence or advised which statutory or common law defences they planned to advance. The defendants strenuously resisted delivering their Statements of Defence before the certification motion on the basis the plaintiffs required leave under the Securities Act and the Statement of Claim may not survive a Rule 21 challenge. The defendants also resisted having the motions heard together. The defendant BDO argued limitations periods applied to the claim against it.

HELD: Motion allowed in part. The plaintiffs were to finalize their pleadings and make no further amendments without leave so that the defendants would know the case to meet. The defendants could not be ordered to plead secondary market claims until leave was granted under s. 138.8 or the Securities Act. It was desirable to close pleadings prior to certification and the defendants had surely investigated material facts by now, so their resistance to pleading was tactical. Compelling Statements of Defence was not unfair generally but, given the requirement of leave under the

Securities Act, the defendants could not be asked to plead to a pregnant Statement of Claim. The defendants also could not be compelled to deliver affidavits in response to the leave motion. However, as delivering an affidavit was essentially the same as delivering a defence, the defendants that chose to deliver affidavits had no valid objection to delivering Statements of Defence and would be required to do so. The other defendants could make the tactical decision whether to deliver defences or not. Rule 25.07 was notionally revised to reflect this situation. Delivery of Statements of Defence would be without prejudice to defendants' rights to bring a Rule 21 motion or challenge whether the plaintiffs had shown a cause of action. Having the leave and certification motions heard together would be more efficient and was not unfair. No motions were to be heard before the combined leave and certification motion other than the plaintiffs' already-scheduled funding motion. The matter was adjourned with respect to the defendant BDO so it could plead its unique limitations defence.

Statutes, Regulations and Rules Cited:

Class Proceedings Act, 1992, S.O. 1992, c. 6, s. 5(1)(a), s. 12, s. 28, s. 35

Rules of Civil Procedure, Rule 1.04, Rule 25.06(1), Rule 25.07, Rule 25.07(7)

Securities Act, R.S.O. 1990, c. S.5, s. 130(3), s. 130(4), s. 130(5), s. 138.3, s. 138.8, s. 138.8(2), Part XXIII.1

Counsel:

Kirk M. Baert and Michael Robb for the Plaintiffs.

Michael Eizenga for Sino-Forest Corporation, Simon Murray, Edmund Mak, W. Judson Martin, Kai Kit Poon and Peter Wang.

Emily Cole and Megan Mackey for Allan T.Y. Chan.

Peter Wardle and Simon Bieber for David J. Horsley.

Laura Fric and Geoffrey Grove for William E. Ardell, James P. Bowland, James M.E. Hyde and Garry J. West.

John Fabello and Andrew Gray for Credit Suisse Securities (Canada) Inc., TD Securities Inc., Dundee Securities Corporation, RBC Dominion Securities Inc., Scotia Capital Inc., CIBC World Markets Inc., Merrill Lynch Canada Inc., Canaccord Financial Ltd., Maison Placements Canada Inc., Credit Suisse Securities (USA) LLC and Banc of America Securities LLC.

Peter H. Griffin and Shara Roy for Ernst & Young LLP.

Kenneth Dekker and Michelle Booth for BDO Limited.

John Pirie and David Gadsden for Pöyry (Beijing) Consulting Company Limited.

REASONS FOR DECISION

P.M. PERELL J.:--

A. INTRODUCTION

1 A motion for an order requiring a defendant to deliver a statement of defence or for an order setting a timetable for a motion should not be a momentous matter. But scheduling is a very big deal in this very big case under the *Class Proceedings Act, 1992*, S.O. 1992, c. 6.

2 The Defendants strenuously resist delivering a statement of defence before the certification motion, and they submit that it would both contrary to law and a denial of due process to require them to plead in the normal course of an action.

3 The Defendants submit that having to plead their statement of defence is contrary to law because the Plaintiffs' statement of claim can be commenced only with leave pursuant to s. 138.8 of the *Securities Act*, R.S.O. 1990, c. S.5 and in *Sharma v. Timminco,* 2012 ONCA 107, the Court of Appeal ruled that the statement of claim does not exist until leave is granted. The Defendants submit that having to plead their statement of defence is a denial of due process because the Plaintiffs' statement of claim includes causes of action that might not survive a challenge under Rule 21 of the *Rules of Civil Procedure*. One of the Defendants, BDO Limited, also argues that claims against it are statute-barred, and, therefore, it should not be required to deliver a statement of defence but should be permitted to bring a Rule 21 motion before the certification hearing.

4 The position of the Defendants is set out in paragraph 2 of the Defendant Sino-Forest Corporation's factum as follows:

> 2. The Responding Parties oppose the relief relating to the delivery of a statement of defence because, as a result of the Ontario Court of Appeal's decision in *Sharma v. Timminco*, the secondary market action has yet to be commenced and will not have been commenced unless and until leave has been granted by this Honourable Court. Accordingly, the Defendants cannot be required to deliver a statement of defence to a proceeding that has yet to be commenced. Moreover, the secondary market claims are intertwined with the balance of the allegations in the statement of claim, such that it would not be realistic to provide a partial or bifurcated defence. In addition, the Responding Parties expect to be bringing a motion to strike the Statement of claim, at least in respect of the portion of the

claim that purports to be brought on behalf of Noteholders, who are prohibited from commencing such a claim by virtue of the no suits by holder clause.

5 In response, the Plaintiffs submit that just as defendants are entitled to know the case they must meet, plaintiffs are entitled to know the defence they confront. The Plaintiffs submit that the law and the dictates of due process do not preclude ordering the delivery of a statement of defence in accordance with the *Rules of Civil Procedure*, and the Plaintiffs' rely on the court's power under s. 12 of the *Class Proceedings Act, 1992* and on what I said in *Pennyfeather v. Timminco*, 2011 ONSC 4257 about the desirability of the pleadings being closed before the certification motion.

6 In the immediate case, the Defendants also strenuously resist the Plaintiffs' request that the leave motion under s. 138.8 the *Securities Act* and the certification motion under the *Class Proceedings Act, 1992* be heard together. Instead of a combined leave and certification motion, the Defendants submit that a series of motions be scheduled, beginning with the leave motion, followed by Rule 21 motions, followed by the certification motion. Some Defendants would begin with the Rule 21 motions before the leave motion, but all wish a sequence of separate motions.

7 The Defendants submit that a combined leave and certification motion would be both inappropriate and also unfair, and particularly so, if they are also required to plead their defences. The Defendants submit that fairness dictates that leave be determined in advance of certification, and that their right to attack all or part of whatever pleading emerges from the leave motion be preserved. They submit that it would be inefficient to deliver a statement of defence when the statement of claim is likely to be amended in a substantial manner depending on the outcome of the Plaintiffs' leave motion and the Rule 21 motions.

8 The Plaintiffs regard the Defendants' proposal of a sequence of motions as something akin to having their action being sentenced to a life of imprisonment on Devil's Island.

9 For the reasons that follow, I adjourn the motion as it concerns BDO Limited, and I order that there shall be a combined leave and certification motion on November 21-30, 2012 (10 days).

10 I order that the "Proposed Fresh as Amended Statement of Claim" be the statement of claim for the purposes of the leave and certification motion and that this pleading shall not be amended without leave of the court. Further, I order that with the exception of the Plaintiffs' funding motion, there shall be no other motions before the leave and certification motion without leave of the court first being obtained.

11 I do not agree that it would be contrary to law or a denial of due process to order the pre-certification delivery of a statement of defence; nevertheless, I shall not order all the Defendants to deliver their statements of defence before the combined leave and certification.

12 Rather, I shall order that a statement of defence be delivered by any Defendant that delivers an affidavit pursuant to s. 138.8 (2) of the *Securities Act*. I order that any other Defendant may, if so

advised, deliver a statement of defence. Further, I order that if a Defendant delivers a statement of defence, then the delivery of the statement of defence is not a fresh step and the Defendant is not precluded from bringing a Rule 21 motion at the leave and certification motion or from contesting that the Plaintiffs have shown a cause of action under s. 5 (1)(a) of the *Class Proceedings Act, 1992.*

13 In my reasons, I will explain why it may be advantageous to a defendant to deliver a statement of defence although it may not be obliged to do so.

14 Finally, in my reasons, I will establish a timetable for the funding motion and for the leave and certification motion, which timetable may be adjusted, if necessary, by directions made at a case conference.

B. FACTUAL AND PROCEDURAL BACKGROUND

15 Sino-Forest is a Canadian public company whose shares formerly traded on the Toronto Stock Exchange. At the moment, trading is suspended because on June 2, 2011, Muddy Waters Research released a research report alleging fraud by Sino-Forest. The release of the report had a catastrophic effect on Sino-Forest's share price.

16 On June 20, 2011, The Trustees of the Labourers' Pension Fund of Central and Eastern Canada ("Labourers") retained Koskie Minsky LLP to sue Sino-Forest. Koskie Minsky issued a notice of action in a proposed class action with Labourers as the proposed representative plaintiff.

17 The June action, however, was not pursued, and in July 2011, Labourers and another pension fund, the Trustees of the International Union of Operating Engineers Local 793 Pension Plan for Operating Engineers in Ontario ("Engineers") retained Koskie Minsky and Siskinds LLP to commence a new action, which followed on July 20, 2011, by notice of action. The statement of claim in *Labourers v. Sino-Forest*, which is the action now before the court, was served in August, 2011.

18 On November 4, 2011, Labourers served the Defendants in *Labourers v. Sino-Forest* with the notice of motion for an order granting leave to assert the causes of action under Part XXIII.1 of the *Ontario Securities Act.*

19 At this time, there were rival class actions. Douglas Smith had retained Rochon Genova, LLP. Rochon Genova issued a notice of action on June 8, 2011. The statement of claim in *Smith v. Sino-Forest* followed on July 8, 2011. Northwest & Ethical Investments L.P. and Comité Syndical National de Retraite Bâtirente Inc. retained Kim Orr Barristers P.C., and on September 26, 2011, Kim Orr commenced *Northwest v. Sino-Forest.*

20 On December 20 and 21, 2011, there was a carriage motion, and on January 6, 2012, I released my judgment awarding carriage to Class Counsel in *Labourers v. Sino-Forest.* I granted leave to the Plaintiffs to deliver a Fresh as Amended Statement of Claim, which may include the

joinder of the plaintiffs and the causes of action set out in *Grant v. Sino-Forest*, *Smith v. Sino-Forest*, and *Northwest v. Sino-Forest*, as the Plaintiffs may be advised.

21 On January 26, 2012, the plaintiffs delivered an Amended Statement of Claim.

22 On March 2, 2012, the Plaintiffs initiated a motion seeking leave to assert causes of action pursuant to ss. 138.3 and 138.8 under Part XXIII.1 of the *Securities Act*.

23 Plaintiffs' motion materials included a draft Fresh as Amended Statement of Claim for the eventuality that leave is granted ("Proposed Fresh as Amended Statement of Claim"). The Proposed Fresh as Amended Statement of Claim substantially amends and extends the allegations contained in the pleading delivered in January 2012.

24 In their various pleadings, the Plaintiffs allege that Sino-Forest and the other Defendants made misrepresentations in the primary and secondary markets. The Plaintiffs claims include: $0.8 billion for primary market claims; $1.8 billion (U.S.) for noteholders; and $6.5 billion for secondary market claims. There are also claims against some of the Defendants for a corporate oppression remedy, negligence, negligent misrepresentation, conspiracy, and unjust enrichment. The following chart describes the claims against each Defendant:

	S.A. s. 130 (prospectus)	S.A. s. 130.1 (offering memorandum)	S.A. s. 138.3 (secondary market)	Negligent misrepresentation (secondary market)	Negligent misrepresentation (prospectus/o-memo)	Negligence (prospectus, offering memorandum)	Unjust Enrichment	CBCA Oppression	Conspiracy
Sino Forest	X	X	X	X	X	X	X	X	X
Chan	X		X	X	X	X	X	X	X
Horsley	X		X	X	X	X	X	X	X
Poon	X		X	X	X	X	X	X	X
Wang	X		X	X	X	X		X	
Martin	X		X	X	X	X	X	X	
Mak	X		X		X	X	X	X	
Murray	X		X	X	X	X	X	X	
Hyde	X		X	X	X	X		X	
Ardell			X	X				X	
Bowland			X	X				X	
West			X	X				X	
Ernst & Young	X		X	X	X	X			
BDO Ltd.	X		X	X	X	X			
Böyry (Beijing)	X		X			X			
Credit Suisse	X				X	X	X		
TD Securities	X				X	X	X		
Dundee Securities	X				X	X	X		
RBC Dominion	X				X	X	X		
Scotia Capital	X				X	X	X		
CIBC World	X				X	X	X		
Merrill Lynch	X				X	X	X		
Canaccord	X				X	X	X		
Maison	X				X	X	X		
Credit Suisse (USA)						X	X		
Banc of America						X	X		

25 On March 6, 2012, there was a case conference, and I scheduled 10 days of hearings from November 21 to November 30, 2012. Apart from deciding that the leave motion must be heard, I did not decide what would be the subject matter of those hearing dates.

26 None of the Defendants has served a statement of defence. None has advised which, if any, statutory or common law defences they will advance in response to the Plaintiffs' claims. In this regard, it may be noted that the Plaintiffs advance claims under s. 130 of the *Securities Act* with respect to misrepresentations in the primary market. These claims raises at least eight possible statutory defences, which are set out in subsections 130(3), (4) and (5) of the *Securities Act*. If leave

is granted, the Plaintiffs also advance claims under Part XXIII.1 of the *Securities Act.* As noted in Sino-Forest's factum for this motion, there are at least 11 defences to secondary market claims.

C. DISCUSSION

1. Introduction

27 In this introductory section, I will address the one relatively easy issue; i.e., the problem of the "moving target" statement of claim.

28 In the sections that follow, I will address the more difficult issues of: (a) whether the Defendants can and should be ordered to deliver statements of defence; (b) whether the leave motion should be combined with the certification motion or instead there should be a sequence of motions; (c) what other motions, if any, should be permitted before the certification motion; and (d) what should the timetable be for the motions.

29 Beginning with the relatively easy problem, at the argument of this motion, the Defendants vociferously complained that the Plaintiffs keep changing their statement of claim. The Defendants pointed to substantial differences among the statement of claim delivered before the carriage motion, the statement of claim delivered after the carriage motion, and the Proposed Fresh as Amended Statement of Claim offered up for the purposes of the leave motion.

30 This complaint about a "moving target" statement of claim was advanced as part of the Defendants' arguments that they cannot legally be ordered to deliver a statement of defence. I, however, do not see how this complaint supports that particular argument.

31 I rather regard the "moving target" complaint as a proper objection that if the Defendants are to be ordered to deliver a statement of defence, the content of the statement of claim needs first to be finalized.

32 I agree that for the purposes of a leave or a certification motion, the content of the statement of claim needs to be finalized, and thus the approach should be to order a pleading to be finalized and to order that this pleading not be amended without leave of the court. I so order.

33 The problem then becomes one of selecting which pleading to finalize for the purposes of the leave and certification motion. It makes common sense to select the pleading for which leave is being sought under the *Securities Act*; i.e. the Proposed Fresh as Amended Statement of Claim, and that indeed is my selection.

2. The Delivery of the Statement of Defence in Class Actions

34 I turn now to the difficult issues of whether the Defendants can be ordered to deliver statements of defence, and if they can be ordered to plead, whether they should be ordered to plead.

35 As will be seen shortly, the Defendants submit that they cannot be ordered to plead to a secondary market claim that does not exist unless and until leave is granted under s. 138.8 of the *Securities Act*. For present purposes, I will accept the correctness of this submission, but it does not follow that the Defendants cannot plead to that portion of the Proposed Fresh as Amended Statement of Claim that is not exclusively referable to the secondary market claims. Assuming that the Defendants are correct that there is a portion of the Proposed Fresh as Amended Statement of Claim to which they cannot be obliged to plead does not negate that there are portions of the Proposed Fresh as Amended Statement of Claim that can and should be answered by a statement of defence.

36 The Defendants' submission rather means that rule 25.07 of the *Rules of Civil Procedure*, which provides the rules of pleading applicable to defences, needs to be amended for the purpose of the leave and certification motion so that defendants do not have to plead to a pregnant action under Part XXIII.1 of the *Securities Act* that may never be born.

37 Rule 25.07 states:

> Admissions
>
> 25.07 (1) In a defence, a party shall admit every allegation of fact in the opposite party's pleading that the party does not dispute.
>
> Denials
>
> (2) Subject to subrule (6), all allegations of fact that are not denied in a party's defence shall be deemed to be admitted unless the party pleads having no knowledge in respect of the fact.
>
> Different Version of Facts
>
> (3) Where a party intends to prove a version of the facts different from that pleaded by the opposite party, a denial of the version so pleaded is not sufficient, but the party shall plead the party's own version of the facts in the defence.
>
> Affirmative Defences

(4) In a defence, a party shall plead any matter on which the party intends to rely to defeat the claim of the opposite party and which, if not specifically pleaded, might take the opposite party by surprise or raise an issue that has not been raised in the opposite party's pleading.

Effect of Denial of Agreement

(5) Where an agreement is alleged in a pleading, a denial of the agreement by the opposite party shall be construed only as a denial of the making of the agreement or of the facts from which the agreement may be implied by law, and not as a denial of the legality or sufficiency in law of the agreement.

Damages

(6) In an action for damages, the amount of damages shall be deemed to be in issue unless specifically admitted.

38 To repeat, for the purposes of the leave motion where a party cannot be obliged to plead and for the combined certification motion, rule 25.07 needs to be revised to accommodate s. 138.8 of the *Securities Act*.

39 Pursuant to the authority provided by s. 12 of the *Class Proceedings Act, 1992*, which authorizes the court to make any order it considers appropriate respecting the conduct of a class proceeding to ensure its fair and expeditious determination, I have the jurisdiction to revise the procedure for a class proceeding to accommodate s. 138.8 of the *Securities Act*, and I do so by notionally adding a new subrule 25.07 (7) as follows:

(7) In an action under the *Class Proceedings Act, 1992* for which leave is also being sought to commence an action under section 138.3 of the *Securities Act* (liability for secondary market disclosure), in a defence, a party who does not file an affidavit pursuant to rule 138.8 (2) and who delivers a statement of defence shall decline to either admit or deny the allegations of fact referable solely to his or her liability for secondary market disclosure and not referable to any other pleaded cause of action.

40 Practically speaking, notional subrule 25.07 (7) divides the Defendants into three classes.

41 First, there are those Defendants who deliver a s. 138.8 (2) affidavit under the *Securities Act*. These Defendants must deliver a statement of defence for the reasons expressed below.

42 Second, there are those Defendants against whom there are no allegations of fact referable to liability for secondary market disclosure, who thus have no right or need to deliver a s. 138.8 (2) affidavit under the *Securities Act* and who choose to deliver a statement of defence. These plaintiffs may, if so advised, simply plead in the normal course.

43 Third, there are those Defendants against whom there are allegations of fact referable to liability for secondary market disclosure and who do not deliver a s. 138.8 (2) affidavit but who deliver a statement of defence.

44 Under notional rule 25.07 (7), these Defendants shall decline to either admit or deny the allegations of fact referable solely to his or her liability for secondary market liability and not referable to any other pleaded cause of action. These defendants must state that they neither admit nor deny the allegations contained in those paragraphs (*identify paragraph numbers*) of the statement of claim referable solely to liability for secondary market liability and not referable to any other pleaded cause of action. As will become clearer after the discussion below, by being required to neither admit nor deny allegations referable solely to secondary market liability, these Defendants cannot circumvent the requirements of s.138.8 (2) of the *Securities Act* that they must file an affidavit in order to set forth the material facts upon which they intend to rely for the leave motion.

45 This brings the discussion and the analysis to whether there might be other reasons not to order the Defendants to deliver a statement of defence. The convention in class actions, which existed from 1996 to 2011, was that a defendant not be required to deliver a statement of defence pre-certification because of the likelihood that the statement of claim would be reformulated as a result of the certification decision and based on the view that the statement of defence had little utility before certification. See *Mangan v. Inco Ltd.* (1996), 30 O.R. (3d) 90 at pp. 94-95 (Gen. Div.); *Glover v. Toronto (City)* [2008] O.J. No. 604 at para. 8 (S.C.J.).

46 In *Pennyfeather*, I suggested that the convention should be revisited and that it was desirable that the pleadings be closed before the certification motion. See also *Kang v. Sun Life Assurance Company of Canada*, 2011 ONSC 6335.

47 In *Pennyfeather* at paras. 37-38, 84-92, I stated:

> 37. Class actions are subject to the *Rules of Civil Procedure,* and there is nothing in the *Class Proceedings Act, 1992* that precludes defendants from pleading before the certification motion. It is informative that the convention of not closing the pleadings is not a statutory rule, and if the Plaintiff insists on the delivery of a pleading, a defendant may need to seek the permission of the court to delay the delivery of the pleading.
> 38. Moreover, the provisions of the *Class Proceedings Act, 1992* indicate that it was the Legislature's intention that the general rule is that the statement of defence should be delivered before the certification motion. Section 2 (3) of the Act

indicates that the timing of the certification motion is measured by the delivery of the statement of defence. ...

84. ... it would be advantageous for the immediate case and for other cases, if the current convention ended and defendants were required in the normal course to deliver a statement of defence before the certification motion. As I will illustrate, there would be several advantages to this approach, and as I mentioned above, the Legislature intended that the general rule should be that the pleadings should be completed before the certification motion.

85. Before I provide some examples of the advantages of closing the pleadings before certification, it is helpful to recall that under s. 5 (1) of the *Class Proceedings Act, 1992*, a plaintiff must satisfy five interdependent criteria for his or her action or application to be certified as a class proceeding. The Plaintiff must: (1) show a cause of action; (2) identify a class; (3) define common issues; (4) show that a class proceeding would be the preferable procedure; and (5) qualify as a representative plaintiff with a litigation plan and adequate Class Counsel.

86. A major advantage of closing the pleadings is that controversies about the first of the five criteria for certification might be resolved or at least narrowed or confined before the certification motion.

87. The delivery of a statement of defence could be a fresh step that could foreclose any subsequent attack by the defendant for any pleadings irregularities and, more to the point, typically defendants do not deliver a statement of defence if there is a substantive challenge to the statement of claim. Rather, they bundle all their challenges to the statement of claim and bring a motion to have the statement of claim or portions of it struck out on both technical and substantive grounds. ...

88. In other words, the requirement of delivering a statement of defence will call out the defendant to make its challenges to the statement of claim and, thus, the s. 5 (1)(a) criterion might be removed as an issue as would any challenge to the pleading for wanting in particulars or for breaching the technical rules for pleading. The s. 5 (1)(a) criterion for certification might be decided before the certification motion.

89. If the defendant brings a comprehensive pleadings challenge before the certification motion, then, the s. 5 (1)(a) criterion would be resolved before the certification hearing one way or the other. It would be particularly useful to resolve a s. 5 (1)(a) challenge before the certification motion when the challenge is based on the court not having subject-matter jurisdiction over the plaintiff's claim. If that challenge is upheld, then the class action would be dismissed or stayed and the enormous costs of a comprehensive certification motion is avoided.

90. Further, hearing an interlocutory motion about the sufficiency of the pleading might be preferable to having the challenge heard at the certification motion as

an aspect of the s. 5 (1)(a) analysis because a common outcome of this analysis is to grant the plaintiff leave to amend his or her statement of claim, which outcome, at a minimum, exacerbates the complexities of determining the certification motion because of the interdependency of the certification criteria.

91. In many cases, the technical or substantive adequacy of a plaintiff's statement of claim is not an issue and, therefore, requiring the completion of the pleadings will involve no interlocutory steps and the analysis of the other four certification criteria would be facilitated by a completed set of pleadings.

92. For instance, having the Statement of defence before the certification motion would provide useful information for analyzing the preferable procedure criterion and the plaintiff's litigation plan. Moreover, it may emerge that there are issues worthy of certification in the defendant's statement of defence.

48 For present purposes, I do not retreat from what I said in *Pennyfeather*, and I shall emphasize several points and add a few more. In this regard, I emphasize that it was the clear intention of the Legislature that the pleadings be closed before certification. I add that this makes sense because the certification criteria of class definition, common issues, preferable procedure, and litigation plan are best adjudicated in the context of the parameters of the action and it may emerge that the defendant has pleaded issues that may usefully be added to the list of common issues.

49 Further, I add that the Legislature also indicated by s. 35 of the *Class Proceedings Act, 1992,* that the *Rules of Civil Procedure* apply to class proceedings, reserving the courts' authority to make adjustments to that procedure under s. 12 of the *Act*. Generally speaking, it is desirable to normalize class actions with the procedure under the *Rules of Civil Procedure*. The *Rules* are the norm for a fair procedure, and the norm of civil procedure is that both sides must disclose the case that their opponent must meet. Defendants are not like an accused in a criminal proceeding with a right to remain silent. It is not regarded as unfair or abnormal to compel a defendant to plead a statement of defence in response to a statement of claim.

50 Further still, I add that having a complete set of pleadings recognizes the maturity of the class action jurisprudence. There already have been many Rule 21 and s.5 (1)(a) challenges, and the viability of many causes of action or types of claim as being suitable for class actions has been informed by twenty years of cases. Recognition of the maturity of the case law in and of itself calls for a rethinking of the convention of not delivering a statement of defence, because assisted by precedents of what has been certified in the past, plaintiffs are better able to exit the certification hearing with their pleadings intact.

51 In other words, in contemporary times the Defendants' concern that they will have wasted time and effort pleading to a statement of claim that may be different after certification will not be borne out. In any event, the complaint of a wasted effort is overblown. Unless pleadings are to be regarded as a work of fictional literature, claims and defences are based on the material facts that existed, and competent counsel will take instructions about all the possible claims and defences that emerge

from those set of facts before the certification motion.

52 I find it hard to believe that the accomplished lawyers in the case at bar are waiting for the outcome of the leave motion and the certification motion before investigating the material facts and researching the applicable law and advising the Defendants about what defences are available to them. The truth of the matter is that the Defendants and their lawyers are not concerned about wasted time and effort but rather they do not wish to plead because they believe it is tactically better to avoid the disclosure of their case that the *Rules of Civil Procedure* would normally mandate.

53 I see no unfairness of denying defendants a tactical maneuver that may be inconsistent with general principle of rule 1.04 that the rules "shall be liberally construed to secure, the just, most expeditious and least expensive determination of every civil proceeding on its merits."

54 I also see no unfairness in denying defendants the tactical maneuver of not delivering a statement of defence before certification when the exchange of pleadings may be tactically and substantively beneficial to defendants. The defendants arguments that class membership is over-inclusive or under-inclusive, that the proposed common issues want for commonality, that the action is not manageable as a class action, that a class proceeding is not the preferable procedure, and that the litigation plan is deficient are best made when the defendants shows the colour of his or her eyes by pleading a defence and these arguments will be stronger than the "is! - is not! - is too!" sandbox arguments of many a certification motion. For whatever it is worth, my own observation from recent certification motions where defendants have pleaded before certification is that both sides and the administration of justice are better for it.

55 Finally, from a public relations point of view - and class actions are by their nature of considerable interest to the public - I would have thought that many defendants would like to seize the opportunity by pleading the material facts of their defence to take the sting out of the plaintiff's argument that the defendants need behaviour management and to level the playing field about the certification criteria.

56 Thus, generally speaking, I persist in my view that the pleadings issues should be completed before the certification motion. The Defendants' argue, however, that whatever may be the situation for class actions generally, the Court of Appeal's decision in *Sharma v. Timminco*, *supra*, has overtaken *Pennyfeather*, and *Sharma* means that in a proposed secondary market class action, a statement of defence cannot be demanded or delivered before leave is granted under s. 138.3 of the *Securities Act*. A defendant cannot be asked to plead to a pregnant statement of claim.

57 The Defendants take the *Sharma* decision to be authority that a class proceeding is not an action commenced under s. 138.3 until leave is granted and leave is required to add the s. 138.3 cause of action to the class proceeding. The Defendants submit that without leave, a s. 138.3 action cannot be enforced. As Sino-Forest put it in its factum: "Until leave has been granted, the plaintiff has nothing: no limitation periods are tolled, and no steps in the proceeding - including the filing of a defence - can be taken."

58 This hyperbolic submission by Sino-Forest and by the rest of the Defendants is not true. Whatever the effect of *Sharma*, it did not take away s. 138.8 of the *Securities Act*, under which subsection (2) requires for the leave motion that the plaintiff and each defendant swear under oath the "material facts upon which each intends to rely."

59 Section 138.8 of the *Securities Act*, which provides the test for leave and which governs the procedure for the leave motion, states:

> Leave to proceed
>
> 138.8 (1) No action may be commenced under section 138.3 without leave of the court granted upon motion with notice to each defendant. The court shall grant leave only where it is satisfied that,
>
> (a) the action is being brought in good faith; and
> (b) there is a reasonable possibility that the action will be resolved at trial in favour of the plaintiff.
>
> Same
>
> (2) Upon an application under this section, the plaintiff and each defendant shall serve and file one or more affidavits setting forth the material facts upon which each intends to rely.
>
> Same
>
> (3) The maker of such an affidavit may be examined on it in accordance with the rules of court. ...

60 Subsection 138.8 (2) may be usefully compared and contrasted with rule 25.06 (1) of the *Rules of Civil Procedure*, which is the predominant rule about pleading in an action. Rule 25.06 (1) states:

> 25.06 (1) Every pleading shall contain a concise statement of the material facts on which the party relies for the claim or defence, but not the evidence by which those facts are to be proved.

Both the subsection and the rule require the party to disclose to their opponent the "material facts"

on which the party "relies." The pleadings rule, however, does not require that the disclosure of material facts be under oath. Assuming that a defendant does file an affidavit under s. 138.8 (2), then the affidavit is, in effect, an under oath version of 25.06 (1)'s requirement that a defendant disclose the material facts upon which he or she relies.

61 I concede that filing an affidavit under s. 138 (8) is not mandatory and that it cannot be assumed that a defendant will deliver an affidavit for a leave motion under the *Securities Act*, and that he or she cannot be compelled to do so. In *Ainslie v. CV Technologies Inc.* 93 O.R. (3d) 200 at paras. 14-20, 24-25 (S.C.J.), Justice Lax interpreted s. 138.8 (2), and she stated:

> 14. Section 138.8(1) sets out a two-part test for obtaining leave to bring an action under Part XXIII.1 of the OSA and places the onus on the plaintiffs to demonstrate that (1) their proposed action is brought in good faith and (2) has a reasonable prospect for success at trial. As s. 138.8(1) requires an examination of the merits, the plaintiffs submit that the section is supplemented with s. 138.8(2) and (3). They rely on the mandatory language in s. 138.8(2) ("and each defendant shall") and submit that without the benefit of this requirement and the ability to cross-examine, a plaintiff would be deprived of the tools necessary to meet the standard the legislature created in s. 138.8(1).
> 15. This submission ignores the legislative purpose of s. 138.8. The section was not enacted to benefit plaintiffs or to level the playing field for them in prosecuting an action under Part XXIII.1 of the Act. Rather, it was enacted to protect defendants from coercive litigation and to reduce their exposure to costly proceedings. No onus is placed upon proposed defendants by s. 138.8. Nor are they required to assist plaintiffs in securing evidence upon which to base an action under Part XXIII.1. The essence of the leave motion is that putative plaintiffs are required to demonstrate the propriety of their proposed secondary market liability claim before a defendant is required to respond. Section 138.8(2) must be interpreted to reflect this underlying policy rationale and the legislature's intention in imposing a "gatekeeper mechanism".
> 16. The plaintiffs appear to be interpreting s. 138.8(2) as if it read: "Upon an application under this section, the plaintiff and each defendant shall serve and file one or more affidavits." But, the subsection continues: "setting forth the material facts upon which each intends to rely". If there are no material facts upon which a defendant intends to rely in responding to a leave motion, how can it be that a defendant is required to file an affidavit? Similarly, if a defendant files one or more affidavits, how can a plaintiff require that defendant to file other affidavits? By discounting this language, the plaintiffs are proposing an interpretation which relieves them of their obligation to demonstrate that their proposed action meets the pre-conditions for granting leave under the Act.
> 17. The plaintiffs' interpretation also fails to address the language used in subsections (3) and (4). Section 138.8(3) reads: "The maker of such an affidavit may be

examined on it in accordance with the rules of court." Section 138.8(4) reads: "A copy of the application for leave to proceed and any affidavits filed with the court shall be sent to the Commission when filed" (emphasis added). Had it been the intention of the legislature to require the parties to file affidavits, irrespective of the onus placed upon the moving party, the legislature would have substituted the word "the" for "any" in s. 138.8(4) and the words "the plaintiff and each defendant" for "maker" in s. 138.8(3). I also note that the legislature attached no consequences to the failure of "each defendant" to file an affidavit.

18. In terms of onus, a useful analogy can be found in the summary judgment rule, Rule 20, of the Rules of Civil Procedure. Rule 20.04 provides:

> 20.04(1) In response to affidavit material or other evidence supporting a motion for summary judgment, a responding party may not rest on the mere allegations or denials of the party's pleadings but must set out, in affidavit material or other evidence, specific facts showing that there is a genuine issue for trial.

19. Similar to s. 138.8(2), rule 20.04 utilizes language suggesting that a responding party "must" or "shall" file affidavit material. Notwithstanding the use of such language, under Rule 20, a responding party retains the option to counter the motion by simply cross-examining the moving party, rather than by leading any direct evidence on the motion. In this regard, rule 20.04 has been interpreted as requiring the respondent to a summary judgment motion to "lead trump or risk losing". Notably, however, the onus to establish that there is no genuine issue for trial remains with the moving party. The onus does not shift to the respondent to show that a genuine issue for trial does in fact exist.8

20. Similarly, in a motion under s. 138.8 of the Act, the onus to demonstrate that the proposed claim meets the required threshold remains with the plaintiffs. The onus does not shift to the defendants. A defendant that does not "lead trump" by filing affidavit evidence in response to a motion under s. 138.8 may well take the risk that leave will be granted to the plaintiffs. It does not follow, however, that a defendant is obligated to file evidence or produce an affidavit from each named defendant. It is a well-established principle that, as a general proposition, it is counsel who decides on the witnesses whose evidence will be put forward. ...

24. In my view, the "gatekeeper provision" was intended to set a bar. That bar would be considerably lowered if the plaintiffs' view is correct. As I have already indicated, a defendant who does not file affidavit material accepts the risk that it may be impairing its ability to successfully defeat the motion for leave and is probably foregoing the right to assert the statutory defences under Part XXIII.1 of the Act. However, parties are entitled to present their case as they see fit and

this includes the right to oppose the leave motion on the basis of the record put forward by the plaintiffs as GT intends, or on the basis of the affidavits of experts as CV intends. [page209]

25. To accept the plaintiffs' submissions would require each defendant to produce evidence that may not be necessary for the leave motion and would serve no purpose other than to expose those defendants to a time-consuming and costly discovery process. It would sanction "fishing expeditions" prior to the plaintiffs obtaining leave to proceed with their proposed action. This is an unreasonable interpretation of s. 138.8(2). It is inconsistent with the scheme and object of the Act. Properly interpreted, the ordinary meaning of s. 138.8(2) is that a proposed defendant must file an affidavit only where it intends to lead evidence of material facts in response to the motion for leave.

62 In *Ainslie*, leave to appeal was granted [2009] O.J. No. 730 (Div. Ct.), but it appears that the appeal was never argued. In *Sharma v. Timminco Ltd.*, 2010 ONSC 790 at para. 32, I agreed with Justice Lax's interpretation of s. 138.8 (2).

63 In the case at bar, I do not know whether any of the Defendants will deliver affidavits under s. 138.8 (2), but I do know that if a Defendant does deliver an affidavit, then its protest that it would be unfair to require a statement of defence loses its potency as does the urgency of the Plaintiffs' request that the Defendants be ordered to deliver their statements of defence. Delivering an affidavit under s. 138.8 is essentially the same as delivering a statement of claim or defence. As Justice Lax notes, a defendant who does not file affidavit material accepts the risk that it may be impairing its ability to successfully defeat the motion for leave. Justice Lax also notes that the defendant is probably foregoing the right to assert the statutory defences under Part XXIII.1 of the Act, but I would not necessarily go that far.

64 Where this analysis takes me is that it while it would be inappropriate to order all the Defendants to deliver a statement of defence to a secondary market claim under the *Securities Act,* it would be proper to order that any Defendant who delivers an affidavit pursuant to s. 138.8 (2) of the *Act* shall also deliver a statement of defence. I so order.

65 Although I am ordering only Defendants who deliver s. 138.8 (2) affidavits to deliver a statement of defence, I order that any other Defendant may, if so advised, deliver a statement of defence. I leave them to make the tactical decision whether or not to deliver a pleading. As I discussed above, there are advantages for a defendant to plead in a class action.

66 For reasons that I will come to next, if a Defendant does deliver a statement of defence, the delivery is without prejudice to the Defendant's right to bring a Rule 21 motion or to challenge whether the Plaintiffs have shown a cause of action as required by s. 5 (1)(a) of the *Class Proceedings Act, 1992.*

67 Here it should be note that the "plain and obvious" test for disclosing a cause of action from

Hunt v. Carey Canada, [1990] 2 S.C.R. 959, which is used for a Rule 21 motion, is used to determine whether the proposed class proceedings discloses a cause of action; thus, a claim will be satisfactory under s. 5 (1)(a) unless it has a radical defect or it is plain and obvious that it could not succeed: *Anderson v. Wilson* (1999), 44 O.R. (3rd) 673 (C.A.) at p. 679, leave to appeal to S.C.C. ref'd, [1999] S.C.C.A. No. 476; 1176560 *Ontario Ltd. v. Great Atlantic & Pacific Co. of Canada Ltd.* (2002), 62 O.R. (3d) 535 (S.C.J.) at para. 19, leave to appeal granted, 64 O.R. (3d) 42 (S.C.J.), aff'd (2004), 70 O.R. (3d) 182 (Div. Ct.); *Healey v. Lakeridge Health Corp.*, [2006] O.J. No. 4277 (S.C.J.) at para. 25.

68 In this last regard, the Defendants submitted that a defendant has a right to challenge whether the plaintiff has pleaded a reasonable cause of action by bringing a Rule 21 motion and a defendant would lose this procedural right if he or she delivered a statement of defence. Pleading over is a fresh step that deprives a defendant of the right to subsequently challenge the substantive adequacy of a pleading: *Bell v. Booth Centennial Healthcare Linen Services,* [2006] O.J. No. 4646 at paras. 5-7 (S.C.J.); *Cetinalp v. Casino,* [2009] O.J. No. 5015 (S.C.J.). From this true premise, the Defendants submit that since some or all of them wish to bring a Rule 21 motion or some or all will be challenging the reasonableness of the plaintiffs' statement of claim as an aspect of the s. 5 (1)(a) criterion of the of test for certification, they should not be required to deliver a statement of defence before the certification motion.

69 The court's typical but not inevitable response to a Defendant's request to bring a Rule 21 motion before certification is to direct the motion to be heard at the certification hearing because the test for granting a Rule 21 motion is the same test that is applied for the s. 5 (1)(a) criterion for certification. Typically, when this direction is made the defendant is not required to deliver a statement of defence.

70 As already noted, in the case at bar, several defendants have indicated that they wish to bring Rule 21 motions on the basis that several of the Plaintiffs' claims do not disclose a reasonable cause of action or on the basis that the bonds contain a "no suits" clause, and BDO Limited wishes to bring a Rule 21 motion based on the argument that it is plain and obvious that claims against it are statute-barred.

71 I agree that the right of Defendants to challenge the reasonableness of the Plaintiffs' statement of claim should be preserved and protected and I also believe that this objective can be accomplished while still permitting defendants to deliver a statement of defence.

72 Once again, using the authority of s. 12 of the *Class Proceedings Act, 1992*, I order that if a Defendant delivers a statement of defence, then the delivery of the statement of defence is not a fresh step and the Defendant is not precluded from bringing a Rule 21 motion at the leave and certification motion or the Defendant is not precluded from disputing that the Plaintiffs have shown a cause of action under s. 5 (1)(a) of the *Class Proceedings Act, 1992*.

3. Leave and Certification

73 The above discussion addresses the matter of the Plaintiffs' request that the Defendants be ordered to deliver statements of defence and the discussion also lays the foundation for the discussion of the Plaintiffs' request that the leave motion under s.138.8 the *Securities Act* and the certification motion under the *Class Proceedings Act, 1992* be heard together and the Defendants' counter-submission that the motions should be sequenced leave motion, Rule 21 motions, and certification motion.

74 In the case at bar, there is a general consensus that the leave motion should go first, and, in any event, because of the Court of Appeal's ruling in *Sharma* that s. 28 of the *Class Proceedings Act, 1992* is useless in protecting claims under Part XXIII.1 of the *Securities Act* from limitation periods, the leave motion must go first, and I have scheduled ten days of hearing commencing November 21, 2012.

75 The question then is whether the certification motion should be combined with the leave motion.

76 The Plaintiffs submit that hearing the two matters together is consistent with the direction from the Ontario Court of Appeal and that Supreme Court of Canada that litigation by installments should be avoided wherever possible because it does little service to the parties or to the efficient administration of justice." *Garland v. Consumers' Gas Company Limited* (2001), 57 O.R. (3d) 127 at para. 76 (C.A.), aff'd [2004] 1 S.C.R. 629 at para. 90. The Plaintiffs note that leave and certification were dealt with together in *Silver v. Imax Corp.*, [2009] O.J. No. 5585 (S.C.J.), leave to appeal refused [2011] O.J. No. 656 (Div. Ct.) and in *Dobbie v. Arctic Glacier Income Fund*, 2011 ONSC 25.

77 An admonition is different from a prohibition, and while the Court of Appeal and the Supreme Court may frown on litigation in installments, they did not prohibit it. Whether to permit motions before the certification motion is a matter of discretion. In exercising its discretion whether to permit a motion before the certification motion, relevant factors include : (a) whether the motion will dispose of the entire proceeding or will substantially narrow the issues to be determined; (b) the likelihood of delays and costs associated with the motion; (c) whether the outcome of the motion will promote settlement; (d) whether the motion could give rise to interlocutory appeals and delays that would affect certification; (e) the interests of economy and judicial efficiency; and (f) generally, whether scheduling the motion in advance of certification would promote the fair and efficient determination of the proceeding: *Cannon v. Funds for Canada Foundation*, [2010] O.J. No. 314 (S.C.J.) at paras. 14-15.

78 Thus, in my opinion, the question to be decided in the immediate case is whether it is fair (the most important factor) and efficient to hear the certification motion and the leave motion together.

79 Provided that any Defendants who deliver s. 138.8 (2) affidavits or any Defendants who deliver statements of defence may bring Rule 21 motions or otherwise challenge all of the certification criteria as they may be advised, I see no unfairness in having the certification motion

heard along with the leave motion. Because of the orders that I shall make, already discussed above, a Defendant may challenge all of the certification criteria regardless of whether the Defendant has pleaded or not. Pursuant to notional rule 25.07 (7), Defendants who do not file a s. 138.8 (2) affidavit and who deliver a statement of defence "shall decline to admit or deny the allegations referable solely to liability for secondary market disclosure and not referable to any other pleaded cause of action." I see no unfairness to the Defendants who may resist both the certification motion and the leave motion as they may be advised.

80 In contrast, the sequential approach being advocated by the Defendants is unfair to the Plaintiffs and to the proposed class and will impede fulfilling the purposes of the class proceedings legislation, which are first and foremost, access to justice, secondarily, judicial economy, and thirdly, behaviour modification, all the while providing due process and fairness to all parties. Unfortunately, the suffocating expense of motions in class actions along with the excruciating delays and the additional costs of the inevitable leave to appeal motions and appeals that follow class action orders is a serious barrier to achieving the purposes of the legislation for both plaintiffs and defendants and a substantial disincentive to class counsel employing the legislation for other than the huge cases that would justify the litigation risks.

81 As night follows day, if I agreed to schedule sequentially, there would be a ten-day leave motion, followed by the unsuccessful party launching the appeal process which will take several years to resolve. Whatever the outcome of the appeal, the action will return to the Superior Court for the certification motion of the claims not referable solely to liability for secondary market disclosure.

82 In the case at bar, if Rule 21 motions were permitted before the certification hearing although work that could be done at the certification hearing will be accomplished, this will come at the cost of another round of appeals that will take several years to resolve only for the action to return again to the Superior Court for the determination of whether the balance of the certification criteria have been satisfied. That determination will also be appealed.

83 In contrast, if I combine the leave motion, the Rule 21 motions, and the certification motion into one hearing, as night follows day, the determination will be appealed but the superior court and the appellate courts including the Supreme Court of Canada will be denied the pleasure of three visits from one or two generations of Class and Defence Counsel.

84 The Defendants argue that there will be no efficiencies in a sequential ordering of the motions because the criteria for leave differs from the certification criteria, as does the burden of proof for these motions. However, courts are obliged to have the perspicacity to be able to deal with different criteria and different onuses of proof, but, more to the point, the evidentiary footprint for the leave and certification motions are the same, and it makes for little efficiency for the parties and little judicial economy to have the evidence and argument for leave and for certification heard more than once.

85 Putting aside the somewhat unique circumstances of BDO Limited, I conclude that the certification hearing should be combined with the leave motion and that with the exception of the Plaintiffs' funding motion, which has already been scheduled, there shall be no other motions before the leave and certification motion without leave of the court first being obtained.

4. BDO Limited's Request for a Rule 21 Motion

86 As noted at the outset of these reasons, I am adjourning the motion as it concerns BDO Limited, whose circumstances may be unique.

87 BDO was a party to the *Smith v. Sino-Forest* and the *Northwest v. Sino-Forest* rival class actions and it was added to the case at bar after the carriage motion. It submits that all of the statutory claims against it are statute-barred as in one of the main common law misrepresentation claims. It submits that it can diminish its involvement in this expensive litigation by a Rule 21 motion based on the pleadings and without evidence.

88 The Plaintiffs' response was that if BDO wished to assert a limitation period defence it should be a pleaded defence to which the Plaintiffs would file a reply demonstrating that it was not plain and obvious that the claims were statute-barred or demonstrating that there were defences to the running of the limitation period, presumably based on fraudulent concealment or estoppel or waiver. The Plaintiffs also asserted that there were other common claims against BDO that were not statute-barred and thus there was no utility in permitting a Rule 21 motion that would see BDO only partially out of the action.

89 BDO's response was that there were no defences that could withstand the ultimate limitation periods of the *Securities Act* and fairness dictated that it should be permitted to substantially reduce being embroiled in this litigation.

90 My own assessment was that the Plaintiffs were correct in submitting that in the circumstances of this case, BDO should plead its limitation defence and the Plaintiffs should have an opportunity to deliver a reply.

91 Once BDO has pleaded, I will be in a better position in determining whether to permit a Rule 21 motion or perhaps a Rule 20 partial summary judgment motion.

92 Accordingly, I am adjourning the motion as it concerns BDO Limited to be brought on again, if at all, after BDO has pleaded its statement of defence and the Plaintiffs their Reply.

5. The Timetable

93 In light of the discussion above, it is ordered that subject to adjustments, if necessary, made at a case conference, the timetable for the Plaintiff's Funding Approval Motion and for the Leave and Certification Motion is as follows:

Funding Approval Motion

March 9, 2012: Plaintiffs to deliver motion record (completed)

March 30, 2012: Defendants to deliver responding records, if any

April 6, 2012: Plaintiffs to deliver factum

April 13, 2012: Defendants to delivery factum

April, 17, 2012: Hearing of the motion

Leave and Certification Motion

April 10, 2012: Plaintiffs to deliver motion record

June 11, 2012: Defendants to deliver responding records

July 3, 2012: Plaintiffs to delivery reply records, if any

September 14, 2012: Cross-examinations to be completed

October 19, 2012: Plaintiffs to deliver factum

November 9, 2012: Defendants to deliver factum

November 21-30, 2012: Hearing of the motion

D. CONCLUSION

94 An order shall issue in accordance with these Reasons with costs in the cause.

P.M. PERELL J.

cp/e/qlacx/qljxr/qljxh/qljxr/qlhcs

Cassano et al. v. Toronto-Dominion Bank
[Indexed as: Cassano v. Toronto-Dominion Bank]

98 O.R. (3d) 543

Ontario Superior Court of Justice,

Cullity J.

July 9, 2009

Civil procedure -- Class proceedings -- Settlement -- Approval -- Plaintiffs bringing class action based on allegedly undisclosed and unauthorized charges levied by defendant bank for foreign currency credit card transactions -- Parties proposing to settle action for $55 million -- Total amount available for distribution to class members being $39,100,000 -- Approximately $10.75 million of that amount to be paid directly to cardholders and balance to be applied cy pres -- Class counsel requesting fee of $11 million -- Settlement approved.

A class action was brought based on allegedly undisclosed and unauthorized charges levied by the defendant bank for foreign currency transactions conducted with credit cards it had issued. The parties proposed to settle the action for $55 million. Approximately $39,100,000 would be available for distribution for the benefit of class members. From that amount, approximately $10.75 million would [page544] be paid directly to cardholders whose cards were issued before certain dates included in the class definition and who were in good standing and active as of June 1, 2009. The balance of approximately $28.4 million would be applied cy pres as it would be impracticable to attempt to identify more than a relatively small percentage of the class members who were potential claimants. Counsel requested a fee of $11 million, which represented 20 per cent of the settlement amount. The parties moved for approval of the proposed settlement.

Held, the motion should be granted.

The proposed division between direct and indirect benefits struck a reasonable balance between reimbursing class members and applying funds cy pres. Although, as a general rule, cy pres distributions should not be approved where direct compensation to class members is practicable, the allocation of $10.75 million to be paid directly to cardholders was on the generous side as proof that one subgroup of them engaged in foreign currency transactions -- and, in consequence, were within the class definition -- would not be required. One-half of the cy pres amount should be used to

create a trust fund to be administered by the Law Foundation of Ontario for the purpose of advancing public access to justice in Canada. The other half should be used to improve the financial literacy of low-income and otherwise economically disadvantaged Canadians and should be paid to, administered by and distributed by Social and Enterprise Development Innovations, a non-profit charitable organizati on. Taking into account the course of the litigation, the risks accepted by counsel and the extent of the recovery achieved for the class, a fee of $11 million was appropriate.

Cases referred to

Incorporated Council of Law Reporting for England and Wales v. Attorney-General, [1972] Ch. 73, [1971] 3 All E.R. 1029, [1971] 3 W.L.R. 853 (C.A.); Laidlaw Foundation (Re) (1984), 48 O.R. (2d) 549, 13 D.L.R. (4th) 491, 18 E.T.R. 77 (Div. Ct.); Levy Estate (Re) (1989), 68 O.R. (2d) 385, [1989] O.J. No. 660, 58 D.L.R. (4th) 375, 33 O.A.C. 99, 33 E.T.R. 1, 15 A.C.W.S. (3d) 206 (C.A.), consd

Other cases referred to

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Statutes referred to

Canadian Charter of Rights and Freedoms

Class Proceedings Act, 1992, S.O. 1992, c. 6, ss. 5(1)(e), 26, (3), (4), (6), 29, (2), 33

Income Tax Act, R.S.C. 1985, c. 1 (5th Supp.)

Law Society Act, R.S.O. 1990, c. L.8, ss. 55, 56(2), 59.1

Legal Aid Services Act, 1998, S.O. 1998, c. 26

Perpetuities Act, R.S.O. 1990, c. P.9, s. 16

Statute of Elizabeth, 1601 (U.K.), 43 Eliz. I, c. 4

Authorities referred to

Ontario Law Reform Commission, Report on Class Actions, vols. 1-3 (Toronto: Queen's Printer, 1982)

MOTION for approval of the proposed settlement of class action.

Harvey T. Strosberg, Q.C., and Patricia A. Speight, for plaintiffs.

Lyndon A.J. Barnes and Laura K. Fric, for defendant.

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[1] **CULLITY J.**: -- The parties moved for approval of the settlement of this action commenced under the Class Proceedings Act, 1992, S.O. 1992, c. 6 ("CPA").

[2] The claims advanced on behalf of the class concern allegedly undisclosed and unauthorized charges levied by the defendant (the "Bank") for foreign currency transactions conducted with Visa credit cards it had issued. The Bank asserts that these were not fees, but rather part of the exchange rates that it was authorized by the provisions of the cardholder agreements to determine from time to time.

[3] The proceeding was certified by the Court of Appeal on November 14, 2007 [(2007), 87 O.R. (3d) 401, [2007] O.J. No. 4406 (C.A.)]. Certification had previously been denied by the Divisional Court [[2006] O.J. No. 2930, 35 C.P.C. (6th) 84 (Div. Ct.)] and in this court [[2005] O.J. No. 845, [2005] O.T.C. 161 (S.C.J.)]. Actions involving similar claims were previously certified and settlements approved by Winkler J. (now Winkler C.J.O.) in Gilbert v. Canadian Imperial Bank of Commerce, [2004] O.J. No. 4260, [2004] O.T.C. 902 (S.C.J.) and by Brockenshire J. in Meretsky v. Bank of Nova Scotia, unreported, January 23, 2009.

The Settlement

[4] Section 29(2) of the CPA provides that a settlement of a class proceeding is not binding unless it is approved by the court. In Gilbert, the principles to be applied for this purpose were summarized by Winkler J. (now Winkler C.J.O.) as follows [at paras. 9-11]: [page546]

> There is a presumption of fairness when a proposed class settlement negotiated at arms length by class counsel is presented to the court for approval. A court will only reject a proposed settlement when it finds that the settlement does not fall within a range of reasonableness.
>
> The test to be applied is whether the settlement is fair and reasonable and in the best interests of the class as a whole. This allows for a range of possible results and there is no perfect settlement. Settlement is a product of compromise, which by definition, necessitates give-and-take. It is a question of weighing the settlement in comparison to the alternative of litigation with its inherent risks and associated costs.
>
> There are a number of factors, not all to be given equal weight, which are to be considered in determining whether to approve a settlement. These include likelihood of success, degree of discovery, the terms of the settlement, recommendation of counsel, expense and duration of litigation, number of objectors, presence of arms length bargaining, extent of communications with the class and the dynamics of the bargaining.

[5] It follows that, in all cases, the court must weigh the benefits to be conferred on the class against the risks of continuing the litigation.

[6] From the inception of the proceeding, the Bank has denied that the charges were fees rather than part of the exchange rates it was authorized to determine from time to time. It has also asserted that the rates were reasonable and that the plaintiffs' interpretation of the cardholder agreements was contrary to the intentions of the parties, as well as inconsistent with commercial realities and the competitive practices adopted by other financial institutions. At the hearing of the motion, the Bank's counsel emphasized that it was the economic considerations of proceeding to trial and not any acknowledgement of the validity of the claims advanced by the plaintiffs that influenced its agreement to settle. The Bank has not resiled from its position that the alleged charges were disclosed to cardholders.

[7] While strongly contesting the correctness of the Bank's characterization of the charges, class counsel were conscious that, on the main issue, this was all-or-nothing litigation and that it would be vigorously defended. Even if the plaintiffs were successful in characterizing the charges as fees, there were still limitations defences that potentially affected a significant number of the class

members' claims. They were also concerned about the length and future expense of the litigation if it proceeded to trial and the difficulty that class members would have in proving their damages if individual determinations were found to be required.

[8] In an affidavit sworn for the purpose of the approval motion, one of the plaintiffs' solicitors, Mr. Paul J. Pape, indicated that, based on reports prepared for the Bank, class counsel had [page547] estimated that the maximum amount recoverable for the class was approximately $161.5 million. After taking into account the risk that the Bank would succeed at trial, class counsel targeted $50 million -- $60 million as a reasonable range for settlement. Mr. Pape stated that they had this in mind when, in December 2008, they agreed to mediation by the Honourable George Adams. The plaintiffs' subsequent acceptance of the Bank's offer to pay $55 million in settlement of the claims was recommended by the mediator.

[9] The settlement amount was negotiated at arm's-length by experienced counsel after more than 11 years of litigation and after extensive productions by the Bank. There is, in my judgment, nothing in the record before me to suggest that the decision to settle for $55 million falls outside the zone of reasonableness and displaces the presumption of fairness referred to by Winkler J. In this case, the most difficult questions relate not to the amount the Bank has agreed to contribute in settlement of the claims advanced by the plaintiffs, but rather to the nature and extent of the distributions that are proposed.

[10] As in Markson v. MBNA Canada Bank (2007), 85 O.R. (3d) 321, [2007] O.J. No. 1684 (C.A.) -- where, again, certification was ordered by the Court of Appeal after having been denied at first instance and in the Divisional Court -- the class consists of several million cardholders whose transactions were entered into over a period of many years. In view of the difficulty of identifying class members with potential claims and quantifying the harm each had suffered, the requirement that the procedure of the CPA must be manageable was given considerable weight in this court and in the Divisional Court. In Markson, the proceeding was held [to] be manageable because, it seems, of the Court of Appeal's conclusion that there was a reasonable likelihood that an aggregate assessment of damages would be possible. The question whether difficulties of distributing damages had any bearing on the issue of manageability was not discussed, and it is notable that, in deciding tha t certification should be granted, the court did not find it necessary to consider whether a "workable" litigation plan had been produced by the plaintiff as required by s. 5(1)(e) of the CPA.

[11] A similar conclusion that an aggregate assessment of damages might be available was reached by the Court of Appeal in this case where, however, Winkler C.J.O. also concluded that the conditions for certification would have been satisfied if the court at a trial of common issues determined that individual assessments were necessary. Moreover, on either approach to the assessment of damages, it appears that the [page548] Chief Justice accepted that problems of distribution may have some relevance to the issue of manageability that is inherent in the requirement that a class proceeding is the preferable procedure. Paragraphs 67-68 of the reasons of the Court of Appeal read as follows:

> The CPA also provides a range of options for distributing amounts awarded under ss. 24 or 25. For example, s. 26(2)(a) permits the court to require the defendant to distribute monetary relief directly to class members "by any means authorized by the court, including abatement and credit". I draw particular attention to s. 26(3), which states:
>
> > 26(3) In deciding whether to make an order under clause (2) (a), a court shall consider whether distribution by the defendant is the most practical way of distributing the award for any reason, including the fact that the amount of monetary relief to which each class member is entitled can be determined from the records of the Bank.
>
> Evidently, the CPA provides a procedural mechanism on which the trial judge could rely to distribute amounts awarded under either s. 24 or s. 25. Thus, in my view, the preferable procedure requirement is satisfied in this case regardless of whether the assessment and distribution of damages, if necessary, are to be conducted on an aggregate or individual basis.

(Emphasis in original)

[12] In this context, I note that the learned Chief Justice attributed no significance to the Bank's evidence that "it would take 1500 people about one year to identify and record the foreign exchange transactions on the cardholder statements that are available only on microfiche and that this would cost about $48,500,000": at para. 48. As in Markson, this "economic argument" was specifically rejected.

[13] Despite the emphasis given to s. 26(3) of the CPA, I do not understand the Chief Justice to have excluded the possibility that the trial judge might rely on other provisions of s. 26, including s. 26(4) and (6), that read as follows:

> 26(4) The court may order that all or a part of an award under section 24 that has not been distributed within a time set by the court be applied in any manner that may reasonably be expected to benefit class members, even though the order does not provide for monetary relief to individual class members, if the court is satisfied that a reasonable number of class members who would not otherwise receive monetary relief would benefit from the order.
>
> . . . . .
>
> (6) the court may make an order under subsection (4) even if the order would benefit,

(a) persons who are not class members; or
(b) persons who may otherwise receive monetary relief as a result of the class proceeding. [page549]

[14] These provisions contemplate what are often called cy pres orders by analogy to the cy pres jurisdiction that courts of equity have traditionally applied in cases involving charities and rules against remoteness. As was the case in Gilbert, such orders are commonly made in settlements approved by the court by a further analogy to the provisions of s. 26. In Gilbert, the settlement that was approved by the court provided for a payment of $1 million out of the settlement amount of $16.5 million to the United Way in order to benefit past cardholders who could no longer be identified. Winkler J. stated (at paras. 15-16):

> One might observe that a situation such as this could be addressed with a settlement that is entirely Cy pres. However, it is not the role of this court to substitute its settlement for that fashioned by the parties. Also, a disadvantage of settlement that is entirely Cy pres is that it does not compensate individual class members.
>
> Past cardholders are not part of the distribution list. The payment to the United Way on their collective behalf is in lieu of this and is acceptable given the peregrinations involved in pursuing these claims. This approach is acceptable in the present circumstances given the impossibility of identifying such class members. The CPA specifically contemplates a cy pres distribution in s. 26(6).

[15] Under the proposed settlement in this case, approximately $39,100,000 would be available for distribution for the benefit of class members after the payment of the counsel fees and disbursements requested, the levy payable to the Law Foundation and administrative expenses out of the settlement amount of $55 million. From the amount of $39,150,000, approximately $10,750,000 would be paid directly to cardholders whose cards were issued before certain dates included in the class definition, and who were in good standing and active as of June 1, 2009. The balance of approximately $28.4 million would be applied cy pres as, despite the Court of Appeal's reference to s. 26(3) of the CPA, the parties are in agreement that it would be impracticable to attempt to identify more than a relatively small percentage of the class members who are potential claimants.

[16] Before finalising their proposals for the division between direct and indirect benefits to class members, counsel devoted considerable time and energy in considering different alternatives. The task of identifying cardholders who had engaged in foreign currency transactions -- as well as the amounts involved -- was hampered by the absence of records, including some that had been destroyed inadvertently during the course of the proceeding. The various alternatives were discussed at case conferences prior to the hearing before counsel agreed on a final proposal. [page550]

[17] I am satisfied that, in the light of these difficulties and when compared with the other alternatives, the proposed division between direct and indirect benefits strikes a reasonable balance between reimbursing class members and applying funds cy pres and should be approved. Although, as a general rule, cy pres distributions should not be approved where direct compensation to class members is practicable, the allocation of $10.75 million to be paid directly to cardholders is on the generous side as proof that one subgroup of them engaged in foreign currency transactions -- and, in consequence, were within the class definition -- will not be required.

[18] As a general rule, the court's jurisdiction on motions under s. 29(2) of the CPA is limited to granting, or withholding, approval. Exceptionally in this case, the minutes of settlement provide that, as part of the approval process, the court may change the amount proposed to be applied cy pres, the cy pres recipients and the division of funds between them. This provision reflects the parties' understanding that, in view of the size of the cy pres amount and the nature of the claims in this case, outright payments to charitable or other non-profit organizations -- the most common form of cy pres distributions -- might not be appropriate. For this reason, it was proposed that special purpose gifts would be made in order to ensure that the purposes for which the funds would be applied bore a sufficient relation to the interests and claims of the class members to justify a conclusion that the distribution would be for their benefit.

[19] The question of the most appropriate cy pres distributions was discussed in a number of case conferences. Proposals by the plaintiffs with respect to one half of the cy pres amount of $28.4 million and by the Bank for the other half were considered.

Cy Pres: The Plaintiffs' Proposal

[20] The plaintiffs' original proposal involved grants to Canadian common-law law schools to be used to foster professionalism and ethical conduct among practising lawyers. The amounts each law school would receive would reflect the distribution of class members across the country. It was suggested that teaching law students to be more professional and ethical in their behaviour when practising law would benefit class members and the public. It was said that:

> Contracts such as those in issue in this action may be more carefully drafted, banks, commercial institutions and all clients may be better advised and, as a result, disputes such as in this action and others may be avoided. [page551]

[21] Apart from the establishment of a committee of five to seven members of the legal profession, with volunteers from the judiciary, to receive proposals and to disburse the funds to the law schools, no method of supervising or controlling the expenditure of the funds by the recipients was suggested. It may have been contemplated that the use of the funds would be entirely within the discretion of the recipients subject only to a moral obligation to apply them for the approved purposes.

[22] Without -- I hope -- being unduly cynical about the optics of the plaintiffs' proposal in the

present context, I suggested that a preferable alternative would be to create a trust fund to be administered by the Law Foundation of Ontario for the purpose of advancing public access to justice in Canada. Although in a number of cases -- including Gilbert -- cy pres distributions that benefit class members together with other members of the public have been approved, the suggested alternative would confer benefits on the class more directly than the original proposal and would do so in a manner that is consistent with, and would advance, one of the objectives of the CPA. Access to justice was relied on heavily by the Court of Appeal in Markson and in this case as a ground for certifying the proceeding. Class members have benefited thereby and they and other members of the public would benefit from its enhancement in the future.

[23] This suggestion was discussed with representatives of the Law Foundation -- including the chair of its board of trustees and they have indicated that it is acceptable in principle.

[24] The proposal contemplates the creation of a special trust-fund to be administered by the trustees of the foundation. Section 56(2) of the Law Society Act, R.S.O. 1990, c. L.8 provides that the trustees have power to accept gifts and donations on trust in furtherance of the objects of the foundation. The objects include "legal aid" -- a term that, I am informed, has been construed broadly by the trustees and has, correctly in my opinion, not been confined to financial aid provided to Legal Aid Ontario -- a corporation that is incorporated pursuant to the Legal Aid Services Act, 1998, S.O. 1998, c. 26 for the purpose of providing access to justice for low-income individuals, and is referred to by name in s. 55 of the Law Society Act.

[25] There are, of course, special difficulties that can be encountered in establishing valid purpose trusts under the laws of Ontario. Such trusts are not valid unless they are exclusively charitable, or can be treated as powers of appointment pursuant to s. 16 of the Perpetuities Act, R.S.O. 1990, c. P.9. In my opinion, this limitation is as applicable to trusts created pursuant to an [page552] order of the court as it is to other trusts and, if that is not correct, it is still one that the court should respect.

[26] Is the purpose of promoting and advancing access to justice a charitable purpose? Given the repeated endorsement by courts, as well as by the Law Reform Commission, of access to justice as a socially valuable objective of the CPA -- and even ignoring some of the rather more dubiously valuable purposes that have been accepted as charitable over the years -- it would, I believe, be extraordinary if it were held that it is not worthy of recognition as a possible object of a valid trust.

[27] The law on charities is notoriously technical and arcane. Numerous judicial pleas for legislative intervention have fallen on deaf ears. Judicial attempts in cases such as Laidlaw Foundation (Re) (1984), 48 O.R. (2d) 549, 13 D.L.R. (4th) 491 (Div. Ct.) and Levy Estate (Re) (1989), 68 O.R. (2d) 385, [1989] O.J. No. 660 (C.A.) to rid the law of its antiquated foundations in the Statute of Elizabeth, 1601 (U.K.), 43 Eliz. I., c. 4 are uncertain in their effects and, since the comments of Rothstein J. in A.Y.S.A. Amateur Youth Soccer Association v. Canada (Revenue Agency), [2007] 3 S.C.R. 217, [2007] S.C.J. No. 42, at paras. 37-39, their correctness is not free

from doubt. In one of the most recent cases in the Supreme Court of Canada -- Vancouver Society of Immigrant and Visible Minority Women v. M.N.R., [1999] 1 S.C.R. 10, [1999] S.C.J. No. 5 -- the court was divided (5-4) on, among other things, the question whether a purpose of assisting immigrant w omen to obtain employment was charitable. The lengthy judgments delivered are replete with conflicting views on the same authorities that have been the subject of inconclusive analyses in a legion of cases stretching back over at least two centuries.

[28] Access to justice connotes access by persons to whom it would not otherwise be available for the purpose of protecting and enforcing their legal rights. Although barriers to access to justice are very commonly -- although by no means exclusively -- financial in nature, a purpose of removing the barriers cannot, I think, be considered to fall exclusively within the first of the three traditional heads of charity -- the relief of poverty: see the Law Reform Commission's Report on Class Actions (Toronto: Queen's Printer, 1982), pp. 119-29. Nor would such a purpose be considered to be religious, or educational, even in the expanded sense in which that term was given in Vancouver Society. That leaves only the fourth head -- other purposes beneficial to the public -- with, or without, in Ontario, the qualification that they must also be within the spirit and intendment of the Statute of Elizabeth, 1601. [page553]

[29] I do not think there is any doubt that a purpose of providing or promoting access to justice must be considered to be beneficial to the public. As the Law Reform Commission stated, at p. 139 of its report:

> Quite clearly, effective access to justice is a precondition to the exercise of all other legal rights.

[30] Access to justice is, in other words, an essential component of the rule of law, which, in turn, is one of the constitutional underpinnings of our democratic constitutional system of government.

[31] If, despite the views expressed in Laidlaw Foundation (Re) and Levy Estate (Re), access to justice will not be a valid charitable purpose unless it is within the spirit and intent of the Elizabethan statute, I believe that requirement is also satisfied.

[32] In Incorporated Council of Law Reporting for England and Wales v. Attorney-General, [1972] Ch. 73, [1971] 3 All E.R. 1029 (C.A.), different approaches for ascertaining whether a purpose was within the spirit and intent of the statue -- or within its "mischief" or "equity" were discussed. The Court of Appeal held that the publication of law reports by a non-profit corporation was a charitable purpose. Russell L.J. placed the purpose under the fourth head of charity. In his view, the correct approach was to apply a presumption that a purpose that benefits the public will be within the equity of the Statute of Elizabeth, and charitable in the absence of good reasons for a contrary conclusion. Sachs and Buckley JJ. preferred to characterize the purpose as educational, but agreed that it would otherwise be upheld on the basis of the reasoning of Russell L.J.

[33] Russell L.J. also considered whether the purpose of the Council would fall within the spirit

and intendment of the statute if the correct approach was to find an analogy with purposes previously held to be charitable. The judge at first instance had referred to the very early judicial acceptance that the purpose of building a courthouse was charitable and Russell L.J. concluded that no distinction could properly be drawn between the provision of physical facilities for the administration of justice, and a dissemination of knowledge of the law to be administered in them.

[34] On either of these approaches, I am satisfied that a trust to provide access to the courts and the administration of justice must be held to be charitable. Access to justice is presupposed by the provisions of the Canadian Charter of Rights and Freedoms and, without it, the provision of courthouses and law reports would be otiose.

[35] For these reasons, I am satisfied that the proposed establishment of a fund to promote access to justice would create a [page554] valid charitable trust. I am also satisfied that such a trust could properly be administered by the Law Foundation as falling within its corporate object of "legal aid". As I have mentioned, this is consistent with the information provided by the chair of the board of trustees of the foundation that the object has in the past been construed broadly and has not been confined to financial aid provided to Legal Aid Ontario.

[36] For reasons of completeness, I note, also, that if, contrary to my opinion, a trust to promote and advance access to justice is not charitable, it could, I believe, be upheld as a specific non-charitable purpose trust that, pursuant to s. 16 of the Perpetuities Act, is to be treated as a power of appointment over capital and income for a maximum period of 21 years.

[37] The precise terms of the trust will be included in the order approving the settlement but, subject to any further submissions of counsel, or representations of the Law Foundation, my present preference would be for the trustees of the foundation to have discretion as to the application of funds for the approved purpose subject only to the limitation that they are not to form part of the Class Proceedings Fund established pursuant to s. 59.1 of the Law Society Act.

Cy Pres: The Bank's Proposal

[38] The Bank proposed that the other half of the cy pres amount should be used to improve the financial literacy of low-income and otherwise economically disadvantaged Canadians. For this purpose, the funds would be paid to, and administered and distributed by, a non-profit charitable organization, Social and Enterprise Development Innovations ("SEDI").

[39] SEDI was incorporated as a corporation without share capital under Part III of the Corporations Act on March 14, 1995. Its objects, as amended by supplementary letters patent of April 21, 1997, are as follows:

1. To establish, maintain and supervise non-profit centres for the encouragement of people who are both poor and unemployed to develop self-employment projects with the objective of preventing and reducing unemployment and its attendant poverty;

2. To provide counselling and supportive services for the benefit of persons who are both poor and unemployed and otherwise economically disadvantaged persons including youth;
3. To set up programmes to carry out the foregoing objects;
4. To consult with other charitable, non-profit community and governmental agencies and organizations in developing programmes to carry out the foregoing objects and to provide funding for same. [page555]

[40] SEDI is registered as a charitable organization within the meaning of the Income Tax Act, R.S.C. 1985, c. 1 (5th Supp.) (Canada). It complies with the annual reporting obligations under the statute. To date, it has been funded largely through grants and donations from federal, provincial and municipal governments, banks and other financial institutions and private charitable foundations.

[41] The promotion of financial literacy has been one of SEDI's principal activities since its creation. To this end, it has worked with governmental agencies and community organizations to develop courses, programmes and projects and to train personnel whose employment brings them in contact with unemployed, poor and otherwise disadvantaged Canadians. SEDI's activities are founded on a conviction that there are social, market and governmental pressures that limit the ability of such persons to make informed financial decisions that are essential to their well-being and their capacity to become economically self-sufficient. Accordingly, financial literacy, in the sense understood by SEDI, refers to the knowledge, skills and ability to understand, analyze and use information to make informed judgments about financial decisions. Such decisions range from simple budgeting skills, to understanding choices between banking and credit products, to understanding rights and obligations created by financial documents such as credit card agreements, to understanding how to effectively save for retirement, home-ownership or post-secondary education.

[42] SEDI is administered under the supervision of a nine-member board of directors who serve without remuneration. In 2008, it had ten permanent and four part-time employees.

[43] By a resolution of the board of directors of October 9, 2008, SEDI's financial literacy activities were expanded and organized by the creation of a new internal division known as the "Canadian Centre for Financial Literacy" (the "Centre"). This is dedicated to assisting and training the staff of community organizations to deliver literacy counselling and supportive services to needy and otherwise disadvantaged groups in society.

[44] The Bank's proposal is for 50 per cent of the cy pres amount to be paid to SEDI. $3.5 million of this would be used for the support of the Centre for a period of five years and the balance would be held as a fund (the "TD Financial Literacy Fund") that, over a period of six years, would be applied in making grants to non-profit organizations who work with economically disadvantaged groups -- such grants to be used by the recipients to promote and support financial literacy among

[page556] the members of such groups. All such grants would require the approval of SEDI's directors.

[45] Counsel for the bank made submissions and filed extensive material in support of its proposals. This included a description of SEDI's activities during the past five years, the annual reports filed with Canada Revenue Agency, explanation of its financial reporting and a legal opinion of SEDI's solicitor, Fasken Martineau, that the promotion of financial literacy is charitable in law as educational and for the relief of poverty, and is within the objects of SEDI. I share that opinion.

[46] In addition, letters attesting to the valuable work performed by SEDI in promoting financial literacy among low-income Canadians were provided by five individuals who have either participated in SEDI's activities or occupied positions with governmental organizations that have been involved with them.

[47] On the basis of the submissions of counsel and the material filed, I am satisfied that the advancement of financial literacy is a worthy method of applying the cy pres amount for the benefit of the class members. I am also satisfied that SEDI is an appropriate entity to administer the funds for this purpose.

[48] For the purpose of settling the terms of the approval order, counsel should consider whether it is necessary to have a trust agreement between the Bank and SEDI with respect to the administration of the funds. In view of the relatively simple and short-term obligations of SEDI, it may be possible to define those obligations adequately in the body of the order. It must, however, be made clear that the funds provided to the Centre for the support of its work are intended to enhance it and not simply to make available for SEDI's other purposes funds that would otherwise be used for the support of the Centre. Given the provisions of the Law Society Act that govern the administration of gifts received by the trustees of the Law Foundation, a separate trust agreement with respect to the other half of the cy pres amount should not be necessary to complement the provisions of the order.

[49] Subject to settling the terms of the order, the settlement will be approved.

Fees of Class Counsel

[50] Counsel have requested a fee of $11 million, which represents 20 per cent of the settlement amount and approximately 28 per cent of the net amount that would be distributable to, or for the benefit of, class members. [page557]

[51] Provision for a fee of 20 per cent of the gross recovery was made in retainer agreements with Dr. Cassano and Dr. Bordoff executed in April 2002 and September 2004, respectively. These written agreements are said to reflect the terms of an oral agreement made at the inception of the proceeding with Dr. Cassano in 1997. Dr. Bordoff was added as a plaintiff on March 9, 2005.

[52] Each of the plaintiffs has supported the request for approval of a fee of $11 million and has expressed appreciation of the quality of the services performed by their counsel.

[53] Contingent fee agreements that provide for fees to be calculated as a percentage of gross recovery have been approved in many class proceedings in this jurisdiction, and an application of percentages in excess of 20 per cent has been approved in several of them. In Garland v. Enbridge Gas Distribution Inc., [2006] O.J. No. 4907, 56 C.P.C. (6th) 357 (S.C.J.), for example, I considered the fee awarded to represent approximately 26.7 per cent of the value of the compensation and other benefits recovered for the class members. In Stastny v. Southwestern Resources Corp., unreported, November 3, 2008, and Casselman v. CIBC World Markets Inc., unreported, December 21, 2007, percentages in excess of 20 per cent were approved by Brockenshire J., and, in Meretsky -- one of the companion actions to this case -- the same learned judge indicated that 20 per cent was acceptable.

[54] Counsel's intention to request a fee of 20 per cent of the gross recovery was communicated to the numerous class members who contacted counsel at different times throughout this lengthy litigation, the information was provided on its website and it was disclosed in the notice of the fairness hearing. Only one member of the class of several million persons has objected to the size of the fee.

[55] This was hard-fought litigation -- conducted with tenacity and skill by counsel who, in effect, snatched victory from the jaws of defeat by persevering with it through successive appeals from the initial decision that denied certification. It is inherent in percentage of recovery agreements that counsel may receive large fees where, as here, the degree of success achieved is substantial. Equally, of course, they take the risk that the results achieved will provide them with little or no compensation.

[56] Taking into account the course of the litigation, the risks accepted by counsel and the extent of the recovery achieved for the class, a fee of $11 million will be approved, together with the disbursements claimed of $138,000. [page558]

[57] There are three other matters on which I believe I should comment.

[58] The first is that Dr. Cassano is the spouse of Ms. Pat Speight, who is a "non-equity partner" in the firm of Sutts Strosberg, who acted as co-counsel for the plaintiffs. A relationship of this kind is one that in some cases will call for close examination and, perhaps, suspicion. It was, however, disclosed at the hearing of the certification motion, and again at the fairness hearing, and Dr. Cassano was accepted as a suitable representative plaintiff and, with Dr. Bordoff, was appointed as such in the order of the Court of Appeal. In these circumstances, I see no reason for considering the relationship to be a factor that should have any bearing on the amount of counsel's fee.

[59] The second matter is that the fee of $11 million represents the application of a multiplier of approximately 5.5 to counsel's approved time. This might well be considered to be excessive if the

retainer agreements had provided for the adoption of the "lodestar approach" reflected in s. 33 of the CPA. They did not do this.

[60] While it has been said that the appropriateness of a fee calculated in the lodestar manner might be tested by comparing it with the percentage of gross recovery it represents, I would be hesitant to use the lodestar method as a firm indicator of the reasonableness of a fee determined by the application of a percentage to the amount recovered. In Martin v. Barrett, [2008] O.J. No. 2105, 67 C.C.P.B. 102 (S.C.J.), at paras. 38-39, I referred to criticisms of the lodestar method. One of these that has been repeatedly mentioned in other cases in this jurisdiction and elsewhere is that the application of a multiplier to a base fee may not only encourage an inefficient use of time and a padding of dockets, it may also fail to reward efficient time-management and the exercise of superior skill by class counsel.

[61] As Smith J. stated in Endean v. Canadian Red Cross Society, [2000] B.C.J. No. 1254, [2000] 8 W.W.R. 294 (S.C.), at para. 74:

> Good counsel should not be penalized for their acuity and efficiency by basing their fees only on the amount of time it took them to accomplish their clients' objectives.

[62] In contrasting the percentage of recovery approach with the application of a multiplier, Cumming J. stated in VitaPharm Canada Ltd. v. Hoffma-La Roche Ltd., [2005] O.J. No. 1117, [2005] O.T.C. 208 (S.C.J.), at para. 107:

> Using a percentage calculation in determining class counsel fees properly places the emphasis on quality of representation, and the benefit conferred on the class. A percentage-based fee rewards "one imaginative, brilliant hour" rather than "one thousand plodding hours". [page559]

[63] Of course, if counsel accept a retainer on the basis that the lodestar method is to apply, the requirements of s. 33 -- including that of a reasonable base-fee -- must be observed. Class counsel did not choose to adopt that method and, having achieved an excellent result, they submit that it would be unreasonable to reduce their fee by reference to the time they expended to do so. They had accepted their retainers on the basis of a fee calculation that would vary directly according to the degree of success that was achieved. The percentage of recovery to be applied was not unreasonable, the risks were considerable, the degree of success was substantial and there is nothing in the manner in which the proceeding was conducted that, in my judgment, would justify a refusal to approve a fee determined in accordance with the terms on which the retainers were accepted.

[64] The final matter relates to the contents of the objection received from Mr. Andrew Martin of Toronto. This was the only objection received from the members of the enormous class. I have not commented on it previously in the above reasons because, to the extent that his criticisms have not been met by the changes I have made to the proposed cy pres distributions, I believe that the authorities I should properly follow foreclose acceptance of them. At the same time, Mr. Martin's

comments address quite fundamental issues relating to settlements of class actions such as this. As it may be that his views are shared by other class members who thought it useless, or just too much trouble, to voice their objections, I have included the substance of Mr. Martin's e-mail letter as an appendix to these reasons, together with my brief comments.

Motion granted.

APPENDIX

From : Andrew Martin

To: [Objections]

I am writing to object to the proposed settlement.

> My reasons relate to the overall terms of the settlement. The amount that will be paid may (or may not) be appropriate relative to the allegations, but I do not believe that this settlement is in the interests of the plaintiff class. Specifically:
>
> -- Either TD did or did not levy unauthorised, undisclosed or inadequately disclosed charges. This needs to be determined so that in future, conditions of use can be drafted and interpreted correctly. [While no one could deny that clarification is desirable, the class action procedure has costs and risks for the representative plaintiffs and their counsel that are not shared by the [page560] other class members who, in effect, have a free ride. Simply as one example, the plaintiffs incurred an expense of approximately $67,000 in respect of the fees of the firm of chartered accountants who received and dealt with the 11,500 cardholders who opted out of the litigation.]
>
> -- In my personal view, given that certain costs were going to be charged in respect of these uses of the credit cards, the plaintiff class has not been disadvantaged and I suspect would have used the cards in any circumstances. The consequences of this litigation may well be to increase future charges. [I do not disagree but the Court of Appeal did, or did not consider these considerations to be relevant.]
>
> -- I strongly object to the proposal to distribute $14 million to charitable organisations. The purpose of a settlement should be to compensate people to who have suffered actual loss, and while these are laudable charitable purposes, I see no way reason for a publicly-owned financial institution, as custodian of its shareholders' money, should

make such a payment as part of a class action settlement. [Mr. Martin does not indicate his preferred position on the facts of this case that involve more than 4.5 million cardholders of whom only a relatively small number of those who entered into foreign currency transactions can be identified.]

-- I also object to the proposal to distribute $14 million to law schools. This is highly offensive and, again, an inappropriate use of shareholder money (to support what are presumably ethical shortcomings of lawyers). It also poses a conflict of interest for the judiciary, which might feel reluctant to query or disallow such a proposal giving their own ties to the profession. [I do not disagree.]

-- The proposal to pay up to $11 million to the lawyers is outrageous. While only (only!) 20 per cent of the total, it is a huge multiple of legal fees likely to have been incurred. This does not seem a particularly complicated case and cannot have consumed that much time. For instance, if it is a 4x multiplier that suggests 7,000 bars at $400/hour. This seems unrealistic, and so the multiplier is presumably much higher. And yet the risk in a case like this is, historically, quite low. I therefore object to any payment of legal fees in excess of 3x docketed hours at a reasonable hourly rate. Any excess between that and $11 million can either be added to the distribution to cardholders, or distributed to organisations providing free legal services to those unable to pay the fees now charged by lawyers. [I am not sure why Mr. Martin believes the risk in cases like this is, historically, quite low. His support of imposing the multiplier approach irrespective of the terms of counsel's agreement with the plaintiffs, the criticism to which the approach has been subjected, and the difficulties of applying it in practice, is not consistent with the provisions of the CPA as judicially interpreted in previous cases.]

It is not currently my intention to appear at the hearing on April 24.

Andrew Martin

Indexed as:

Parsons v. Canadian Red Cross Society

PROCEEDING UNDER the Class Proceedings Act, 1992
Between
Dianna Louise Parsons, Michael Herbert Cruickshanks, David Tull, Martin Henry Griffen, Anna Kardish, Elsie Kotyk, Executrix of the Estate of Harry Kotyk, deceased and Elsie Kotyk, personally, plaintiffs, and
The Canadian Red Cross Society, Her Majesty the Queen in Right of Ontario and the Attorney General of Canada, defendants
And between
James Kreppner, Barry Issac, Norman Landry, as Executor of the Estate of the late Serge Landry, Peter Felsing, Donald Milligan, Allan Gruhlke, Jim Love and Pauline Fournier, as Executrix of the Estate of the late Pierre Fournier, plaintiffs, and
The Canadian Red Cross Society, the Attorney General of Canada and Her Majesty the Queen in Right of Ontario, defendants

[2000] O.J. No. 2374

49 O.R. (3d) 281

[2000] O.T.C. 968

46 C.P.C. (4th) 236

97 A.C.W.S. (3d) 1082

Court File Nos. 98-CV-141369 and 98-CV-146405

Ontario Superior Court of Justice

Winkler J.

Heard: February 14-16, 1999.
Judgment: June 22, 2000.

(77 paras.)

Counsel:

Harvey Strosberg, Q.C., Heather Rumble Peterson and Patricia Speight, for the plaintiffs.
R.F. Horak and Michèle Smith, for Her Majesty the Queen in Right of Ontario.
Michel Lapierre, for the Attorney General of Canada.
Beth Symes, for the Thalassemia Foundation of Canada, friend of the Court.
William P. Dermody, for the intervenors, Hubert Fullarton and Tracey Goegan.
Terrence J. O'Sullivan and Vanessa Jolles, for the plaintiffs.
R.F. Horak and Michèle Smith, for Her Majesty the Queen in Right of Ontario.
Michel Lapierre, for the Attorney General of Canada.
Janice E. Blackburn, for the Canadian Hemophilia Society, friend of the Court.

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1 **WINKLER J.**:-- This is a motion for approval of the counsel fees in two companion class proceedings, Parsons et al. v. The Canadian Red Cross Society et al. (the "Transfused Action") and Kreppner et al. v. The Canadian Red Cross Society et al. (the "Hemophiliac Action") commenced under the Class Proceedings Act 1992, S.O. 1992, c. 6. These actions were brought on behalf of all individuals in Canada, except for those in the provinces of Quebec and British Columbia, who were infected with Hepatitis C from the Canadian blood supply during the period of January 1, 1986 to July 1, 1990. There are concurrent class proceedings before the courts of Quebec and British Columbia for individuals in those provinces. The parties in all of the class proceedings across Canada have entered into a pan-Canadian settlement of the litigation. In reasons released on September 22, 1999, I approved the settlement as it applied to the national classes in the Transfused Action and the Hemophiliac Action. The settlement has also been approved by the courts in Quebec and British Columbia as it relates to the actions in those provinces.

2 The Settlement Agreement was presented to the courts for approval by all of the parties to the litigation. It contemplated payment of total class counsel fees for all of the actions in the amount of $52,500,000.00. That figure was used in the actuarial calculations in order to permit the courts to assess the settlement and the sufficiency of the Trust Fund established for the payment of claims to the class members in the litigation. The Ontario class counsel groups in the Transfused Action and in the Hemophiliac Action now bring this motion for the approval of their fees specifically.

BACKGROUND

3 The defendants in the Ontario class actions are the Canadian Red Cross Society ("CRCS"), Her Majesty the Queen in Right of Ontario and The Attorney General of Canada. In addition, all other provinces and territories of Canada, with the exception of British Columbia and Quebec, intervened

for the purposes of joining the settlement. Only the governments participated in the settlement, the proceedings against the CRCS having been stayed as a result of an Order of Mr. Justice Blair in respect of ongoing proceedings concerning the CRCS under the Companies Creditors Arrangement Act, R.S.C. 1985, c. C-36.

4 The Transfused Action and the Hemophiliac Action were commenced as a result of the contamination of the Canadian blood supply with the Hepatitis C virus ("HCV") during the 1980s. The classes in the Actions, however, are described more narrowly as those persons infected by HCV from the blood supply between January 1, 1986 and July 1, 1990.

5 The classes are confined to the 1986-90 time period because of the basis of the claims asserted in the Actions. During the class periods, the CRCS was the sole supplier and distributor of whole blood and blood products in Canada. The federal, provincial and territorial governments ("FPT governments") provided funding to the CRCS and staffed an overseer committee known as the Canadian Blood Committee ("CBC") which was composed of their representatives. The claims in these Actions are founded on the decision by the CRCS, and its overseers the CBC, not to conduct testing of blood donations to the Canadian blood supply after "surrogate" testing for HCV became available and had been put into widespread use in the United States. It was alleged by the plaintiffs in both Actions that had the defendants taken steps to implement the surrogate testing, the incidents of HCV infection from contaminated blood and blood products would have been reduced by much as 75% during the class period. Consequently, the plaintiffs brought actions on behalf of the classes described above in which claims were asserted in negligence, breach of fiduciary duty and strict liability as against all of the defendants.

6 As a result of the pan-Canadian Settlement Agreement, these claims have been settled, although without any admission of liability on the part of any of the defendants. Pursuant to the terms of the Settlement Agreement the class counsel in each of the Actions now seek court approval of their fees. This motion is in respect of the fees in the class actions commenced in Ontario on behalf of the national classes. Similar motions have been brought in the actions in British Columbia and Quebec.

7 The motion was heard over a three day period during which submissions were made by or on behalf of the class counsel in both actions, by counsel for the federal and Ontario governments and by counsel for certain intervenors and friends of the court. In addition, the parties filed affidavit evidence, transcripts of the cross-examinations on the affidavits and, in the case of the federal and Ontario governments, a document which was purported to be an expert's report in respect of fees. The author of this report was cross-examined and a transcript of the cross-examinations was included in the record.

8 It was apparent at the conclusion of this extensive hearing that there is agreement among the all of the participants with respect to certain facts. These are as follows:

(1) The Settlement Agreement contemplates that total lawyers fees in the Ontario, Quebec and British Columbia actions may amount to $52,500,000. There will be

no impact on the sufficiency of the Fund to provide the benefits to the claimants set out in the Agreement so long as the counsel fees do not exceed this amount.

(2) All participants are of the view that class counsel conducted the litigation in a skilful and effective manner and achieved an excellent result for the class members through the negotiated settlement.

(3) There is no issue with the total number of hours docketed by class counsel during the proceedings, nor is there any issue with respect to the number of law firms or lawyers engaged in negotiating this settlement on the part of the plaintiffs.

(4) The factual account of the conduct of the negotiations as set out in the affidavits of the class counsel group are accepted as being accurate.

(5) All participants acknowledge that the class counsel are entitled to a fair and reasonable fee.

9 Where the defendants and the intervenors part company with class counsel is in respect of the characterization of what, in principle and quantum, constitutes a "fair and reasonable fee".

LAW

10 The fixing of fees in a class proceeding is governed by ss. 32 and 33 of the CPA. These sections provide in pertinent part:

> 32(1) An agreement respecting fees and disbursements between a solicitor and a representative party shall be in writing and shall,
>
> (a) state the terms under which fees and disbursements shall be paid;
> (b) give an estimate of the expected fee, whether contingent on success in the class proceeding or not; and
> (c) state the method by which payment is to be made, whether by lump sum, salary or otherwise.
>
> (2) An agreement respecting fees and disbursements between a solicitor and a representative party is not enforceable unless approved by the court, on the motion of the solicitor.
>
> ...
>
> (4) If an agreement is not approved by the court, the court may,
> (a) determine the amount owing to the solicitor in respect of the fees and disbursements;
> (b) direct a reference under the rules of court to determine the amount owing; or

(c) direct that the amount owing be determined in any other manner.

33(1) Despite the Solicitors Act and An Act Respecting Champerty, being chapter 327 of Revised Statutes of Ontario, 1897, a solicitor and a representative party may enter into a written agreement providing for payment of fees and disbursements only in the event of success in a class proceeding.

(2) For the purpose of subsection (1), success in a class proceeding includes,
(a) a judgment on common issues in favour of some or all class members; and
(b) a settlement that benefits one or more class members.

11 The leading Ontario case on the quantification of appropriate fees in class proceedings is Gagne v. Silcorp Limited (1998), 41 O.R. (3d) 417 (C.A.). Goudge J.A., writing for the court, addressed the purpose of awarding premium fees in respect of successful class proceedings. He stated at 422-23:

> [a] fundamental objective [of the CPA] is to provide enhanced access to justice to those with claims that would not otherwise be brought because to do so would be prohibitively uneconomic or inefficient. The provision of contingency fees where a multiplier is applied to the base fee is an important means to achieve this objective. The opportunity to achieve a multiple of the base fee if the class action succeeds gives the lawyer the necessary economic incentive to take the case in the first place and to do it well. However, if the Act is to fulfil its promise, that opportunity must not be a false hope. (Emphasis added.)

12 Although the issue before, the Court of Appeal in Gagne involved a premium fee in the form of a multiplier of a base fee, it has been held that this is not the only acceptable form of premium fee arrangement in class proceedings conducted under the CPA. (See Nantais v. Telectronics Proprietary (Canada) Ltd. (1996), 28 O.R. (3d) 523 (Gen. Div.); Crown Bay Hotel Ltd. Partnership v. Zurich Indemnity Co. of Canada (1998), 40 O.R. (3d) 83 (Gen. Div.)).

13 Notwithstanding the different forms that a premium fee arrangement may take, the principle enunciated by Goudge J.A. regarding the purpose of awarding premium fees in a class proceeding has a general application. If the CPA is to achieve the legislative objective of providing enhanced access to justice then in large part it will be dependent upon the willingness of counsel to undertake litigation on the understanding that there is a risk that the expenses incurred in time and disbursements may never be recovered. It is in this context that a court, in approving a fee arrangement or in the exercise of fixing fees, must determine the fairness and reasonableness of the counsel fee. Accordingly, the case law that has developed in Ontario holds that the fairness and reasonableness of the fee awarded in respect of class proceedings is to be determined in light of the risk undertaken by the solicitor in conducting the litigation and the degree of success or result

achieved. (See Maxwell v. MLG Ventures Ltd (1996), 3 C.P.C. (4th) 360 (Ont. Gen. Div.); Windisman v. Toronto College Park Ltd. (1996), 3 C.P.C. (4th) 369 (Ont. Gen. Div.); Serwaczek v. Medical Engineering Corp. (1996), 3 C.P.C. (4th) 386 (Ont. Gen. Div.)). This approach was approved by Goudge J.A. in Gagne where he stated at 423:

> ... In my view, [it is correct to focus] on these two considerations. Section 33(7)(b) makes clear the relevance of "the risk incurred in undertaking and continuing the proceeding under an agreement for payment only in the event of success". Section 33(9) invites a consideration of the manner in which the solicitor conducted the proceedings.

ANALYSIS

14 In my view, there are a variety of methods that may be utilized under the CPA to determine an acceptable premium on fees. It is appropriate to utilize this flexibility in fixing the fees in class proceedings where necessary. Here, class counsel seek to have their fees fixed on a lump sum basis pursuant to the retainer agreements with the representative plaintiffs and the provision in the Settlement Agreement. While this is acceptable in form, in my view, the court must still adhere to the principles discussed in Gagne in assessing the fairness and reasonableness of the counsel fee, whether that fee is calculated on a lump sum basis or otherwise.

A. Result Achieved in the Litigation

15 I will deal first with the success or result achieved in the instant litigation. I note in passing that one of the most staking aspects of the fee hearing was the number of issues upon which all participants expressed agreement. As stated above, it was common ground that an excellent result was obtained for the class members through the negotiated settlement of the litigation.

16 Nonetheless, the court, in fulfilling its role in the approval of fees, must form its own view of the success achieved. The characterization of the result by the parties and other participants is but one factor to be considered. The court's analysis must be objective. In this regard, I concluded in approving the settlement that class counsel have produced the best possible result short of trial. (See Parsons v. Canadian Red Cross Society, [1999] O.J. No. 3572 at para. 91). Moreover, the settlement provides for payments according to the degree of harm suffered by the class members, as well as for progressive increases in those payments to class members should their condition worsen. This avoidance of the "once and for all" lump sum payment approach commonly applied in personal injury tort litigation entails an overriding advantage for class members and consequently must augur favourably for class counsel in any considered analysis of the result.

17 From the perspective of the class members, however, the total compensation or nature of payment cannot be the only criteria on which to judge the result obtained through settlement. Significant weight must also be given to the relative ease or difficulty of access to the benefits achieved through the settlement by a class member. (See also Gagne at 425.) In this case, a

procedure for claims administration has been wrought into the settlement that will see most class members able to obtain compensation without the need for further legal assistance or proceedings. This contrasts favourably with many class proceedings where, despite a global settlement, class members are still required to engage in extensive legal proceedings to obtain the benefits. The relative ease of access to compensation is an important feature. It provides some certainty as to the quantum of compensation that class members will receive at each level, but more so, it demonstrates the thoroughness of class counsel in fashioning a satisfactory settlement.

B. Risk Undertaken by Class Counsel

18 I turn now to the risk factor. In the context of the CPA, the premium on fees for undertaking risk in litigation means that there should be a reward for taking on meritorious but difficult matters. Conversely, this does not mean that there should be a reward for bringing forward speculative cases of dubious merit. In my view, the instant matter falls squarely into the first category. Nonetheless, it was strongly contended by the defendants and intervenors that the extra-legal considerations at play in these actions mitigated the risk. The underlying premise for this submission was that this was not litigation in the ordinary sense because the government defendants were inclined to settle for policy and political reasons that had little or nothing to do with the merits of the litigation or the vigorous manner in which it was being pursued. Accordingly, the defendants and intervenors took the position that the risks attendant to litigation generally were not present here. I disagree.

19 It was common ground among the parties that there were political overtones to the litigation. Nonetheless, to accept the proposition that any extra-legal influence reduced the risk of the litigation would be to engage in a purely speculative, after the fact interpretation of the events that transpired during the course of this litigation. But, more to the point, this proposition is contradicted by the evidence. It is clear that this settlement was driven by the threat of litigation and not by political considerations. This is demonstrated by the chronology of the events, set out in the chart below, leading up to the announcement by the federal, provincial and territorial governments ("FPT governments") on March 27, 1998 that a fund of $1,100,000,000 would be set aside to satisfy the claims of those persons infected by HCV from the blood supply.

	DATE	EVENT
1.	June 21, 1996	Quebec Transfused Class Action is filed.
2.	September 9 to 11, 1996	The FPT governments announced their decision declining compensation to blood victims.

3.	December 19, 1996	The British Columbia Transfused Class Action is commenced.
4.	October 24, 1996	The FPT Health Ministers announce that they have decided against compensation.
5.	May 22,1997	The British Columbia Transfused Class Action is certified.
6.	July 7, 1997	There is an agreement on lead counsel for the Ontario HCV Class Action.
7.	September 16, 1997	Notice of the Ontario Transfused Class Action is given to Ontario and the other provincial governments.
8.	November 26, 1997	The final report of the Krever Inquiry is released.
9.	February 10, 1998	The Statement of Claim in the Ontario Transfused Class Action is issued on behalf of a national class.
10.	February 23, 1998	The Quebec Transfused Class Action is certified.
11.	March 27,1998	On behalf of the FPT Ministers of Health, the Honourable Allan Rock announces a financial assistance package to persons infected with HCV between 1986 to 1990 of up to $1,100,000,000.00.

20 It can be seen from this sequence of events that the FPT governments did not make any overtures toward compensating defendants until class proceedings had been certified in British Columbia and Quebec and there was a potential for certification of a national class encompassing all those persons in the rest of Canada in the Ontario proceedings. It must also be noted that even though the announcement of March 27, 1998 could hardly be considered a formal binding offer of settlement, it was only intended to apply to those persons included in the class proceedings. The litigious nature of the settlement negotiations is further evidenced by the length of time and effort taken to reach a binding agreement. Even then, there were still numerous conditions attached because of the desire of the FPT governments to,have one pan-Canadian settlement for all of the actions. Furthermore, there has never been any admission of liability by the defendants. Indeed the final Settlement Agreement contains a specific disclaimer of liability.

21 The evidence of Douglas Elliot, a member of the class counsel group, is instructive. Mr. Elliot is a highly experienced lawyer in blood litigation in Canada. As a result of his involvement with the issues surrounding the Hepatitis C litigation and his participation at the Krever Commission inquiry, he attempted to assemble a counsel group to prosecute a class proceeding on behalf of those infected with HCV from the blood supply.

22 In his affidavit, Mr. Elliot chronicles three years of unsuccessful attempts to find counsel in Ontario willing to lead and participate in a class proceeding related to the HCV problems stemming from the contamination of the Canadian blood supply. He deposed that it was difficult to find any law firm, large or small, willing to take on the litigation, especially in the role of lead counsel. It is his evidence that none of the counsel he approached regarded the potential political considerations as altering the fundamentally litigious nature of these proceedings. Their rejections were based strictly on the legal problems which the case presented. He states in paragraph 41 of his affidavit:

> 41. I believe that there were few lawyers who were knowledgeable about the operation of the blood system in Canada to begin with, and many regarded tainted-blood cases on behalf of plaintiffs as unattractive owing to their complexity and their prohibitive costs. The trial in Pittman, which was by this time completed, had lasted almost one year. To put the matter simply and directly, the lawyers to whom I spoke well understood that, in relation to this class action and the complex issues of liability, there were simply much easier ways to earn a living. And so they declined to become involved.

His evidence in this respect was not challenged by the defendants or intervenors. In the result, I must conclude that any suggestion that the political implications of the issues made the litigation less risky, apart from being inaccurate, was not apparent to most of the lawyers in Ontario at the outset of the litigation.

23 In consideration of the chronology of the events in this litigation and the uncontested evidence of Mr. Elliot, I am unable to accept the contention that political considerations operated to either transform this litigation or diminish the risk associated with it in any material way.

24 This leads in turn to another argument that was advanced by the government defendants. They contended that, even if the proceedings were considered to be litigation in the ordinary sense, the inherent risks diminished with time as the negotiations progressed. In consequence, they submit that any premium on the fee should reflect this diminishing risk. In support of this proposition, these defendants filed the report of Michael Ross, a vice-president of the accounting firm KPMG. Mr. Ross, in accordance with his instructions, attempted in his report to apply mathematical parameters, including a factor for changing risk, to the determination of an appropriate counsel fee in a class proceeding. However, this report was less than helpful, in part because of the flaws in the underlying premise that the risk factor in litigation can be ascertained with mathematical precision, and in part because of his fundamental misconception of the nature of a class proceeding and the CPA.

25 That said, I realize that Mr. Ross was given an impossible task. His assignment was, in reality, to attempt to define a subject with more precision than the subject would bear. As Goudge J.A. stated in Gagne, the fixing of an appropriate fee in a class proceeding is "an art, not a science". As such, the court must be wary of attempts to measure appropriate fees by the application of

pseudo-scientific or mathematical methods. Such an approach is inherently unreliable when a subject with as many variables as this litigation is considered.

26 Mr. Ross based his evidence on the premise that the premium on a fee should be reflective of the "judgmental probability of success" in the litigation. In his opinion, the amount of the premium over the ordinary fees should be a reciprocal of the risk of the litigation. As a theoretical example, this would ensure that counsel taking on litigation with an estimated 50% probability of success would not suffer any economic prejudice if the fee earned in the successful actions was multiplied by a factor of 2. For every two actions, one unsuccessful, one successful, that counsel undertake, the fees would balance out and there would be no loss.

27 This mathematical approach is fundamentally flawed. The probability of success in any litigation cannot be fixed with mathematical precision at any stage of the proceeding. The vagaries of litigation simply do not permit it.

28 Mr. Ross also propounded the theory that the risk of the litigation changed as it progressed and that therefore, the premium should reflect the changing risk. While there may be some truth to the assertion that the risk of litigation changes over the course of the proceeding, it must be considered that changes can occur which both diminish and exacerbate risk at different points in the litigation. There is no more prospect of assigning a precise mathematical value to the risk on a segmented, progressive basis than there is at the outset of the litigation.

29 Moreover, class action litigation introduces additional complications. Complex class actions subsume the productive time of counsel. The risk undertaken by counsel is not merely a function of the probability of winning or losing. Some consideration must also be given to the commitment of resources made by the class counsel and the impact that this will have in the event the litigation is unsuccessful. Winning one of two class actions may be a reasonable hallmark of success. However, for the lawyer who's first action turns out to be a loser, the complete exhaustion of resources may leave him or her unable to conduct another action. Thus the real risk undertaken by class counsel is not merely a simple reciprocal of the "judgmental probability of success" in the action, even if that calculation could be made with any degree of certitude. There is a point in complex class action litigation where, degree of risk notwithstanding, class counsel may truly be, as Mr. Strosberg put it in his submissions, "betting his or her law firm". This must be considered in assessing the "risk" factor in regard of the appropriate fee for counsel.

30 Equally troubling is the fact that Mr. Ross did not consider the unique features of the CPA in formulating his theory regarding the "judgmental probability of success". This was apparent from the transcript of his cross-examination. For example, it was clear that Mr. Ross did not appreciate the risk induced into class action litigation by the additional element of the requirement to attain certification. In the result, the probability of success or failure on the certification motion was not a factor that Mr. Ross considered. This is a significant omission if his fee theory is to be applied to class proceedings. More importantly, it is illustrative of the inherent unreliability of this evidence,

and further, is indicative that Mr. Ross is offering an opinion to the court that is clearly outside his area of expertise.

31 In the result, I conclude that the report of Mr. Ross is of no value in determining either the risk assumed by class counsel or the reasonableness of the fee in these actions.

32 The government defendants chose to rely heavily on this report and did not offer any other evidence on the assessment of the risk involved in the litigation. They did not file affidavits from any member of the counsel group that were involved in the negotiations on behalf of the governments, nor did they provide any evidence from any person at a senior administrative level in the governmental departments responsible for the litigation. Instead, the government defendants conceded that the accounts of the negotiations proffered by the affiants deposed on behalf of the class counsel group were accurate. Interestingly in this regard, the government defendants chose to file as part of their evidence the affidavits of class counsel in the British Columbia and Quebec actions.

33 A picture emerges from the affidavits preferred by class counsel and the government defendants of negotiations that were logistically difficult, intense and time-consuming, adversarial and hard fought. There were obvious points at which potential "deal-breaking" issues surfaced and the success of the negotiations hung in the balance. The various affiants cite examples.

34 Bonnie Tough, the lead counsel for the Hemophiliac Action, states in her affidavit:

> 107. There was throughout the negotiations and even following the Framework Agreement in December of 1998 the risk that one or more governments would not approve the settlement. It was never clear to me the extent to which the various provinces and territories were represented at the negotiating table. It was clear that to the extent they were represented by one or more lawyers, those lawyers were without authority to conclude a deal.
>
> 108. Even within the governments, it was not clear who was instructing the lawyers, i.e. Attorneys' General, Department of Justice, Ministries of Health, Cabinet, Treasury Boards, etc. I was concerned that the successful conclusion of any deal depended upon the attitudes and conduct of a phantom group with whom I was not directly speaking. I did not know the extent to which political differences might influence the acceptance or rejection of any settlement. Changes in governments throughout the time only exacerbated this concern.

35 Heather Peterson, a member of the class counsel group in the Transfused Action, states in her affidavit:

> 78. During [the] last stages of negotiations additional issues arose, some of which also threatened to undermine the negotiations. Two of the most serious examples come to mind:

(a) The Framework Agreement provides ... that the [Settlement] Fund would generate interest as if the amount had been notionally invested at the interest rate paid "from time to time on Long Term Government of Canada Bonds from April 1, 1998 for the duration of the Plan." However during negotiations, the federal government took the position that only the T-bill rate should be paid. Class Action Counsel took the position that maintenance of this position by the FPT governments would be a "deal breaker".

(b) On or about May 9 and 10, 1999, at a negotiation meeting in Vancouver, the FPT Governments raised the prospect of including in the settlement persons who had contracted HCV from immune globulins. The Framework Agreement and all of the ensuing negotiations until that date had not included any reference at all to this group.

> ... [the Ontario governments took the position that [it] wished to be finished with all HCV blood litigation and thus wanted persons who contracted HCV from immune globulins in the Class Period included in the settlement. Strosberg's response was that there was simply no basis to include these persons in the plaintiffs' class. The end of these discussions came on May 13, 1999 at the Toronto offices of McCarthy Tetrault ... [when] Strosberg told counsel to the FPT Governments that their insistence upon including recipients of immune globulins in the class was a "deal breaker," that it was their choice, but under no circumstances would he accept this group in the class. Strosberg intended to break off negotiations if the FPT Governments did not yield on the issue. Strosberg and I left that session uncertain as to whether negotiations had broken down. Thankfully, the FPT Governments eventually relented.

36 It is apparent from the record that even though this litigation was conducted from the middle of 1998 forward as a negotiation toward a settlement, the risks assumed by class counsel were no less real at any point than if that time had been devoted to a disposition through a trial process.

37 In addition, the legislation enabling class proceedings introduces several features that distinguish these actions from ordinary litigation. One aspect that bears on the risk inherent in class actions is the requirement of court approval of any settlement reached. Protracted negotiations involve a commitment of the time and resources of counsel and the litigants. However, in a class proceeding, a court will not approve a settlement that it does not regard as being in the best interests of the class, regardless of whether class counsel take a different view. Thus, class counsel may find themselves in the position of having committed time and resources to the negotiation of a settlement, that they believe is in the best interests of the class, only to find that the court will not approve the settlement achieved. While this creates a risk simpliciter, it also creates an advantage for a defendant who can successfully extend the negotiations to the point that class counsel's resources are exhausted before making a "final settlement offer" that may not ultimately receive

court approval. In those cases, class counsel may have exhausted their resources attempting to obtain a reasonable settlement only to find themselves, as a consequence, unable to pursue the litigation. Accordingly, the risk in a class proceeding is not merely a function of whether or not litigation is anticipated and whether or not that litigation will be successful. Rather, there are risks inherent in the adoption of, and commitment to, any particular strategy for achieving a resolution.

38 In view of the foregoing, I am unable to accept the contention that there was less risk in this proceeding merely because the parties chose to proceed down a negotiation route. Moreover, contrary to the submissions made by certain of the intervenors, it is apparent that the time and resources committed to the negotiations by the class counsel meant that the risk was increasing rather than decreasing as the negotiations continued. As the parties moved toward a settlement, the negotiations became more difficult as the issues narrowed with the result that the risk of an insurmountable impasse increased rather than diminished. This made the negotiations more perilous as they progressed. In that respect, one need look no further than to the actual settlement approval process which required a review of the settlement by this court. In order to obtain the approval of this court, modifications were required to the settlement agreement. Although the court took the view that these modifications were "non-material" as that term was set out in the agreement, the federal government took a different view, as related in the affidavit of Ms. Peterson. She deposed as follows:

> 92. After Mr. Justice Winkler's [sic] delivered his reasons on December 22, 1999 counsel for the federal government and counsel for Ontario asserted orally that the modifications he had suggested and the reasons were indeed "material differences".
>
> 93. After delivery of Mr. Justice Winkler's reasons, counsel for the federal government urged class action counsel to join with him in attempting to persuade Mr. Justice Winkler that his suggested modification relating to the surplus should be abandoned. He told us that if we did not agree he would recommend to the federal government to take issue at Mr. Justice Winkler's suggested modification. He said that, in his opinion, the modification was a "material difference" and that, therefore, there was not court approval of the settlement agreement. He urged class action counsel to make those fundamental choices before the telephone conference he was having with the FPT Deputy Ministers of Health to be held on October 14, 1999. Strosberg believed strongly that the FPT governments would ultimately accept the three modifications proposed by Mr. Justice Winkler. Class action counsel deferred to Strosberg's political judgement and did not agree with counsel for the federal government, and ultimately the FPT governments consented to the three modifications. Even after the delivery of Mr. Justice Winkler's reasons, then, fundamental tactical decisions were required and considerable uncertainty remained over whether or not there was actually a settlement. (Emphasis added).

Clearly the risk continued up until the final judgment was entered.

39 There was an additional submission by one of the intervenors that despite the fact that there may have been risk associated with the negotiations, there was a general cooperative tenor to the negotiations that lessened the risk. I cannot accede to this submission for several reasons. First, It is contrary to the evidence. J.J. Camp, lead counsel for the class in the British Columbia action, whose affidavit was filed on this motion by the federal government, deposed:

> 95. On July 9, 1998 I had an extensive telephone conference with [government counsel] during which they proposed a new counter offer. The tenor of the discussion at times became quite acrimonious with both sides alleging how disappointed they were with the position of the other ...

This is echoed in the affidavit of Bonnie Tough, lead counsel for the class in the Hemophiliac Action. She states:

> 79. Finally, in November of 1998, there was a meeting in Ottawa with Transfused Class Counsel, Hemophilia Class Counsel and counsel for the governments. The meeting was acrimonious and ended with all parties walking from the table in frustration.

40 But, in any event, risk is not synonymous with acrimony in a negotiation process. Even if the tenor of the negotiations changed somewhat for the better after certain points of contention were resolved, there is nothing in the record which would indicate that these negotiations were anything less than hard fought to the end. As such, they were capable of being derailed at any point, regardless of the level of acrimony between the participants. Indeed, the federal government chose to characterize the negotiations in exactly this manner in its submissions to the court on the settlement approval motion. As stated in the factum filed on that motion by counsel for the federal government:

> 106. It is common ground between the parties that the agreement was reached only after an excess of a year of hard fought negotiations between the Parties.
> 108. The March 1998 announcement expressly contemplated that:
>
> "details of assistance will be determined through a negotiation process submitted to the courts for approval. This should ensure fairness. Victims and their legal representatives will be part of this process."
>
> Apart from this direction, however, Ministers [sic] merely outlined certain "principles" and "suggestions" for what the final negotiated arrangement would look like ...

> 111. Further negotiations and an extensive drafting exercise took place subsequent to the Agreement in Principle which resulted in the Agreement before the court today. There can be no dispute but that the Agreement is the product of intense negotiations between counsellor the plaintiffs and FPT governments. (Emphasis added).

41 Further evidence of the tone of the negotiations, or at least the position taken by the parties, can be found in the affidavit of Ms. Peterson. She stated:

> 79. During the negotiations, counsel for the federal government occasionally observed that the option always remained for the FPT governments, or one or some of them, to legislate a program in place of a court-approved negotiation settlement within the framework of the class actions. This option was always a real and substantial risk for class action counsel and our counsel group ...
> 81. Settlement was always dependent upon formal cabinet approval by all 14 FPT governments. During the negotiations, tensions were palpable among the FPT governments. Counsel for the various FPT governments at times asserted differing, disconsolate positions; so also did class action counsel. Through it all, it became clear to me that, from the FPT government side of the negotiating table, political considerations were as important as legal issues. The concerns about political ramifications was a constant risk, because there were numerous provincial elections and changes in provincial governments (including the creation of a new territory) in the course of the negotiations from April 1998 to October 1999.

42 While I do not equate acrimony with risk, complexity, on the other hand, breeds risk in any proceeding. In this case, the logistical complexity was overwhelming. The insistence of the governments that there be one pan-Canadian settlement of all of the actions meant that any settlement attained required approval of 14 FPT governments, each with differing political agendas and policies. Although obtaining approval from this group alone was daunting enough, the class counsel groups in the various actions on the other side of the bargaining table were by no means speaking in a unified voice at all times. In the Transfused and Hemophiliac Actions in Ontario, the combined class counsel groups were comprised of over 60 lawyers and supporting legal personnel. In addition, the negotiations were played out against the backdrop of changes in the provincial and territorial governments, changes in the Ministers of Health for all of the governments, and political activism directed at attaining a universal settlement for all persons infected with HCV by blood in Canada, regardless of the date of infection. The expenditures of class counsel in terms of time and money were at risk of loss if any politician in authority decided as a matter of expediency or policy not to settle the class proceedings or decided to unilaterally institute a no-fault compensation program and thereby bypass class counsel and the litigation. There was always the inherent danger

that the pan-Canadian settlement would be impossible to achieve, either because of a reluctance on the part o a particular government or a class in a particular action to approve an agreement.

43 The evidence is compelling. This litigation, notwithstanding the fact that it was conducted as a protracted negotiation, was redolent with risk. Moreover, insofar as it is appropriate to assess the risk assumed by class counsel on a sliding scale or range depending on the nature of the action in comparison to other actions, I am satisfied that the risk enuring to class counsel in these actions should be considered to be at the high end of any such scale.

C. Fair and Reasonable Fee

44 A fair and reasonable fee must be reflective of the risk undertaken by class counsel and the result attained for the class in the action. My analysis of those factors is set out in the foregoing. The next step is to determine, through their application, whether the fees being sought by the class counsel groups, $15,000,000 in the Transfused Action and $5,000,000 in the Hemophiliac Action, constitute fair and reasonable fees in the circumstances.

45 In considering this, I cannot accede to the submissions of the various intervenors with respect to the fees. Taking their submissions as a group, the intervenors submitted that fees ranging between approximately $6,000,000 and $11,000,000 should be awarded in the Transfused Action. In the Hemophiliac Action, the range of the intervenors' submissions was from approximately $2,000,000 and $3,500,000. Although the intervenors did not seriously question the allocation of lawyers and legal staff, they did attack the hourly rates of certain counsel. This attack lacked any evidentiary basis however and thus must be rejected. The second, and main, submission of the intervenors was that there was a diminution of risk either because of the political considerations or the fact that these proceedings were conducted as a negotiation rather than as a completely adversarial trial process. Since I have rejected these underlying propositions as being unsupported by the evidence, it follows that the submission founded on them must be rejected as well.

46 I have considerable difficulty with the submission of the government defendants on different grounds. While I have rejected the intervenors' submissions as founded on erroneous assumptions, there was, to their credit, an implicit acknowledgement, and application, within those submissions of the dual factors of result and risk to be considered in determining a fair and reasonable fee. In contrast, the government defendants submitted figures in respect of the fees that represented less than the monetary value of the docketed time of the class counsel groups. This submission was made despite the acknowledgement by the government defendants of the "high degree of competence of the class counsel" and the recognition of the satisfactory result attained for the classes. Further they took no issue with the hours expended by the class counsel groups, the number of counsel within those groups, or the class counsel evidence with respect to the difficulty of the negotiations. The fee proposed by the governments was arrived at by combining an arbitrary reduction of the hourly rates of the class counsel group and an addition of a premium of approximately 10% of the reduced amount. If accepted, the net effect of the governments'

submission would be to deprive class counsel of any premium, multiplier or reward of any nature reflecting risk or result.

47 The position taken by the government defendants is untenable. Considered in the context of these proceedings, the fees they propose are not reflective of either the result obtained or the risk undertaken even if just one of those factors were to be considered in isolation. More so however, the fees proposed by the government defendants are at variance with the apparent underlying policy of the CPA and the interpretation of that policy by the Court of Appeal in Gagne.

48 It was suggested by Mr. O'Sullivan, who appeared on behalf of the class counsel group in the Hemophiliac Action, that it was obvious that the government defendants' position was driven by political expediency rather than by a sincere effort to assist the court in determining an appropriate fee. In support of this analysis, he provided several press clippings, including some culled from newspaper editions published during the three days of this hearing, that were critical of the fees being sought by the class counsel group. He suggested that the government position, when compared to the positions taken by class counsel and the intervenors, was so far outside the range of reasonableness that it could only be inferred that political, rather than legal considerations must be at play.

49 Notwithstanding these submissions, it is not within the purview of the courts role on this motion to impute ulterior motives to any party and I make no finding in respect of the submissions of Mr. O'Sullivan. As I stated in my reasons regarding the settlement approval, "extra-legal concerns, even though they may be valid in a social or political context, remain extra-legal and outside the ambit of the court's review ...".

50 Nonetheless, the concern expressed over extra-legal considerations may well be symptomatic of a general lack of understanding of the legal framework in which these proceedings evolved. The court was invited to address this issue in these reasons by Mr. Dermody, counsel for the intervenors. He expressed a concern that there was a general misunderstanding regarding the nature of these proceedings that had the potential to create animosity between the class members, their counsel and the FPT governments which might, in turn, erode the salutary benefits of the settlement and reflect negatively on the fair compensation of counsel. This point is well taken.

51 In addressing the issue, the starting point must be an understanding that the proceedings were litigious in nature and that the settlement offered by the FPT governments was driven by the prospect of an unfavourable determination, however probable or improbable, if the litigation proceeded to a conclusion. There is no evidence to support any assertion to the contrary. In the result, there was nothing untoward in the way that the government defendants or the class counsel groups conducted themselves in resolving the litigation. Hard bargaining is a fact of life in any high stakes negotiation. Outright capitulation from either side of the table is not a realistic expectation. There were arguable defences and a legitimate question as to the ultimate liability of the governments. While recognizing that the victims had suffered a tragedy, the governments, as

litigants, always had to bear in mind that they were the representatives of all of the people and the keeper of the public purse. The tension created by these two concerns obviously complicated matters for the FPT governments and for the class counsel groups. Despite these complexities, the parties persevered through arduous negotiations and reached an agreement to settle the outstanding litigation within a legal framework.

52 In recognition of the legal framework within which the settlement was negotiated, the Agreement crafted speaks directly to the question of class counsel fees in that it stipulates a limit on those fees. All counsel agreed that the fees sought would not exceed $52,500,000 in total. The details of the background negotiations that led to this provision are contained in the affidavits of the British Columbia and Quebec class counsel. The government elicited an agreement from the class counsel groups that they would not seek fees on the basis of a percentage of the total settlement and further, that the counsel group would agree to a cap on the total amount of fees. In addition to the other concessions extracted by the governments, counsel were required to surrender any fee agreements that they may have executed with individual class members. Mr. Camp deposes to this at para. 148:

> 148. Under my fee agreement, [the class counsel group] were entitled to charge up to one-third of the settlement amount attributed to the British Columbia class action. Quebec class counsel also had a percentage contingency fee agreement with their representative plaintiff. Class Counsel in both the Framework Agreement and the Settlement Agreement have waived their rights to seek recovery of class counsel fees based on a percentage of the settlement amount. Without doubt, in my opinion, the compromise by class counsel of their right to claim class counsel fees on the basis of percentage of any settlement or judgment, which in my case amounted to up to one-third, was a significant concession which assisted the parties in coming to an agreement.

Mr. Lavigne similarly stated in Ms affidavit:

> 145. It should be noted that 166 of the 450 victims who are on the M.M.M.F. lists have agreed, by giving a written mandate, a copy of which is attached hereto, to pay a sum amounting to 20% of any amount that was obtained by a judicial process or negotiation process or by government compensation;
> 146. The client's expectations in this respect have been clearly established since 1995 and have always comprised a clear, plain and precise working basis for all of the people who came into contact with our firm;
> 147. This percentage agreement, which is entirely proper and legal in Quebec, has been set aside as regards a claim of 20% in the total amount of the settlement;
> 148. In the final quibbling during the negotiations that led to the Agreement of June 15, 1999, the applicant solicitors agreed to this additional concession, which was demanded by the governments, and particularly by the federal government, so

that the Agreement could be concluded;

149. However, consideration for this was provided: that an agreement would be negotiated and concluded after the Agreement was signed to avoid any question of conflict of interest. Those negotiations have never taken place, and so it is impossible for us to take a position jointly with the respondents regarding the amount of the fees;

53 A final agreement regarding fees was never negotiated. Nevertheless, in consideration of the negotiated surrender of the individual contingency fee agreements, the undertaking by class counsel not to seek a fee on a percentage basis and the express cap of $52,500,000 on total fees, there is no other reasonable conclusion than that there was a tacit understanding between class counsel and the governments that this amount represented a fair and reasonable fee for counsel in the circumstances.

54 To put this in its proper context, it must be remembered that over 400 of the then identified class members in British Columbia and Quebec had negotiated individual contingency fee arrangements whereby they would have paid between 20% and 33% of any compensation received. This arrangement would produce a counsel fee of over $220,000,000, at a minimum, if extrapolated against the total settlement and the estimated class size as a whole. In comparison, the cap on fees negotiated by the governments is very favourable indeed.

55 However, while this tacit agreement between the parties regarding fees is instructive, it is not in itself determinative. In order to arrive at the appropriate premium fee, "all the relevant factors must be weighed".

56 The fees being sought are substantial. However, the quantum of a counsel fee, in and of itself, does not provide a valid basis for attacking the fee. The test in law, as set out in Gagne, is whether the fees are fair and reasonable in the circumstances. The legislature has not seen fit to limit the amount of fees awarded in a class proceeding by incorporating a restrictive provision in the CPA. On the contrary, the policy of the CPA, as stated in Gagne, is to provide an incentive to counsel to pursue class proceedings where absent such an incentive the rights of victims would not be pursued. It has long been recognized that substantial counsel foes may accompany a class proceeding. To this effect, the authors of the Ontario Law Reform Commission's Report on Class Actions (1982) stated at 135-138:

> Critics of class actions often compare the total amount of administrative costs and lawyer's fees with the amount of each class member's claim, and then suggest that these costs and fees have the effect of depriving class members of any significant recovery. However, a comparison of total costs and fees with an individual class member's claim gives a rather myopic view of the issue. A better sense of whether the costs and fees of a class action are reasonable can be achieved by determining the percentage of the class recovery consumed by such costs and fees.

> Empirical data also has been collected concerning the percentage of class recoveries consumed by lawyers' fees alone. [in the United States] the data collected ... indicates that, in slightly more than fifty percent of the cases for which such information was available, lawyers' fees represented twenty-five percent or less of the recovery, while in only 10.7 percent of the cases did such costs exceed fifty percent of the recovery.
>
> These percentages of class action awards consumed by lawyers' fees and administrative costs do not appear particularly unreasonable, given the complexity of class suits. Moreover, the figures revealed by the empirical studies do not appear to be out of line with the proportion of individual recoveries consumed by lawyers fees and disbursements in individual litigation in Ontario, if the Law Society of Upper Canada was correct in suggesting that Ontario clients tend to receive a "net recovery" reduced by fifteen to twenty-five percent.
>
> In evaluating the fairness of lawyers' fees documented by the empirical studies, it is important to remember that, at least in the case of individually non-recoverable claims, any attempt to assert the claim through an individual suit would, by definition, consume 100 percent of the claim. Measured by this standard, the proportion of an individual class member's recovery consumed by class lawyers' fees in the United States does not appear inherently unreasonable. Moreover, in some cases, the costs of individual litigation may consume, a substantial proportion of even those claims that are individually recoverable and, in such situations, the class action will also result in cost savings, even if the share consumed by lawyers fees remains substantial.

57 The OLRC Report has been widely acknowledged to be the most sophisticated and extensive analysis of class actions undertaken in the world. (See the Report of the Attorney General's Advisory Committee on Class Action Reform, (Ontario, February 1990) at p. 20.) The pragmatic approach it displays towards counsel fees in class actions was based on careful study and analysis. It is significant that the authors of the report did not consider counsel fees representing 25% of the total recovery "inherently unreasonable".

58 However, the appropriateness of a premium fee, whether as a lump sum, as a percentage of the recovery or as a multiplier of a base fee must be assessed against the facts of each case. The adoption of any standard multiplier or percentage fee would undoubtedly result in fee awards that have little relation to the risk undertaken or the result achieved. This was recognized by Goudge J.A. in Gagne. To use these proceedings as an example, notwithstanding the OLRC Report and the

typical awards in class proceedings, a fee based on 20% or more of the recovery would be clearly excessive and represent a windfall for the counsel groups.

DISPOSITION

59 Class counsel in the Transfused Action and the Hemophiliac Action seek court approval of "lump sum fees" in the amounts of $15,000,000 and $5,000,000 respectively, and ask that the fees be fixed in those amounts, pursuant to written retainer agreements with the representative plaintiffs. This lump sum method of payment is expressly contemplated by s. 32(1)(c) of the CPA and by the Settlement Agreement, which provides at para. 13.03:

> The fees, disbursements, costs GST and other applicable taxes of Class Action Counsel will be paid out of the Trust. Fees will be fixed by the Court in each Class Action on the basis of a lump sum, hourly rate, hourly rate increased by a multiplier or otherwise, but not on the basis of a percentage of the settlement amount. (Emphasis added.)

60 Moreover, it has been held that the contingency fee provisions of the CPA are not limited to a base fee and multiplier arrangement, but instead permit of fee arrangements of various types, including lump sums and as percentages of recovery. In Nantais v. Telectronics Proprietary (Canada) Ltd. (1996), 28 O.R. (3d) 523 (Gen. Div.), Brockenshire J., in approving a lump sum fee, stated at 528:

> The special provisions relating to "multipliers" for hourly rates [do not prevent], in any way, other arrangements as specifically authorized under s. 32(1)(c). I view s. 33(1) and (2) as permitting, despite other statutes, all kinds of fee arrangements contingent upon success, and not just hourly rate multipliers.

61 In Crown Bay Hotel v. Zurich Indemnity Co. of Canada (1998), 40 O.R. (3d) 83 (Gen. Div.), this court stated at 87-88:

> A contingency fee arrangement limited to the notion of a multiple of the time spent may, depending upon the circumstances, have the effect of encouraging counsel to prolong the proceeding unnecessarily and of hindering settlement, especially in those cases where the chance of some recovery at trial seems fairly certain. On the other hand, where a percentage fee, or some other arrangement such as that in Nantais ... is in place, such a fee arrangement encourages rather than discourages settlement ... Fee arrangements which reward efficiency and results should not be discouraged.

62 However, regardless of the manner in which a premium fee is awarded in a class proceeding, whether by lump sum or otherwise, to adopt the words of Goudge J.A. in Gagne, the premium must be one that "results in fair and reasonable compensation to the solicitors" having regard for the risk

undertaken and the result achieved.

63 In Gagne, Goudge J.A. set out a series of useful corroborating tests for analysing the fairness and reasonableness of the fee. These involve, variously, testing the fee as a percentage against recovery, as a multiple of base fees, as against the retainer agreement and whether, in the circumstances, the fee will provide sufficient incentive for counsel to take on difficult cases in the future. As he stated at 425:

> In the end, [these considerations must result] in fair and reasonable compensation to the solicitors. One yardstick by which this can be tested is the percentage of gross recovery that would be represented by the multiplied base fee. If the base fee as multiplied constitutes an excessive proportion of the total recovery, the multiplier might will be too high. A second way of testing whether the ultimate compensation is fair and reasonable is to see whether the multiplier is appropriately placed in a range that might run from slightly greater than one to three or four in the most deserving case. Thirdly, regard can be had to the retainer agreement in determining what is fair and reasonable. Finally, fair and reasonable compensation must be sufficient to provide a real economic incentive to solicitors in the future to take on this sort of ease [sic] and to do it well.

64 The first of the corroborating factors is a test of the fee as a percentage of the class recovery. I note that the Settlement Agreement expressly prohibits class counsel from asking that their fees be fixed as a percentage of the settlement amount. Nevertheless, it remains a valid basis for comparison purposes. The fees sought in the Transfused Action represent 2.36% of the portion of the Settlement apportionable to the Ontario national class victims. The work in the Hemophiliac Action was for the benefit of all Hemophiliacs. The fees sought in the Hemophiliac Action equate to 3.33% of the total amount of the Settlement apportionable to the Hemophiliac class members. On this basis, the fees, although large, are more than reasonable.

65 Secondly, the fee should be tested as a multiple of the base fees docketed by class counsel. On this basis, the fees sought are consistent with the suggested range set out in Gagne for "the most deserving case". I note that the calculation is made more complex by the fact that class counsel continued to do work necessary to ensure the implementation of the settlement after the date of the expiry of the period for appeal of the approval. The Settlement Agreement contemplates that additional fees will be paid to counsel for certain administrative work, over and above the class counsel fee, at an hourly rate. However, as stated above, an important consideration in measuring the result achieved is whether or not the job is complete. Accordingly, it is my view that the work that has been performed to date was properly required of class counsel to ensure that the settlement was implemented. Counsel have valued the additional work at approximately $675,000 for counsel in the Transfused Action and $148,000 for counsel in the Hemophiliac Action from the end of the appeal period on January 22, 2000 to May 14, 2000. They have made a written submission to the court that their work as class counsel was completed on May 14, 2000. I cannot accede to this

submission. While the administration is functional and claims are now being received, processed and paid, some details must still be completed. Thus, there will be no further compensation to counsel for any additional time spent in attending to these matters. The premium fee being sought in these actions is being sought on the basis of a "job well done". The court will not approve an additional fee for this work, or any additional work remaining to be done in order to complete the implementation of the settlement and its administration.

66 Without considering the value of the "additional work", the lump sum fees constitute a multiplier of 3.57 in the Transfused Action and 4.29 in the Hemophiliac Action. When the fees for this additional work are included however, the multipliers are 3.07 and 3.80 respectively. For the Hemophiliac Action, the base fee and multiplier approach yields a figure at the high end of the range set out in Gagne, but the result obtained for the Hemophiliac class members justifies such an award. The qualifying threshold negotiated by class counsel eliminates a potentially insurmountable burden of proof that those class members would otherwise have faced.

67 Thirdly, the fees may also be measured by the expectation of the representative plaintiff as evidenced by the retainer agreement. Here, unlike the usual case, the specific amount of the fees were agreed to by reasonably informed representative plaintiffs. Moreover, the retainer agreements executed by the representative plaintiffs are a marked improvement over the individual fee agreements signed by the class members in Quebec and British Columbia.

68 The fee must also provide a sufficient economic incentive to attract counsel to cases of a similar nature in the future. The words of Goudge J.A. bear repeating. As he stated in Gagne at 422-23:

> The opportunity to achieve a multiple of the base fee if the class action succeeds gives the lawyer the necessary economic incentive to take the case in the first place and to do it well. However, if the Act is to fulfil its promise, that opportunity must not be a false hope. (Emphasis added.)

In the present circumstances, given the difficulty in securing counsel for the classes, let alone the experienced counsel that were ultimately retained, the incentive of a reasonable premium was necessary to ensure that these victims had counsel of the highest calibre without the benefit of whom this settlement could not have been achieved. The lump sum fees set out in the retainer agreements meet this test.

69 Additionally, the fees compare favourably with the fees awarded in other major class proceedings in Canada as shown by the following chart:

Action	Total Class Recovery	Class Percentage Counsel of Fees Recovery	Further Legal Fees Anticipated

			to be Incurred by Class Members
Harrington v. Dow Corning Corp. [1999] B.C.J. No. 320 (S.C.) (Quicklaw)	$40,000,000	$6,000,000	15%	Yes
Doyer v. Dow Corning Corp. (Sept. 1, 1999), 500-06-000013-834 Superior Court of Quebec, Tingley J.S.C.	$52,000,000	$10,400,000	20%	Yes
Nantais v. Telectronics Proprietary (Canada) Ltd. (1996), 28 O.R. (3d) 523 (Gen. Div.)	$23,140,000	$6,000,000	26%	Yes
Pelletier v. Baxter Health Care Corp.*, [1999] Q.J. No. 3038 (S.C.) (Quicklaw)	$21,525,000	$3,648,000	16.9%	Yes

* combined with Jones v. Baxter Health

Care Corp. in Ontario

70 Finally, the fees, as set out in the retainer agreements, if approved, will not impair the sufficiency of the Trust Fund established to provide the benefits to the class members. The actuarial report prepared by Eckler and Partners specifically addresses this issue.

71 These class proceedings have been described throughout as the largest personal injury case in Canadian legal history. The global settlement amounts to over $1.5 billion dollars when all benefits are included. The settlement is Pan-Canadian in scope. The defendants include all of the federal, provincial and territorial governments in Canada. The prime defendant, CRCS, is under court protection pursuant to the CCAA. The benefits are to be paid out of Trust Fund established for the class members rather than out of the general revenue accounts of the governments. The nature of the benefits provided through the settlement is imaginative and incorporates some of the innovative measures regarding compensation in personal injury lawsuits that courts have been advocating for over 20 years.

72 The logistics of the litigation must also be considered. It took almost three years to find lawyers willing to undertake the case because of the size and complexity. The investment required of class counsel, and the inherent risk of non-recovery, were daunting. Over 60 lawyers and legal staff were involved in bringing this litigation to a successful conclusion. Neither the governments nor the intervenors challenged the number of people or the hours required of those people to finalize the settlement.

73 The evidence of class counsel regarding the negotiations was accepted. Indeed, the government defendants echoed the evidence of class counsel in their own submissions on the earlier motion for settlement approval. It was common ground that class counsel did an excellent job. There was unanimity as to the quality of the settlement. Further, in so far as there were arbitrary points of contention raised on this motion, the evidence of class counsel on those points stands unchallenged and uncontradicted. Simply put, neither the intervenors nor the government defendants have put forward any principled or evidentiary basis for reducing the proposed counsel fees. Accordingly, I cannot accept their submissions; that the fees specified in the retainer agreements should be reduced.

74 To look back with the clarity of hindsight and re-evaluate the relevant factors in light of subsequent events when fixing fees is unfair. A court must, as best as it is able, consider the elements of the litigation as they would have appeared to the parties at the material times. To do otherwise would be inconsistent with the underlying policy of the CPA. Here, the fees sought as agreed to by the representative plaintiffs are large but so were the lawsuits and the settlement. The Settlement Agreement evidences that the size of the fee was anticipated by the governments who now object. As Goudge J.A. stated, the opportunity for class counsel to receive a premium for taking on difficult litigation and doing it well must not be "a false hope". It is an essential ingredient of the CPA that counsel be provided with a significant incentive to take on meritorious class

proceedings. This means that premium fee awards must reflect the reality of the risk and the success of the efforts of class counsel in a meaningful way. Without this, injured parties will be denied the services of the most experienced counsel.

75 This litigation was of the most difficult kind on a number of fronts. It epitomized risk as that term is used in the context of fee awards under the CPA. It is questionable whether any single member of the class would have had the financial resources to prosecute a lawsuit to a successful conclusion in consideration of the scope, the factual complexity of such a case, the myriad of legal issues that would have arisen and the countless years that such litigation would consume. In contrast, this settlement provides class members with access to immediate benefits without any further legal impediments to their claims. Given the risk undertaken and result achieved by class counsel in this litigation, the lump sum fees contemplated in the retainer agreements are "fair and reasonable".

76 Accordingly, the retainer agreements in the Transfused and the Hemophiliac Actions are approved. The lump sum fees set out therein are also approved and fixed. Counsel may attend before me to address the matter of disbursements. The final order will address the outstanding work to be done by class counsel.

77 In light of the magnitude of these Actions, and the issues involved, the court permitted and indeed, encouraged submissions from persons with a stake, in one form or another, in the litigation. The fees submitted by counsel for these stakeholders, identified variously as intervenors and friends of the court, are also approved.

WINKLER J.

cp/s/qlbbd/qlalm/qlbdp

Case Name:

Sayers v. Shaw Cablesystems Ltd.

Between
Trevor Sayers and Victor Miranda, Plaintiffs, and
Shaw Cablesystems Limited and Shaw Communications Inc.,
Defendants
PROCEEDINGS UNDER the Class Proceedings Act, 1992

[2011] O.J. No. 637

2011 ONSC 962

16 C.P.C. (7th) 367

2011 CarswellOnt 858

Court File No. 04-CV-276846CP

Ontario Superior Court of Justice

P.M. Perell J.

Heard: February 10, 2011.
Judgment: February 10, 2011.

(41 paras.)

Civil litigation -- Civil procedure -- Parties -- Class or representative actions -- Certification -- Settlements -- Approval -- Motion by plaintiffs to certify the action as a class action and for approval of a settlement and the agreement with counsel respecting fees and disbursements allowed -- Plaintiffs worked for defendant as independent contractors but were then found to be independent contractors by Revenue Canada, and required to repay business deductions claimed -- Plaintiffs sued defendant in negligence -- Fee Agreement provided that class counsel would be paid 30 per cent of any settlement recovered Criteria for certification satisfied -- Settlement was fair, reasonable, and in the best interests of those affected by it -- Fee agreement was reasonable.

Motion by the plaintiffs to certify the action as a class action and for approval of a settlement and

the agreement with counsel respecting fees and disbursements. The plaintiffs worked as independent contractors under an Owner-Operator Agreement for the defendant. Revenue Canada then ruled that the plaintiffs were employees and not independent contractors, requiring the plaintiffs to repay business deductions claimed. The plaintiffs then commenced the present action, claiming the defendant was negligent in failing to properly characterize the relationship under the Owner-Operator Agreement. The proposed class members were 106 individuals who had worked under the Owner-Operator agreement and who were found to be employees by Revenue Canada. The settlement involved consent certification, creation of three funds, and a claims process. The settlement provided a small payment to all class members and a potentially significant payment to class members who were reassessed by Revenue Canada and who could demonstrate that the reassessment was for unanticipated tax liability relating to disallowance of business deduction. No objections to the settlement had been received. The Fee Agreement provided that class counsel would be paid 30 per cent of any settlement recovered on behalf of the class. The total settlement amount was less than the actual value of the fees and disbursements to date and would represent a substantial but not full, indemnity award.

HELD: Motion allowed. For settlement purposes, all the criteria for certification had been satisfied. The action was thus certified as a class proceeding. The settlement was fair, reasonable, and in the best interests of those affected by it. Class counsel's fee should be approved. Class counsel expended considerable time over a six-year period without any guarantee of payment. The case called for ingenuity and creativity in negotiating a settlement that would provide a payment for every class member and a potentially significant contribution toward the reassessed tax liability of others. While the recovery was only partial, it was doubtful any recovery at all would have been possible but for the lawyers' willingness to assist the class.

Statutes, Regulations and Rules Cited:

Class Proceedings Act, 1992, S.O. 1992, c. 6, s. 5(1)

Counsel:

Malcolm N. Ruby, for the Plaintiffs.

M. Paul Michell, for the Defendants.

REASONS FOR DECISION

P.M. PERELL J.:--

A. Introduction and Overview

1 Trevor Sayers and Victor Miranda move to certify this action as a class proceeding against the Defendants Shaw Cablesystems Limited and Shaw Communications Inc. They also request the court's approval of a settlement and the agreement with counsel respecting fees and disbursements.

2 For the Reasons that follow, I grant the relief requested.

B. Factual Background

3 Between 1997 and 2000, Mr. Sayers and Mr. Miranda installed cable and internet services for the customers of Shaw Cablesystems Limited and Shaw Communications ("Shaw") under an "Owner-Operator Agreement." Under the agreements, Messrs. Sayers and Miranda, were described as independent contractors. During this period, Messrs. Sayers and Miranda were part of a group of contractors working for Shaw under the Owner-Operator Agreement.

4 On the understanding that the Owner-Operator Agreement did not create an employment relationship, Shaw did not deduct or submit Canada Pension Plan ("CPP") or Employment Insurance ("EI") payments or make source deductions for income tax for the group of contractors. Messrs. Sayers and Miranda and the other contractors filed tax returns and claimed deductions on the understanding that they were earning income as independent business persons.

5 In or about 2000, the Minister of National Revenue ruled that class members were Shaw employees and not independent contractors. As a result, the Minister determined that Shaw was required to remit CPP and EI payments on their behalf. The Ministry of National Revenue also advised some of the contractors that deductions claimed for business expenses on tax returns filed for the years between 1997 and 1999 would not be allowed.

6 Shaw appealed the Minister's ruling to the Tax Court of Canada, but the appeal was dismissed on June 13, 2002. A further appeal to the Federal Court of Appeal was dismissed on April 1, 2003.

7 Several of the contractors, including Mr. Miranda, objected to the disallowance of the business expenses as deductions. Ultimately, Mr. Miranda received a Notice of Reassessment indicating that he owed $26,760.44.

8 In September 2004, Mr. Sayers commenced a proposed class action against Shaw. He alleged negligence, breach of implied terms of contract, and negligent misrepresentation. He alleged that Shaw owed the contractors a duty to properly characterize the relationship under the Owner-Operator Agreement and, having failed in that duty, must compensate the contractors for foreseeable damages suffered, including the amount of unanticipated additional tax liability. A claim was also made for the contractors' statutory benefits such as vacation pay.

9 The proposed class comprises 106 individuals. The proposed class definition is:

All persons who entered into Owner-Operator Agreements with Shaw relating to

the sale or installation of its cable television and/or Internet services that were found by the Tax Court of Canada to create employment rather than independent contractor relationships.

10 The proposed common questions are:

(a) Did Shaw owe a duty to class members who signed Owner-Operator Agreements to ensure that the agreements created independent contractor, rather than employment, relationships? If so, did Shaw breach its duty?

(b) Was Shaw negligent in representing to class members, in the Owner-Operator Agreements, that the agreements gave rise to independent contractor relationships when in law they gave rise to employment relationships?

(c) Did Shaw owe class members a duty to warn that the Owner-Operator Agreements may give rise to employment, rather than independent contractor relationships and did Shaw breach that duty?

(d) Did Shaw breach the terms of its contracts with class members by failing to create an independent contractor, rather than an employment, relationship?

(e) Did the Owner-Operator Agreements contain an implied contractual term that Shaw would pay business income, rather than employment income, from which class members would be entitled to deduct business expenses?

(f) Is Shaw liable to compensate class members for any amounts for which they were re-assessed by the CRA based on their status as employees rather than independent contractors?

(g) Is Shaw liable to compensate class members for any amounts that were ordinarily payable to them as employees, including time spent in training, statutory overtime pay, vacation pay, termination pay, or severance benefits?

(h) Is Shaw liable to class members for punitive damages?

11 Shaw denied liability and resisted certification. Shaw's position was that the class members voluntarily entered into the Agreement and accepted responsibility for their own tax liability. Shaw's position was that the action was not suitable for certification because each contractor's tax situation is an individual issue.

12 The affidavit of Ms. Bashnick delivered in response to the motion for certification indicates that Shaw suggests that those class members who were reassessed failed to mitigate their damages by obtaining and filing CRA T2200 forms that would have permitted at least some "business" expenses, "including motor vehicle expenses and supplies", to be deducted from employment income. Ms. Bashnick also takes the position that some class members were reassessed for reasons other than the independent contractor/employment distinction because they claimed deductions for

"personal and living expenses" that "would not have been deductible even if the CRA had considered the owner-operators to be independent contractors."

13 The action moved towards a certification hearing, but after the exchange of certification materials, the parties began settlement discussions. The negotiations were intense and adversarial. Messrs. Sayers and Miranda were represented by Malcolm N. Ruby of Gowling Lafleur Henderson, who is an experienced counsel with expertise in class action litigation. Shaw was represented by Charles Scott and M. Paul Michell of Lax O'Sullivan Scott Lisus LLP, both experienced litigation lawyers.

14 In advancing the case for the contractors, a major challenge for proposed class counsel was obtaining details of the tax situations of the various members of the proposed class. Letters were sent out to the contractors whose addresses were known. A private investigator was hired to locate contact information for other contractors.

15 In the settlement negotiations, Messrs. Sayers and Miranda, were disadvantaged by the factor that even if success was achieved on a contested certification motion, the chances of recovering from Shaw on the merits of the claim were uncertain and would involve substantial time and expense. Uncertainty arises, among other reasons, from the novelty of the negligence claim and the possibility that the claims based on statutory entitlements were statute-barred. In addition, assuming the case went to individual issue trials, there were significant mitigation issues.

16 Between April and October 2010, the parties, through their counsel, arrived at a settlement. The Defendants do not admit liability. The settlement involves consent certification, creation of three funds, and a claims process.

C. Details of the Settlement

17 Details of the settlement are as follows:

* A fund of $137,800 is created for fixed payments of $1,300 (less legal fees and costs) to all class members for vacation pay and other statutory entitlements. To qualify for a payment, a class member must submit a claim stating that he or she entered into an Owner-Operator Agreement between 1997 and 1999 and provided services under the Agreement to Shaw clients during that period.
* A fund of $200,000 is created for payments (less legal fees and costs) to those class members who were reassessed by the CRA for additional income taxes based on misclassification as independent contractors rather than employees. To qualify for a payment, a class member must (a) show that he or she was reassessed by the CRA for any taxation year between 1997 and 1999 in an amount greater than $2,250, and (b) submit a properly documented claim demonstrating that his or her reassessment by CRA was

attributable to being classified as an independent contractor rather than employee.

* Unclaimed amounts from the statutory benefits fund will be allocated to the income tax payments fund.
* Counsel for the parties will administer all claims. They may obtain, if necessary, the assistance of a small business tax accountant, David Gellman, C.A, to deal with individual claims.
* If a disagreement arises as to whether a particular claim qualifies for payment, the claim will be submitted to a neutral claims officer for resolution. If, at the conclusion of the claims process, there are any unclaimed monies, the monies will revert to Shaw.
* A fund of $50,000 is created for legal fees and disbursements required to obtain settlement approval and for claims administration.
* The Settlement Agreement provides for a claims bar date of 90 days from the date of settlement approval or until May 2, 2011.
* The opt-out period for all class members is May 2, 2011.

18 Messrs. Sayers and Mirandas' counsel recommended the settlement because it provided a small payment to all class members and a potentially significant payment to class members who were reassessed by the CRA and who can demonstrate that the reassessment was for unanticipated tax liability relating to disallowance of business deductions. Messrs. Miranda and Sayers have accepted counsel's recommendation to seek approval of the settlement.

D. Notification of the Proposed Settlement

19 On November 8, 2010, the court approved a notice informing class members that a settlement approval hearing would take place on February 10, 2011.

20 The November Notice appended claim forms. Class members were encouraged to fill out and return the forms by December 31, 2010 because, in the words of the notice, "the number of forms received and the amounts claimed by class members [would] assist the court in determining whether the proposed settlement is fair, reasonable, and in the best interests of the class." The Notice also appended opt-out forms for those class members who did not wish to participate in the class proceeding and/or the proposed settlement.

21 Subsequently, letters were prepared and sent to each class member (including those located by the investigator) containing copies of the notice and claim/opt out forms. To date, 30 claim forms have been received. The total value of known reassessment claims is now $356,817.44.

22 No objections to the settlement have been received.

E. Certification

23 Pursuant to s. 5(1) of the *Class Proceedings Act, 1992*, S.O. 1992, c. 6, the court shall certify a proceeding as a class proceeding if: (a) the pleadings disclose a cause of action; (b) there is an identifiable class; (c) the claims of the class members raise common issues of fact or law; (d) a class proceeding would be the preferable procedure; and (e) there is a representative plaintiff who would adequately represent the interests of the class without conflict of interest and who has produced a workable litigation plan.

24 Where certification is sought for the purposes of settlement, all the criteria for certification must still be met: *Baxter v. Canada (Attorney General)* (2006), 83 O.R. (3d) 481 (S.C.J.) at para. 22. However, compliance with the certification criteria is not as strictly required because of the different circumstances associated with settlements: *Bellaire v. Daya*, [2007] O.J. No. 4819 (S.C.J.) at para. 16; *National Trust Co. v. Smallhorn*, [2007] O.J. No. 3825 (S.C.J.) at para. 8; *Nutech Brands Inc. v. Air Canada*, [2008] O.J. No. 1065 (S.C.J.) at para. 9.

25 I am satisfied that for settlement purposes, all the criterion for certification have been satisfied in the case at bar. I, therefore, certify this application as a class proceeding pursuant to the *Class Proceedings Act, 1992*.

F. Settlement Approval

26 To approve a settlement of a class proceeding, the court must find that in all the circumstances the settlement is fair, reasonable, and in the best interests of those affected by it: *Dabbs v. Sun Life Assurance*, [1998] O.J. No. 1598 (Gen. Div.) at para. 9; *Parsons v. Canadian Red Cross Society*, [1999] O.J. No. 3572 (S.C.J.) at paras. 68-73.

27 In determining whether to approve a settlement, the court, without making findings of facts on the merits of the litigation, examines the fairness and reasonableness of the proposed settlement and whether it is in the best interests of the class as a whole having regard to the claims and defences in the litigation and any objections raised to the settlement: *Baxter v. Canada (Attorney General)* (2006), 83 O.R. (3d) 481 (S.C.J.) at para. 10.

28 When considering the approval of negotiated settlements, the court may consider, among other things: (a) likelihood of recovery or likelihood of success; (b) amount and nature of discovery, evidence or investigation; (c) settlement terms and conditions; (d) recommendation and experience of counsel; (e) future expenses and likely duration of litigation and risk; (f) recommendation of neutral parties, (g) if any; number of objectors and nature of objections; (h) the presence of good faith, arms-length bargaining and the absence of collusion; (i) the degree and nature of communications by counsel and the representative parties with class members during the litigation; and (i) information conveying to the court the dynamics of and the positions taken by the parties during the negotiation: *Dabbs v. Sun Life Assurance Company of Canada* (1998), 40 O.R. (3d) 429 (Gen. Div.) at 440-44, aff'd (1998), 41 O.R. (3d) 97 (C.A.), leave to appeal to S.C.C. refused Oct.

22, 1998, [1998] S.C.C.A. No. 372; *Parsons v. The Canadian Red Cross Society*, [1999] O.J. No. 3572 (S.C.J.) at paras. 71-72; *Frohlinger v. Nortel Networks Corp.*, [2007] O.J. No. 148 (S.C.J.) at para. 8; *Kelman v. Goodyear Tire and Rubber Co.*, [2005] O.J. No. 175 (S.C.J.) at paras. 12-13; *Vitapharm Canada Ltd. v. F. Hoffmann-La Roche Ltd.* (2005), 74 O.R. (3d) 758 (S.C.J.) at para. 117; *Sutherland v. Boots Pharmaceutical plc*, [2002] O.J. No. 1361 (S.C.J.) at para. 10.

29 In my opinion, the settlement in this case is fair, reasonable, and in the best interests of the Class Members.

G. Fee Approval

30 Mr. Sayers entered into a Class Action Retainer Agreement in August 2004. The Fee Agreement provides, among other things, that Gowlings will be paid 30% of any settlement recovered on behalf of the class.

31 Lawyers, students, and paralegals have docketed about 320 hours on the file since it was opened in March 2004. If billed at normal hourly rates, the current value of the accumulated fees, disbursements and taxes would be about $155,000.

32 The disbursements are currently $3,245.41 and applicable taxes are $9,707.70. The total disbursements will likely increase to cover the costs of a chartered accountant, David Gellman C.A., who will be retained by Gowlings to review all reassessment information provided by class members in support of their claims.

33 Under the terms of the settlement, assuming all funds are paid to class members, Gowlings will recover 30% of $337,800 ($137,800 + $200,000) or about $101,340 plus $50,000 for a total of $151,340 for fees, disbursements, and all applicable taxes to cover services rendered until all claims are processed and/or adjudicated.

34 The total settlement amount, taking into account all taxes, fees and disbursements incurred to date, and fees and disbursements anticipated to complete the settlement (including a chartered accountant), is less than the actual value of Gowlings' fees and disbursements to date without any fee or premium and would represent a substantial but not full, indemnity award.

35 The fairness and reasonableness of the fee awarded in respect of class proceedings is to be determined in light of the risk undertaken by the lawyer in conducting the litigation and the degree of success or result achieved: *Serwaczek v. Medical Engineering Corp.*, [1996] O.J. No. 3038 (Gen. Div.); *Parsons v. Canadian Red Cross Society* (2000), 49 O.R. (3d) 281 (S.C.J.); *Smith v. National Money Mart,* [2010] O.J. No. 873 (S.C.J.) at paras. 19-20.

36 Where the fee arrangements are a part of the settlement, the court must decide whether the fee arrangements are fair and reasonable, and this means that counsel are entitled to a fair fee which may include a premium for the risk undertaken and the result achieved, but the fees must not bring

about a settlement that is in the interests of the lawyers, but not in the best interests of the Class Members as a whole: *Smith v. National Money Mart, supra*, at para. 22.

37 Fair and reasonable compensation must be sufficient to provide a real economic incentive to lawyers to take on a class proceeding and to do it well: *Smith v. National Money Mart, supra*, at para. 23.

38 Factors relevant in assessing the reasonableness of the fees of Class Counsel include: (a) the factual and legal complexities of the matters dealt with; (b) the risk undertaken, including the risk that the matter might not be certified; (c) the degree of responsibility assumed by Class Counsel; (d) the monetary value of the matters in issue; (e) the importance of the matter to the Class; (f) the degree of skill and competence demonstrated by Class Counsel; (g) the results achieved; (h) the ability of the Class to pay; (i) the expectations of the Class as to the amount of the fees; (j) the opportunity cost to Class Counsel in the expenditure of time in pursuit of the litigation and settlement: *Smith v. National Money Mart, supra*, at paras. 19-20.

39 In my opinion, class counsel's fee should be approved. Gowling, LaFleuer Henderson LLP expended considerable time over a six-year period without any guarantee of payment. The case called for ingenuity and creativity in negotiating a settlement that would provide a payment for every class member and a potentially significant contribution toward the reassessed tax liability of others. While the recovery is only partial, it is doubtful any recovery at all would have been possible but for the lawyers' willingness to assist the class. If the lawyers were not paid a substantial portion of their actual time, there would be no incentive to take on this type of proceeding.

40 I approve the counsel fee. I believe that the lawyers have earned their fee. The fee is fair and reasonable compensation in all the circumstances.

H. Conclusion

41 For the above Reasons, I certify this action as a class proceeding, approve the settlement, and approve the counsel fee.

P.M. PERELL J.

cp/e/qllxr/qljzg/qlpxm/qljxr/qlced

Indexed as:

Gagne v. Silcorp Ltd.

Proceeding under the Class Proceedings Act, 1992
Between
Sherrie B. Gagne, (plaintiff), and
Silcorp Limited, (defendant)

[1998] O.J. No. 4182

41 O.R. (3d) 417

167 D.L.R. (4th) 325

113 O.A.C. 299

39 C.C.E.L. (2d) 253

27 C.P.C. (4th) 114

83 A.C.W.S. (3d) 125

Docket No. C28348

Ontario Court of Appeal
Toronto, Ontario

Charron, Rosenberg and Goudge JJ.A.

Heard: May 27, 1998.
Judgment: October 21, 1998.

(14 pp.)

Barrister and solicitor -- Compensation -- Agreements, contingent fees -- Review and approval -- Multiplier -- Calculation of -- Accounts -- Hourly rates -- Measure of compensation -- Relevant considerations -- Reasonable charges, reasonably performed -- Respecting successful services -- Class services.

Appeal by solicitors for the plaintiff in a class action, Gagne, from the dismissal of their motion for court approval to increase their base fee by a multiple of three. Gagne brought a class action for wrongful dismissal against the defendant, Silcorp. Pursuant to a written agreement, the lawyers took her class action on a contingency basis as permitted by the Class Proceedings Act. They agreed that the base fee would be the product of the hours worked by the lawyers and their usual hourly rates. Negotiations resulted in a fairly quick settlement. Mini hearings were held to resolve individual claims. The final total gross recovery was $1,945,723. The lawyers motion for court approval to increase their base fee by a multiple of three was denied, and they were allowed only their base fee. The motions judge found that there was no material risk in accepting the retainer and that the base fee was fair compensation for the lawyers' services in obtaining the degree of success they had. They appealed to the Ontario Court of Appeal.

HELD: Appeal allowed. A multiplier of two was to be applied to the base fee. This was fair and reasonable compensation as contemplated by the retainer, and it represented a multiplied fee that was much less than ten per cent of gross recovery. It provided a sufficient real incentive for solicitors in future similar cases. The motions judge erred by failing to give due weight to relevant risk and success considerations. Both the degree of risk assumed by the lawyers and the degree of success they achieved were relevant considerations. Here, while the risk of an adverse finding on liability was minimal, there was a material risk of non-certification. As well, there were significant elements of success in the way the solicitors conducted the proceedings. Weighed against these success factors was the fact that individual class members incurred further legal fees to finally realize on their claims after the settlement. Class members' views about whether the base fee should be increased were not to be considered.

Statutes, Regulations and Rules Cited:

Class Proceedings Act, 1992, S.O. 1992, c. 6, s. 33, 33(2), 33(7)(b).
Employment Standards Act, R.S.O. 1990, c. E-14.

Counsel:

Paul S.A. Lamek, Q.C., for the appellant solicitors.
McGowan & Associates and Jeff Burtt, advocate.

The judgment of the Court was delivered by

1 **GOUDGE J.A.**:-- The Class Proceedings Act, 1992, S.O. 1992, c. 6 (the "Act") permits a solicitor to take a class action on a contingency basis. If the action is successful the Act permits the solicitor to seek the court's approval to increase his or her base fee by applying a multiple to that

fee. This appeal concerns the appropriate considerations that should inform the court's decision on such a motion.

2 The appellants are solicitors who acted on behalf of the plaintiff Sherrie Gagne in a class action against the defendant Silcorp Limited. The action was concluded successfully and the appellants, having taken the case on a contingency basis, moved to increase their base fee by a multiple of three. Southey J. denied this request, allowing the solicitors only their base fee, namely the product of their usual hourly rates and their hours worked on the matter. This is an appeal from that disposition.

THE FACTUAL BACKGROUND

3 Beginning in late 1996, the defendant Silcorp proceeded to merge the operations of the Becker's and Mac's convenience store chains which it owned. As a consequence of the merger, a number of its employees were no longer needed and were dismissed. Initially Silcorp offered those terminated only an amount that was less than the minimum termination and severance pay to which they were entitled under the Employment Standards Act, R.S.O. 1990, c. E.14.

4 On March 24, 1997 the appellant solicitors commenced a class action for wrongful dismissal on behalf of those former employees who had been terminated. Sherrie Gagne was the representative plaintiff.

5 Immediately after commencing the action, the appellants brought a motion before Southey J. seeking an injunction to compel Silcorp to comply with the Employment Standards Act. This motion was adjourned from April 3, 1997 to April 17, 1997 on the undertaking of Silcorp to immediately comply with the requirements of that Act.

6 The parties then engaged in intensive negotiations which culminated in minutes of settlement dated April 14, 1997. On April 17, 1997, that settlement was approved by Southey J. as required by s. 29 of the Act. The settlement order was very complex but its essential elements were the following:

* The action was certified as a class proceeding for the purposes of the Act.
* Sherrie Gagne was appointed the representative plaintiff on behalf of the class of former employees who had been terminated by the defendant Silcorp.
* The appellant solicitors were appointed as counsel for the class.
* The defendant was adjudged liable for compensatory damages and Employment Standards Act entitlements.
* The claims for punitive and exemplary damages were dismissed.
* Pursuant to s. 25 of the Act, a reference was directed to determine the quantum of damages for each class member.
* The terms of the reference created a mini-hearing process with a mediation

stage and an arbitration stage.

* The class members were each permitted to be represented in the mini-hearing process by a personal lawyer rather than the appellant solicitors.

7 Between the date of the settlement and August 26, 1997, when the appellant solicitors prepared the material seeking to triple their base fee, thirty-five individual claims were finally resolved through the mini-hearing process. This court was further advised that by the time of this appeal, all sixty-five class members had resolved their individual claims for a total gross recovery of $1,945,723.

8 As required by the Act, the appellant solicitors executed a written agreement with the representative plaintiff respecting their fees and disbursements. It provided that the payment of any legal fees was contingent on the class action being concluded successfully as defined by the Act. It also provided that the base fee would be the product of the hours worked by the solicitors and their usual hourly rates. In addition, it set out that the solicitors could seek court approval for a multiplier to be applied to that base fee. Finally, the agreement described two examples of how this might work:

> 7. The Consortium and the Client acknowledge it is difficult to estimate what the expected fee will be. However, the following are estimates:
>
> (a) If the class action results in a quick settlement for the class, within 3 months after the date of this retainer, and at that time the Base Fee is $50,000 and if the court sets the Multiplier at 3.0, then the fee will be $50,000 x 3.0 = $150,000.
>
> (b) If the trial of the common issues occurs within 2 or 3 years and is decided in favour of the class and no appeals are taken, and at the time the Base Fee is $250,000 and if the court sets the Multiplier at 2.0, then the fee will be $250,000 x 2.0 = $500,000.
>
> These estimates do not include work for any mini-hearings or other proceedings which may be necessary to deal with individual damage claims.

9 The motion brought by the appellants sought a multiplier of 3. In denying this request Southey J. considered two factors, namely the degree of risk in accepting the retainer and the degree of success achieved by the solicitors. He set out his analysis of each of these factors clearly and concisely as follows:

> As to the first of the above elements, I am unable to see any reason why the employees who were dismissed would not be entitled to their "entitlements"

> under the Employment Standards Act and to compensatory damages, if any. It appears to me that there was no serious issue as to liability in this case. In these circumstances, I cannot find that there was any material risk in accepting the retainer.
>
> When I asked counsel for the Consortium to explain the risk, his reply was that the difficulty arose out of procedural complexity. In my judgment, that is not the sort of risk that should influence the multiplier. That sort of risk is adequately covered by an award of a Base Fee in the full amount of the usual charges made by the legal professionals, as I have approved in this case ...
>
> As to the second element, what has been achieved? Former employees now have available to them a procedure for the prompt determination of their claims. For Achieving that result, the solicitors, in my opinion, are fairly compensated for their services to August 8 last by the Base Fee of $109,411.28, including GST. Any premium based on a high degree of success must depend on the recovery in each case, which was not the subject of evidence before me.

10 The appellants argue that Southey J. erred in his consideration of both the risk factors and the success factors and, further, that he failed to give weight to the views of the class members who, it is argued, appear content with a significant multiplier. No one appeared in opposition to the appellants.

ANALYSIS

11 Central to a consideration of these arguments is s. 33 of the Act. It reads as follows:

> Agreements for payment only in the event of success
> 33.-(1) Despite the Solicitors Act and An Act Respecting Champerty, being chapter 327 of Revised Statutes of Ontario, 1897, a solicitor and a representative party may enter into a written agreement providing for payment of fees and disbursements only in the event of success in a class proceeding.
>
> Interpretation, success in a proceeding
> (2) For the purposes of subsection (1), success in a class proceeding includes,
> (a) a judgment on common issues in favour of some or all class members; and
> (b) a settlement that benefits one or more class

members.

Definitions
(3) For the purposes of subsections (4) to (7), "base fee" means the result of multiplying the total number of hours worked by an hourly rate; "multiplier" means a multiple to be applied to a base fee.

Agreements to increase fees by a multiplier
(4) An agreement under subsection (1) may permit the solicitor to make a motion to the court to have his or her fees increased by a multiplier.

Motion to increase fee by a multiplier
(5) A motion under subsection (4) shall be heard by a judge who has,
(a) given judgment on common issues in favour of some or all class members; or
(b) approved a settlement that benefits any class member.

Idem
(6) Where the judge referred to in subsection (5) is unavailable for any reason, the regional senior judge shall assign another judge of the court for the purpose.

Idem
(7) On the motion of a solicitor who has entered into an agreement under subsection (4), the court,
(a) shall determine the amount of the solicitor's base fee;
(b) may apply a multiplier to the base fee that results in fair and reasonable compensation to the solicitor for the risk incurred in undertaking and continuing the proceeding under an agreement for payment only in the event of success; and
(c) shall determine the amount of disbursements to which the solicitor is entitled, including interest calculated on the disbursements incurred, as totalled at the end of each six-month period following the date of the agreement.

> Idem
> (8) In making a determination under clause (7)(a), the court shall allow only a reasonable fee.
>
> Idem
> (9) In making a determination under (7)(b), the court may consider the manner in which the solicitor conducted the proceeding.

12 This section makes clear that the motion seeking to apply a multiplier to the base fee can be brought only after the class proceeding has been concluded successfully as defined in s. 33(2). Section 33(7)(b) gives the judge a discretion in determining whether to apply a multiplier or not. Hence, on appeal, while this court is not free to simply substitute its own exercise of discretion for that exercised at first instance, reversal of the order appealed from may be justified if the motions judge gave no weight or insufficient weight to considerations relevant to his decision. See Friends of the Old Man River Society v. Canada (Minister of Transport), [1992] 1 S.C.R. 3 at 76-77.

13 In applying this standard of review to the decision appealed from, it is appropriate to begin with a consideration of the genesis of the Class Proceedings Act, 1992. It was enacted following much legislative study and in the wake of a detailed report of the Ontario Law Reform Commission laying out the broad rationale for such legislation. One of the objects which the Act seeks to achieve is the efficient handling of potentially complex cases of mass wrongs. See Dabbs v. Sun Life Assurance Company of Canada, a judgment of the Ontario Court of Appeal, released September 14, 1998 at p. 3.

14 Another fundamental objective is to provide enhanced access to justice to those with claims that would not otherwise be brought because to do so as individual proceedings would be prohibitively uneconomic or inefficient. The provision of contingency fees where a multiplier is applied to the base fee is an important means to achieve this objective. The opportunity to achieve a multiple of the base fee if the class action succeeds gives the lawyer the necessary economic incentive to take the case in the first place and to do it well. However, if the Act is to fulfill its promise, that opportunity must not be a false hope.

15 With that background, I turn to the judgment appealed from. As I have said, Southey J. addressed two criteria in concluding that he would not apply a multiple to the base fee: the degree of risk assumed by the solicitors and the degree of success they achieve. In my view, he was correct in focusing on these two considerations. Section 33(7)(b) makes clear the relevance of "the risk incurred in undertaking and continuing the proceeding under an agreement for payment only in the event of success". Section 33(9) invites a consideration of the manner in which the solicitor conducted the proceedings. However, for the reasons that follow I have concluded that he erred in giving no weight to considerations relevant to each of the risk and success criteria.

Risk Factors

16 The multiplier is in part a reward to the solicitor for bearing the risks of acting in the litigation. The court must determine whether these risks were sufficient that together with the other relevant considerations a multiplier is warranted. While this determination is made after the class proceeding has concluded successfully, it is the risks when the litigation commenced and as it continued that must be assessed.

17 The only risk factor considered by Southey J. was whether the defendant might ultimately escape liability. Because there was no real doubt about that liability, he determined that there was no material risk in accepting the retainer.

18 Since this class proceeding was concluded quickly, the risk assessment was properly focussed on the risks incurred at the outset in undertaking the proceeding and did not have to extend to the risks, if any, in continuing it. Nonetheless, in my view there was from the beginning a second material risk that was a relevant consideration, namely the risk that comes with this action being brought as a class proceeding, particularly the risk of non-certification. The certification step in a class action is a significant one, often requiring extensive preparation by counsel. If certification is denied, a solicitor who has agreed to a fee contingent on success recovers nothing. Moreover, when this action was commenced, certification could not be predicted with certainty. A debate was quite possible about whether the common issues requirement would be met or whether a class proceeding was the preferable procedure given the enforcement mechanisms provided by the Employment Standards Act. This risk factor was material and ought to have been given weight.

19 It is true that this risk factor will be present in most class proceedings. This factor should be recognized so that solicitors faced with a class proceeding retainer will have the necessary economic incentive to take on the matter. They will know that if, in prosecuting the action, they can meet the success criterion there will be a real opportunity to have some multiple attached to the base fee. To accord due weight to this consideration is to serve the legislative objective of enhanced access to justice.

Success Factors

20 Section 33(9) invites the court, in determining whether a multiplier is appropriate, to consider the manner in which the solicitor conducted the proceeding. Just as the real opportunity to receive an enhanced reward for incurring the risks of the litigation serves as an incentive for the solicitor to take on the retainer, that opportunity is also designed to serve as an incentive for the solicitor to achieve the best possible results for the class, expeditiously and efficiently.

21 The only success factor considered by Southey J. was that a procedure had been provided to former employees for the prompt determination of their claims. This was insufficient, in his view, to warrant the application of any multiple to the base fee.

22 In my view, this fails to recognize that the solicitors achieved immediate, partial success in extracting a commitment from the defendant to comply forthwith with the Employment Standards

Act. Second, the ultimate settlement of the common issues was achieved quickly. Third, the settlement provided for a creative and effective mini-hearing process that resulted in the complete resolution of all individual claims within little more than a year. These factors are all relevant to the degree of success with which the solicitors conducted the proceedings and all deserved to be considered in determining whether a multiplier was appropriate.

Views of Class Members

23 In reaching his decision Southey J. did not consider the views of class members about whether a multiplier should properly be applied to the base fee. In my view, he was correct in doing so. The Act does not appear to invite such a consideration. Moreover, in this case those views, which are said to constitute acceptance or even approval of a multiplier, can be gleaned only by a very tenuous process of inference. One simply cannot say with any certainty that the views of class members on this issue are as they are argued to be.

24 In summary, therefore, I have concluded that Southey J. erred in the exercise of his discretion in failing to give due weight to relevant risk and success considerations. If appropriate weight is accorded them, I think the conclusion must be that this is an appropriate case to apply a multiplier to the base fee.

25 I recognize that the selection of the precise multiplier is an art, not a science. All the relevant factors must be weighed. Here, while the risk of an adverse finding on liability was minimal, there was a material risk of non-certification. As well, as I have outlined, there were significant elements of success in the manner in which the solicitors conducted the proceedings. Weighed against these success factors is the fact that following the April 17, 1997 settlement, individual class members had to incur further legal fees to finally realize on their claims.

26 In the end, these considerations must yield a multiplier that, in the words of section 33(7)(b), results in fair and reasonable compensation to the solicitors. One yardstick by which this can be tested is the percentage of gross recovery that would be represented by the multiplied base fee. If the base fee as multiplied constitutes an excessive proportion of the total recovery, the multiplier might well be too high. A second way of testing whether the ultimate compensation is fair and reasonable is to see whether the multiplier is appropriately placed in a range that might run from slightly greater than one to three or four in the most deserving case. Thirdly, regard can be had to the retainer agreement in determining what is fair and reasonable. Finally, fair and reasonable compensation must be sufficient to provide a real economic incentive to solicitors in the future to take on this sort of case and to do it well.

27 In this case, then, taking into account all the relevant considerations I have recited, in my view the appropriate multiplier is two. This reflects the risk and success factors at play. It represents a multiplied fee that is significantly less than ten per cent of gross recovery. It reflects the fact that this case does not exemplify the greatest risk or the greatest success. It is within the range contemplated by the retainer agreement. And finally, the resulting compensation should provide a

sufficient real incentive for solicitors in future similar cases.

DISPOSITION

28 I would therefore allow the appeal and provide for a multiplier of two to be applied to the base fee up to April 17, 1997, the date of the settlement order. I would vary the order below accordingly. The appellants do not seek costs of the appeal and I would order none.

GOUDGE J.A.
CHARRON J.A. -- I agree.
ROSENBERG J.A. -- I agree.

cp/d/ln/aaa/DRS

Indexed as:

Endean v. Canadian Red Cross Society

Between
Anita Endean, as representative plaintiff, plaintiff, and
The Canadian Red Cross Society, Her Majesty the Queen in Right of British Columbia, and the Attorney General of Canada, defendants, and
Prince George Regional Hospital, Dr. William Galliford, Dr. Robert Hart Dykes, Dr. Peter Houghton, Dr. John Doe, Her Majesty the Queen in Right of Canada, and Her Majesty the Queen in Right of the Province of British Columbia, third parties
(Vancouver Registry No. C965349)
And between
Christopher Forrest Mitchell, plaintiff, and
The Canadian Red Cross Society, the Attorney General of Canada, and Her Majesty the Queen in Right of the Province of British Columbia, defendants
(Vancouver Registry No. A981187)

[2000] B.C.J. No. 1254

2000 BCSC 971

[2000] 8 W.W.R. 294

78 B.C.L.R. (3d) 28

45 C.P.C. (4th) 39

97 A.C.W.S. (3d) 550

Vancouver Registry Nos. C965349 and A981187

British Columbia Supreme Court
Vancouver, British Columbia

K.J. Smith J.

Heard: December 8 - 10, 1999 and January 18 - 20, 2000.
Judgment: June 22, 2000.

(103 paras.)

Barristers and solicitors -- Compensation -- Agreements, contingent fees -- Review and approval -- Calculation of (incl. multiplier) -- Measure of compensation -- Class actions.

Application by lawyers in a class action for court approval of their fees. The lawyers represented British Columbia claimants in a national action against the Canadian Red Cross. The claimants formed two groups, the Endean group and the Mitchell group. The Endean group comprised British Columbia hemophiliacs who contracted hepatitis C because of Red Cross practices. The Mitchell group comprised others in the province who contracted the disease by transfusion. Nationally, lawyers reached a settlement totalling $1.6 billion, with legal costs to be paid out of the trust fund established to handle the award. The parties agreed that legal fees were not to exceed $52.5 million. All lawyers involved across Canada agreed to a global fee of $45 million for the Endean-type claimants and $7.5 million for the Mitchell-type. The Endean lawyers themselves sought $15 million plus disbursements and the Mitchell lawyers sought $500,000. The lawyers had engaged in extremely complex litigation as well as research into medical topics and public health care. One of the Endean lawyers was the first in the country to achieve certification of a class in the action, energizing the litigation nationally. He also served on a committee overseeing the structuring of the compensation. The Endean group's fee request amounted to a multiplier of 3.75. The multiplier for the Mitchell lawyers' request, on a somewhat more favourable result per claimant, was 5.5, although the Mitchell lawyers agreed that the bulk of the work on their case had been performed in Ontario.

HELD: Application allowed. Fees were approved as requested. Concerning the Endean group, counsel went far beyond the scope of services usually rendered by lawyers. They devoted a large percentage of their time to the case and turned down other retainers because of it. The litigation was highly complex and important, involving the largest settlement of a personal injury claim in Canadian history. Counsel were of high standing, acting for claimants who could not otherwise have paid for their services. They achieved excellent results against substantial risk of no recovery. Contingent fees were meant to reflect the risks involved, and British Columbia counsel sought reasonable fees commensurate with their participation in the result. Their requested fee represented only 4.26 per cent of the recovery. Many of the same considerations applied to the Mitchell group's counsel, whose requested fee represented only three percent of the result achieved for 11 per cent of the claimants nationally.

Statutes, Regulations and Rules Cited:

British Columbia Supreme Court Rules, Rule 8-4(2).

Class Proceedings Act, s. 38.

Class Proceedings Act, 1992, S.O. 1992, c. 6, s.33.

Companies' Creditors Arrangement Act, R.S.C. 1985, c. C-36.

Infants Act, R.S.B.C. 1996, c. 223.

Law Society of British Columbia Rules, Rule 8.

Legal Profession Act, S.B.C. 1998, c. 9, ss. 66(2), 68(2), 68(6).

Counsel:

J.J. Camp, Q.C., David P. Church, Sharon D. Matthews and Bruce W. Lemer, for the plaintiff, Anita Endean.
Marvin R.V. Storrow, Q.C., and David E. Gruber, for the plaintiff, Christopher Forrest Mitchell.
Gordon Turriff, D. Clifton Prowse and Keith Johnston, for the defendant/third party, Her Majesty the Queen in Right of the Province of British Columbia.
Gordon Turriff and John R. Haig, Q.C., for the defendant, the Attorney General of Canada and the third party, Her Majesty the Queen in Right of Canada.

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1 K.J. SMITH J.:-- This application raises the question of the proper approach to the compensating of plaintiffs' counsel in class actions brought in British Columbia.

I. INTRODUCTION

2 These are two of six parallel lawsuits commenced in British Columbia, Quebec, and Ontario on behalf of residents of Canada infected directly and secondarily with Hepatitis C virus ("HCV") by the Canadian blood supply between January 1, 1986, and July 1, 1990. The Endean action concerns those British Columbia residents whose claims result from transfusion and the Mitchell action deals with infected haemophilic residents of the province. The background of these actions is described in Endean v. Canadian Red Cross Society (1997), 148 D.L.R. (4th) 158, [1997] 10 W.W.R. 752, 36 B.C.L.R. (3d) 350, 37 C.C.L.T. (2d) 242, 11 C.P.C. (4th) 368, rev'd in part (1998), 157 D.L.R. (4th) 465, [1998] 9 W.W.R. 136, 106 B.C.A.C. 73, 48 B.C.L.R. (3d) 90, 42 C.C.L.T. 222 (C.A.), leave to appeal granted, [1998] S.C.C.A. No. 260 (S.C.C.) ("Endean No. 1"), wherein I certified the Endean action as a class proceeding pursuant to the Class Proceedings Act, R.S.B.C. 1996, c. 50.

3 A settlement was ultimately reached between the plaintiffs and the Federal, Provincial, and Territorial Governments (the "FPT Governments") in one pan-Canadian negotiation and was approved by orders granted in each of the British Columbia Supreme Court, the Ontario Superior Court of Justice, and the Quebec Superior Court. The terms of the settlement and the reasons for

approval are described in my decision in Endean v. Canadian Red Cross Society (1999), [2000] 1 W.W.R. 688, 68 B.C.L.R. (3d) 350, the decision of Winkler J. in Parsons v. Canadian Red Cross Society, [1999] O.J. No. 3572 (S.C.J.), and the decision of Morneau J. in Honhon c. Canada (Procureur général), [1999] J.Q. no 4370 (S.C.).

4 The settlement agreement requires the FPT Governments to pay monies into a trust fund to be invested and managed for the benefit of the class plaintiffs. Payment of fees to class counsel is provided for in clause 13.03 of the agreement as follows:

> The fees, disbursements, costs, GST and other applicable taxes of Class Action Counsel will be paid out of the Trust. Fees will be fixed by the Court in each Class Action on the basis of a lump sum, hourly rate, hourly rate increased by a multiplier or otherwise, but not on the basis of a percentage of the Settlement Amount.

Although it was not spelled out in the formal agreement, the parties agreed, as well, that the fees as approved by the courts shall not exceed $52,500,000 in total.

5 Counsel for the plaintiffs have agreed among themselves to seek approval of fees of $7,500,000 for those representing the haemophilic classes and $45,000,000 for those representing the transfused classes. Mr. Camp and Mr. Lemer, counsel for Ms. Endean and the class she represents, seek approval of a fee of $15,000,000 plus disbursements. From their fee, they will pay the fees of several other lawyers who acted for particular members of the British Columbia transfused class. Mr. Storrow, counsel for the plaintiffs in the Mitchell action, seeks approval of a fee of $500,000 plus disbursements. Each of the applicants has a contingent-fee contract with his representative plaintiff providing for payment of a lump-sum fee in the amount claimed and disbursements.

II. THE LAW

1. The Class Proceedings Act

6 The applications are brought pursuant to s. 38 of the Class Proceedings Act, which provides, in relevant part, as follows:

> 38. (1) An agreement respecting fees and disbursements between a solicitor and a representative plaintiff must be in writing and must
>
> (a) state the terms under which fees and disbursements are to be paid,
> (b) give an estimate of the expected fee, whether or not that fee is contingent on success in the class proceeding, and
> (c) state the method by which payment is to be made, whether by lump

sum or otherwise.

(2) An agreement respecting fees and disbursements between a solicitor and a representative plaintiff is not enforceable unless approved by the court, on the application of the solicitor.

. . .

(7) If an agreement is not approved by the court, the court may
(a) determine the amount owing to the solicitor in respect of fees and disbursements,
(b) direct an inquiry, assessment or accounting under the Rules of Court to determine the amount owing,
(c) direct that the amount owing be determined in any other manner, or
(d) make any other or further order it considers appropriate.

7 The agreements in question satisfy the requirements of s-s. 38(1). The issue is whether they should be approved pursuant to s-s. 38(2) and, if not, what disposition should be made pursuant to s-s. 38(7).

8 The Class Proceedings Act provides no guidance as to how the court should approach the approval. Accordingly, the statutory and common law of general application in respect of solicitors' fees must apply. I will return to this aspect of the discussion after considering the approach proposed by Mr. Turriff on behalf of the FPT Governments.

2. The approach proposed by the FPT Governments

9 I preface these comments by observing that I requested the assistance on this application of counsel for the FPT Governments. In my view, they are in a uniquely advantageous position to comment on the litigation risks run by plaintiffs' counsel and on the value of the contributions made by them to the ultimate settlement, which are the two issues upon which Mr. Turriff focussed his submissions. However, Mr. Turriff did not put before me any evidence of the opinions or observations of Messrs. Whitehall, Haig, or Prowse, who carried these actions for the FPT Governments and negotiated the settlement with plaintiffs' counsel. That is unfortunate, as I remain of the view that their opinions would have been helpful.

10 Mr. Turriff suggested a method of assessing lawyers' fees based on an approach that has been used in Ontario and in the United States, known in those jurisdictions respectively as the "base-fee/multiplier" approach and the "lodestar/multiplier" approach. In Mr. Turriff's submission, this method is grounded in economic theory and is a rational and scientific approach to the assessment of lawyers' fees. He contrasted this with the traditional approach in British Columbia, which he characterized as based on "intuition and impression."

11 As the multiplier method has a history in Ontario and in the United States, I will first consider

the situation in those jurisdictions.

12 The Ontario Class Proceedings Act, 1992, S.O. 1992, c. 6, provides, in s-s. 33(1), that lawyers for a representative plaintiff may enter into fee agreements providing for payment of fees only in the event of success. Sub-sections 33(3) to (8) provide for the multiplier approach advocated by Mr. Turriff. "Base fee" is defined in s-s. (3) as the product of the total number of hours worked by the solicitor and an hourly rate, and "multiplier" is defined as a multiple to be applied to the base fee. Sub-sections (4) through (8) enact that the solicitor may apply to have his or her fees increased by a multiplier and that, on such an application, the court must determine a "reasonable" base fee and may then apply a multiplier that "results in fair and reasonable compensation to the solicitor for the risk incurred in undertaking and continuing the proceeding."

13 However, contingent fees derived other than from a base fee/multiplier are not prohibited in class actions in Ontario: see Nantais v. Telectronics Proprietary (Canada) Ltd. (1996), 28 O.R. (3d) 523 (Gen. Div.) and Crown Bay Hotel Ltd. Partnership v. Zurich Indemnity Co. of Canada (1998), 40 O.R. (3d) 83 (Gen. Div.). In the latter decision, Winkler J. approved a percentage contingent fee and observed, at p. 88, that percentage contingent fees may be desirable to promote the policy objective of judicial economy in that they encourage efficiency in the litigation and discourage unnecessary work that might otherwise be done by the lawyer simply in order to increase the base fee.

14 Mr. Justice Winkler's observation has support in the American experience, which is discussed in the decision of the United States Court of Appeals, District of Columbia Circuit, in Swedish Hosp. Corp. v. Shalala, 1 F.3d 1261 (D.C. Cir. 1993). In that case, the Court observed, at pp. 1265-66, that the percentage-of-the-fund method of calculating fees was the most common approach in the United States until 1973. The rationale underlying this method is that plaintiffs' attorneys who create a common fund for a class of individuals should be paid a reasonable fee from the fund as a whole in order to avoid the unjust enrichment of class members who would not otherwise contribute to the legal costs [p. 1265].

15 The Court recounted that, in Lindy Brothers Builders, Inc. v. American Radiator & Standard Sanitary Corp., 487 F.2d 161 (3d Cir. 1973), the Third Circuit introduced the "lodestar/multiplier" approach in reaction to a perception that percentage fees sometimes resulted in large fee awards. The lodestar, like the base fee in Ontario, is the product of the hours reasonably spent and a reasonable hourly rate. Under this approach, the lodestar is to be adjusted upward or downward by a multiplier to reflect such factors as the contingency nature of the case and the quality of the lawyers' work.

16 The Court went on to explain, at p. 1266, that the lodestar approach gained predominance in the United States until the Third Circuit appointed a task force to compare the respective merits of the two approaches. The task-force report described the lodestar method as a "cumbersome, enervating, and often surrealistic process of preparing and evaluating fee petitions that now plagues

the Bench and Bar." The report enumerated several criticisms of the lodestar approach, which are summarized at pp. 1266-67 as follows:

> 1) it "increases the workload of an already overtaxed judicial system"; 2) the elements of the process "are insufficiently objective and produce results that are far from homogeneous"; 3) the process "creates a sense of mathematical precision that is unwarranted in terms of the realities of the practice of law"; 4) the process "is subject to manipulation by judges who prefer to calibrate fees in terms of percentages of the settlement fund or the amounts recovered by the plaintiffs or of an overall dollar amount"; 5) the process, although designed to curb abuses, has led to other abuses, such as "encouraging lawyers to expend excessive hours engag[ing] in duplicative and unjustified work, inflat[ing] their 'normal' billing rate[s], and includ[ing] fictitious hours"; 6) it "creates a disincentive for the early settlement of cases"; 7) it "does not provide the district court with enough flexibility to reward or deter lawyers so that desirable objectives, such as early settlement, will be fostered"; 8) the process "works to the particular disadvantage of the public interest bar" because, for example, the "lodestar" is set lower in civil rights cases than in securities and antitrust cases; and 9) despite the apparent simplicity of the lodestar approach, "considerable confusion and lack of predictability remain in its administration."

17 The task force concluded, as is set out at p. 1267, that the lodestar approach should be retained in "statutory fee" cases but that the percentage fee was the best approach for "common fund" cases. This distinction is significant for the present analysis, and is explained in In Re Prudential Ins. Co. of America Sales Litigation, 148 F.3d 283 (3d Cir. 1998) at p. 333:

> ... The percentage-of-recovery method is generally favored in cases involving a common fund, and is designed to allow courts to award fees from the fund "in a manner that rewards counsel for success and penalizes it for failure." ... The lodestar method is more commonly applied in statutory fee-shifting cases, and is designed to reward counsel for undertaking socially beneficial litigation in cases where the expected relief has a small enough monetary value that a percentage-of-recovery method would provide inadequate compensation.... It may also be applied in cases where the nature of the recovery does not allow the determination of the settlement's value necessary for application of the percentage-of-recovery method....

Clearly, the actions presently under consideration are analogous to the common fund cases in the American jurisprudence.

18 Class actions are new to British Columbia: the Class Proceedings Act was enacted in 1995 and the Ontario Class Proceedings Act, 1992, from which it drew heavily, was enacted in 1992. In M.

Eiezenga, M. Peerless, and C. Wright, Class Actions Law and Practice (Markham: Butterworths, 1999) at s. 1.12, p. 1.4, the authors noted that class actions for damages first became available in the United States in 1938 and observed:

> The American experience is thus more mature than its newer Canadian counterpart and was available as relevant background for Canadian legislators to draw upon.

Accordingly, there is much to be learned from the long experience of American courts with the methods of compensating successful class counsel, and the cases that I have just mentioned provide a valuable context in which to view the issue presently up for decision.

19 I reject Mr. Turriff's submission that the base-fee/multiplier approach should be imported into British Columbia as the method of assessing the fees of plaintiffs' class counsel pursuant to s. 38 of the Class Proceedings Act. The deficiencies in this methodology were identified by the Third Circuit task-force report, supra, and its introduction into our jurisprudence is undesirable and unnecessary. Its role should be confined to serving in appropriate circumstances as a tool for testing the court's initial assessment.

20 One of the disadvantages inherent in the multiplier approach is exemplified in this case, where Mr. Turriff applied for an order compelling production for his inspection of all plaintiffs' files and plaintiffs' counsels' billing records in the transfusion action and for leave to cross-examine Mr. Camp on his affidavit. I reserved judgment on the application to cross-examine Mr. Camp, and I will come to that shortly. I dismissed the application for production of records because it would have constituted an unwarranted invasion by the defendants of the plaintiffs' solicitor-client privilege and, as well, because it was unnecessary.

21 I reiterate the opinion that I expressed in that oral ruling that the review of fees pursuant to s. 38 of the Class Proceedings Act is similar to the review of fees in an infant settlement conducted pursuant to the Infants Act, R.S.B.C. 1996, c. 223, and that the approach should therefore be similar. I referred to Harrington (Guardian ad litem of) v. Royal Inland Hospital (1995), 131 D.L.R. (4th) 15, 69 B.C.A.C. 1, 14 B.C.L.R. (3d) 201, 45 C.P.C. (3d) 105 (C.A.) and, in particular to the remarks of Finch J.A. at para. 253 to the effect that, except in unusual cases, it is not necessary to examine the lawyers' files and accounting records. In that case, the solicitor obtained approval of his fee from a judge of this Court after another judge had adjourned his initial application and requested further submissions. When this anomaly came to light, the second judge revoked her approval and the first judge embarked on an examination of the solicitors' files from which he concluded that the solicitor had grossly exaggerated the amount of time that he had claimed to have spent on the matter.

22 There has been no suggestion of any conduct of that sort here, and I remain of the opinion that the type of discovery sought by Mr. Turriff is not appropriate in this context. The course that Mr. Turriff was set upon would have resulted in a separate, lengthy, and complex proceeding to assess

the reasonableness of the proposed fees and would set a precedent that is neither necessary nor contemplated by s. 38 of the Act.

23 As well, I give no weight to the evidence of the economist, Mr. Ross, which was offered by Mr. Turriff as expert opinion on, as Mr. Ross described it in his written report:

> ... the appropriate framework for determining the amount, if any, that should be added to what would otherwise be a reasonable market value fee for professional legal services provided by plaintiffs' counsel to ensure an economic incentive for competent lawyers to take on class action contingency work that should be taken forward.

24 Mr. Ross advocated formulae for the mathematical calculation of fees. They involved, at the first stage, an "earnings equivalent multiplier" to be used to calculate the base fee using "judgmental probability", that is, the probability that the action will succeed. At the second stage, a "risk aversion multiplier" was offered to measure such things as the particular lawyer's risk of erratic long-term income resulting from a series of unsuccessful contingency cases. The proper fee in any given case, according to Mr. Ross, is the result produced by the following formula:

> REASONABLE FEE = Reasonable hours worked X reasonable hourly rates X (earnings equivalent multiplier X risk aversion multiplier)

where the multipliers change as the risks change from time to time throughout the retainer.

25 The chance of success in a given lawsuit and the risks to be run by an individual lawyer in taking it involve a myriad of objective factors and many quintessentially subjective considerations. These chances and risks are incapable of scientific calculation. The proposal advanced by Mr. Ross gives the impression of mathematical precision but, at its heart, is no less arbitrary and subjective than the approach conventionally followed by the courts of this province. The economic opinion evidence is, therefore, not helpful.

26 As I understand Mr. Turriff's submission, his application to cross-examine Mr. Camp on his affidavit is not based on the usual ground that Mr. Camp's assertions of fact were put in issue by contrary evidence from Mr. Turriff's clients. There was no such evidence. Rather, he wished to investigate Mr. Camp's actions and state of mind at various times throughout his retainer for the purpose of establishing a factual basis for the application of the formula offered by Mr. Ross. As I have rejected the formula, there is no need for the cross-examination. Moreover, any attempt to quantify changes in litigation risk as events transpired would likely be futile and would consume an unwarranted amount of time. Accordingly, the application to cross-examine Mr. Camp is dismissed.

27 Mr. Turriff's submissions on the effects of changing risks deserve comment. He identified a number of events that he characterized as "risk-reducing." All of them, but one, related to the evolving settlement agreement. It is true that the parties were moved along the path to settlement by

such things as the publication in November 1997 of the Final Report of the Commission of Inquiry on the Blood System in Canada (the "Krever report") and the announcement in March 1998 by the FPT Governments of the availability of $1,100,000,000 to settle these actions. However, I cannot accept that these events reduced the risk of failure of the negotiations in any real or measurable way. The risk of failure continued to hinge on a multitude of factors any one of which could have aborted the negotiations, a danger that continued even after the settlement had received court approval.

28 The other "risk-reducing" factor identified by Mr. Turriff was the certification of the Endean action. However, it would be wrong to treat counsel's success on this application as justification for reducing the contingent fee on the theory that the skill and effort of counsel have made a successful result more probable. At the outset of the retainer, counsel and clients knew that the enterprise would fail if certification were denied. The chance of success or failure at this stage was therefore a factor in the percentage fee initially agreed upon and, as well, by reason of the settlement agreement, in the lump sum fee that was later substituted for it. It would be wrong to use hindsight to give different weight to that risk than the lawyers and clients gave to it at the outset.

2. The proper approach to assessing reasonableness

29 Mr. Turriff began his submission with the proposition that the courts of Quebec, Ontario, and British Columbia must consider and weigh the evidence presented in all jurisdictions in order to ensure "that no lawyer in any of the three jurisdictions becomes entitled to a fee which does not accurately reflect his or her relative contribution towards the pan-Canadian settlement agreement." In his submission, there is a possibility for conflicting judgments in this respect that, he contends, would impair the integrity of all three awards and would undermine the legitimacy of all three courts.

30 I agree that gross inconsistency between the fee awards in the three provinces should be avoided if possible. On the other hand, it cannot be forgotten that each province has its own laws and traditions in respect of solicitors' fees. I must act on the evidence presented in this Court and I must apply the laws of British Columbia to arrive at my decision. However, in doing so, I must have appropriate regard to the national context in which the legal actions have been resolved.

31 Section 66 of the Legal Profession Act, S.B.C. 1998, c. 9 governs contingent fee agreements. Sub-section 66(2) provides that the benchers may make rules respecting contingent fee agreements, including rules regulating the limits to lawyers' charges. By s-s. 68(2), the client has the right to have the registrar examine a fee agreement and, by s-s. 68(6), the registrar is empowered to modify or cancel the agreement if it is found to be unfair or unreasonable "under the circumstances existing at the time the agreement was entered into."

32 Part 8 of the Law Society Rules, entitled "Lawyers' Fees", sets up a standard of fairness and reasonableness. The relevant provisions say:

> 8-1 (1) A lawyer who enters into a contingent fee agreement with a client must ensure that, under the circumstances existing at the time the agreement is entered into,
>
> (a) the agreement is fair, and
> (b) the lawyer's remuneration provided for in the agreement is reasonable.
>
> (2) A lawyer who prepares a bill for fees earned under a contingent fee agreement must ensure that the total fee payable by the client
>
> (a) does not exceed the remuneration provided for in the agreement, and
> (b) is reasonable under the circumstances existing at the time the bill is prepared.

33 In addition to the statute law, the court has inherent jurisdiction to review the reasonableness of solicitors' fees arising out of contingent fee agreements and, as well, inherent parens patriae jurisdiction to ensure the reasonableness of legal fees incurred on behalf of class members who are under legal disability: see Harrington (Guardian ad litem of) v. Royal Inland Hospital, supra at p. 264, para. 192 and pp. 266-67, paras. 197-99.

34 The meanings of the words "fair" and "reasonable" were considered in Commonwealth Investors Syndicate Ltd. v. Laxton (1990), 50 B.C.L.R. (2d) 186 (C.A.) ("Commonwealth No. 1"). There, the Court was considering a predecessor of s. 66 of the Legal Profession Act, namely, s. 99 of the Barristers and Solicitors Act, R.S.B.C. 1979, c. 26, which, for present purposes, did not differ in any material way. At pp. 198-99 of Commonwealth No. 1, the Court set out a two-step inquiry:

> The first step investigates the mode of obtaining the contract and whether the client understood and appreciated its contents. . . .
>
> The second inquiry, assuming the contract is found to be "fair" involves an investigation of the "reasonableness" of the contract. On this investigation, extending from the time of the making of the contract until its termination or its completion, all of the ordinary factors which are involved in the determination of the amount a lawyer may charge a client are to be considered . . . .

Thus, "reasonableness" relates to the amount of the fee.

35 In a second appeal in the Commonwealth case, reported as Commonwealth Investors Syndicate Ltd. v. Laxton (1994), 94 B.C.L.R. (2d) 177 (C.A.), app. for leave to appeal dis'd, [1994] S.C.C.A. No. 427, March 30, 1995 ("Commonwealth No. 2"), the Court dealt with the meaning of

"reasonableness". McEachern C.J.B.C., speaking for the Court, referred to the oft-cited decision in Yule v. Saskatoon (1955), 1 D.L.R. (2d) 540 (Sask. C.A.) and to the factors set out therein, namely: the extent and character of the services rendered; the labour, time and trouble involved; the character and importance of the litigation; the amount of money and the value of the property involved; the professional skill and experience called for; the character and standing of counsel in the profession; the results achieved; and, to some extent at least, the ability of the client to pay. He observed, at pp. 183-84, para. 25, that further considerations apply in respect of contingent fees including, at least, the risk of no recovery at all and the expectation of a larger fee based upon the result than would be warranted in non-contingency cases.

36 However, the assessment is not produced by simply summing the results of the considerations of each factor. McEachern C.J.B.C. made that clear at p. 187, para. 47, where he said:

> All the circumstances must be considered, including the Yule factors, the risks and expectations, and the terms of the bargain which is the subject matter of the inquiry. With all this in mind, the court must then ask, as a matter of judgment, whether the fee fixed by the agreement is reasonable and maintains the integrity of the profession?

37 Mr. Laxton's contingent fee agreement in the Commonwealth cases related to a conventional lawsuit, not to a class action. In my view, the approval of counsels' fees in class actions involves additional considerations that are not present in the ordinary case.

38 First, the rationale for using percentage fees in "common fund" cases in the United States is relevant. Class actions differ from conventional actions in that the beneficiaries of the action do not participate actively in it, leaving the instruction of counsel to the representative plaintiff. As was observed in Swedish Hosp. Corp. v. Shalala, supra at p. 1265, fees in these cases must be shared by the beneficiaries of the fund in order to avoid their unjust enrichment. American courts have recognized that this approach shifts the emphasis from the fair value of the time expended by counsel, or what we would refer to as a quantum meruit fee, to a fair percentage of the recovery: see Swedish Hosp. Corp. v. Shalala, supra at p. 1266.

39 In my opinion, the equitable sharing of fees by the recipients of the award or settlement is a proper consideration in assessing the reasonableness of lawyers' fees in class actions. What is a fair fee for the work done by the lawyer is important, but equally important is that each member of the class should share in payment of a fair fee for the result achieved, as viewed from his or her perspective. This notion has been recognized as a proper consideration in the approval of class counsel fees in British Columbia. In Harrington v. Dow Corning Corp. (1999), 64 B.C.L.R. (3d) 332 (S.C.), at para. 18, E.R.A. Edwards J. observed that the factors that ought to be considered include "the individual claimants' contribution to the fee as a portion of their recoveries." This passage was applied by Brenner J. (as he then was) in Sawatzky v. Soci t Chirurgicale Instrumentarium Inc. (8 September 1999), Vancouver C954740 (B.C.S.C.) at para. 8 and by

Williamson J. in Fischer v. Delgratia Mining Corporation, [1999] B.C.J. No. 3149, (7 December 1999), Vancouver C974521 (B.C.S.C.) at para. 22. Accordingly, the proportion that the proposed fee bears to the recovery is prominent in the analysis.

40 A second consideration arises from the unique nature of class proceedings. In a conventional action, the causal relationship between the lawyers' work and the result achieved is normally unquestioned. That is not necessarily so in class actions where the extent of the benefit brought about by the lawyer's work must be ascertained. This concept is illustrated in In Re Prudential Ins. Co. of America Sales Litigation, supra, where a class action was brought on behalf of millions of policyholders alleging deceptive sales practices by a life insurer. The Court held that class counsel should not be given full credit for the result when it was based, in part, on a compensation scheme implemented as a result of an investigation by the New Jersey Insurance Commissioner, who recommended a remediation plan to compensate affected policyholders, to prevent future violations, and to restore public confidence in the insurance industry. In remarks that are apposite here, the Court said, at p. 337:

> While a party need not be the only catalyst in order to be considered a "material factor" and may be credited for extra-judicial benefits created, there must still be a sound basis that the party was more than an initial impetus behind the creation of the benefit. Allowing private counsel to receive fees based on the benefits created by public agencies would undermine the equitable principles which underlie the concept of the common fund, and would create an incentive for plaintiffs attorneys to "minimize the costs of failure . . . by free riding on the monitoring efforts of others."

41 As I have already remarked, the American experience with class actions is instructive. I adopt that reasoning and conclude that it is necessary, in considering the reasonableness of the fee in relation to the results achieved, to consider the causal relationship between the efforts of class counsel and the benefits conferred on the class claimants by the resulting recovery.

42 I turn now to a consideration of the fees proposed in these actions.

III. ANALYSIS AND CONCLUSIONS

1. Fees in the transfused class action

43 While an examination of the factors identified as relevant to the inquiry is necessary and will be useful, it ought not to overwhelm the recognition of the "judgment, audacity and legal skill" of counsel, to adopt a descriptive phrase used by McEachern C.J.B.C. in Commonwealth No. 2, supra at p. 187, para. 46. In my view, Mr. Camp is one of only a few lawyers in this province with the combination of legal talent, experience, and boldness necessary to have achieved this outcome.

(a) The extent and character of the services rendered

44 The scope of the services rendered by counsel in this case extended far beyond what is normally encountered in the practice of law. Mr. Camp and Mr. Lemer had to deal with difficult legal issues pertaining to product liability, professional negligence, and public policy in the context of public blood-banking and infectious diseases. As well, they had to become familiar with the epidemiology and natural history of HCV, a disease about which little was known at the outset and about which medical opinion was evolving throughout the course of their retainer. Further, they had to learn and to understand the workings of the public health care system in Canada and the interplay between federal, provincial, and territorial governments in the administration of these matters. The medical and political issues were overarching and were, to a large extent, out of their control. They had to react to these things and to accommodate their approach as matters evolved. Throughout, they were faced with disagreements between groups of infected persons and with the changing political winds as these issues were debated in the public media and as governments and government officials changed. At the same time, they had to deal with the many class members who were understandably pressing them for a resolution of the matter. In short, the gravity and difficulty of the task they faced was of the highest order.

(b) The labour, time and trouble involved

45 It is necessary at this point to consider the duration of the retainer of class counsel.

46 The effective approval date for the settlement was January 22, 2000. Since that time, however, Mr. Camp and Ms. Matthews have expended considerable time, along with counsel in the other jurisdictions, in getting the settlement plan up and running to the point where benefits could be paid to class members. Much of that time was necessitated by the removal and replacement of the initial plan Administrator and, as well, considerable time was invested in preparing the many documents required for the processing of claims.

47 The issue arises because the terms of the settlement provide for the creation of a Joint Committee, comprised of three class counsel from the transfused class actions and one class counsel from the haemophilic class actions. The terms of the settlement invest the Joint Committee with the overall supervision of the administration of the plan, including the recommending of persons for appointment by the courts as plan Administrator and the preparation of all necessary protocols. The fees of the members of the Joint Committee are to be submitted to the courts for approval from time to time throughout the life of the plan.

48 Mr. Camp is a member of the Joint Committee and, as I understand it, Mr. Turriff's position is that the time expended by Mr. Camp and Ms. Matthews since January 22, 2000, should be billed as Joint Committee fees and should not be taken into consideration on the approval of class counsel fees.

49 I cannot agree. Class counsel were retained to recover money for the class plaintiffs on

account of their claims, and the work of counsel under their retainer agreements is not finished until that has happened. I understand that payments to class plaintiffs have begun this month. Accordingly, now is the appropriate time to measure the reasonableness of the proposed fees. It should be noted that Mr. Camp does not take the position that he should be entitled to charge for this work as Joint Committee work in addition to his fee as class counsel. Quite properly, in my view, he asks that his work to date be considered in relation to the reasonableness of his contingent fee.

50 A second preliminary issue concerns the relevance of the time and effort expended by counsel in preparing for and conducting the hearing of the application to approve class counsel fees. Mr. Turriff's position is that this time was not spent for the benefit of class plaintiffs and is therefore not relevant to the reasonableness of the proposed fee. However, s. 38 of the Class Proceedings Act requires class counsel to seek court approval of their fees. This requirement is an integral part of the statutory scheme for class actions. Moreover, it is a term of each of the fee agreements in issue that the agreed fee will be subject to court approval. Accordingly, the obtaining of court approval of their fees is part of the work plaintiffs' counsel were required to do and the time spent by them in doing so must be considered in the assessment of the reasonableness of their fees.

51 In addition to their efforts in relation to the lawsuit and to the settlement, members of Mr. Camp's firm have spent a great deal of time over the past four years dealing with the questions and concerns of class claimants. As well, much time was devoted to meeting with HCV support groups across the country and with the media. As of June 12, 2000, Mr. Camp's firm has docketed approximately $3,200,000 in work in progress on this file. Mr. Camp and Ms. Matthews have devoted the majority of their time to this action since it was commenced and, as a result, they have declined many other retainers. For his part, Mr. Lemer has recorded more than $500,000 in time on this file since its inception and has spent a large proportion of his professional time on it at the expense of turning down remunerative work.

(c) The character and importance of the litigation

52 The character of the litigation and its importance to the plaintiffs bear mentioning. As a class action, this action involved many procedural and practical difficulties not encountered in conventional litigation. As well, it was a highly complex product liability/medical negligence case attendant with great risk. The members of the plaintiff class are infected with a debilitating disease that will, in many cases, lead to a protracted and uncomfortable death. The events that precipitated this lawsuit constituted a national public-health disaster. This case was therefore of immense importance to the class plaintiffs and was important, as well, to the Canadian public for the light that it shed on the problems that gave rise to this national tragedy.

(d) The amount of money involved

53 The total value of the settlement, in present-value terms, is in the order of $1,600,000,000. So far as I am aware, this is the largest settlement of a tort claim for damages for personal injuries in

Canadian history.

(e) The professional skills and experience called for

54 Mr. Turriff conceded that the work done by plaintiffs' counsel required a high level of skill; that it was complex, difficult, and well-done; and that the result achieved was excellent. These points cannot be understated. To handle all of these matters and to persevere through to the settlement ultimately achieved involved a quality of representation by counsel that is uncommon. As was observed by McEachern C.J.B.C. in Commonwealth No. 2, supra at p. 185, para. 36:

> ... Because of the breadth of their experience, and their special adversarial skills ... senior counsel are quick learners who master the details, understand the issues, conceptualize the difficulties, and figure out how to achieve the desired result. The problems faced by Mr. Laxton were complex and formidable.

Those remarks aptly describe Mr. Camp and the difficulties he faced. This view is shared by Jack Giles, Q.C., a highly-regarded barrister of some forty years experience. In his opinion letter, which was filed in evidence, he said that the result was:

> ... a truly remarkable achievement. It was obtained in the face of daunting obstacles and grave risks. It called for a high degree of experience, skill, courage and determination.

(e) The character and standing of counsel

55 Mr. Giles commented, as well, that Mr. Camp was uniquely fitted by his experience and standing for the role of lead counsel in this matter. The evidence supports that view. Moreover, Mr. Lemer has a wealth of experience in blood-related litigation and made good use of his knowledge and experience and, as well, of his relationships with experts in the related fields and with counsel of similar interests.

(f) The ability of the clients to pay

56 The class plaintiffs began with doubtful claims and it is highly unlikely that any of them could have afforded to pay for individual legal representation in this case. Certainly, Ms. Endean could not have done so. The cost of lawyers and experts, and the potential costs payable to the defendants in the event of failure, were simply prohibitive. These actions were able to go forward only because they were carried by counsel pursuant to contingent fee agreements.

(g) The results achieved

57 The class members will recover full and generous benefits as a result of the settlement and they will do so through a simple, administrative procedure without the necessity of engaging

lawyers. Moreover, their costs of claiming compensation are to be covered by the settlement fund. The results achieved can only be described as excellent.

(h) The Risk of No Recovery

58 The risk of no recovery at all was substantial.

59 A demonstration of that proposition is the fact that the other two law firms consulted by the prospective class plaintiffs were unwilling to take the case on a pure contingency. One was prepared to take it only if paid hourly rates, with the plaintiffs to pay disbursements, and the other, although prepared to act for a contingent fee, insisted that the plaintiffs pay the disbursements. Of the three candidates for the action, only Messrs. Camp and Lemer were willing to undertake the action on a contingent fee at no cost to the plaintiffs.

60 The plaintiffs' best chance of establishing liability was against the Canadian Red Cross, but those hopes were dashed when this action was stayed against that organization and it was granted protection from its creditors pursuant to the Companies' Creditors Arrangement Act, R.S.C. 1985, c. C-36, leaving minimal assets available for satisfaction of any judgment. As well, the stay impeded the ability of counsel for the plaintiffs to obtain important evidence from the Canadian Red Cross through pre-trial discovery. On the other hand, the risk of failure on liability against the FPT Governments was real and significant.

61 It was not only the risk of failure in the lawsuit that counsel had to contend with. There were also political risks. The danger existed throughout that the FPT Governments might establish a no-fault compensation scheme that would undermine these actions. This risk was heightened when the Krever Commission recommended in November 1997 that a no-fault compensation scheme be implemented by government for all those infected with HCV. Had that happened, these actions would have been for naught and plaintiffs' class counsel would have had to absorb the considerable costs they had incurred in carrying them.

62 There was also a significant risk that the settlement negotiations might fail. This was a matter of grave concern because the prospects of achieving comparable recovery through a trial were poor. Throughout the negotiations, counsel were frequently faced with potentially deal-breaking issues. As well, there were disputes between the class plaintiffs and other groups of infected persons that threatened to thwart a comprehensive settlement. There was, further, the risk that the courts would not approve the settlement. After that obstacle was overcome, the risk of the settlement negotiations aborting continued because of the modifications suggested by the courts. The FPT Governments initially took the position that these modifications were material, which would have allowed them to withdraw from the settlement, and it was only through further arduous bargaining that they were persuaded to accept the changes.

63 Accordingly, the risk of no recovery was a substantial and omnipresent risk that did not diminish over the course of the retainer but continued until the FPT Governments finally accepted

the court-suggested modifications to the settlement agreement.

64 Moreover, the consequences of failure to Mr. Camp and Mr. Lemer would have been devastating. Mr. Camp correctly described this enterprise during his submission as "bet-your-firm-litigation."

(i) The expectation of a larger fee than in a non-contingency case

65 It is the nature of contingent fees that counsel and client expect that the fee, if success is achieved, will exceed what would otherwise be appropriate for the work done. Counsel shoulder the risk of failure in these cases and they and their clients legitimately expect that they will recover an enhanced fee for doing so. The evidence of Ms. Endean on this application bears this out.

(j) The contribution of counsel to the result

66 I do not think that it can be said that counsel are seeking to take advantage of any "extra-judicial" benefit to the class plaintiffs, as was the case in In Re Prudential Ins. Co. of America Sales Litigation, supra. The first indication of a willingness by the FPT Governments to pay compensation was on March 27, 1998, after the transfused class actions in British Columbia and Quebec had been certified on behalf of residents of those provinces and after the action on behalf of all other class members resident in Canada had been commenced in Ontario. Moreover, the announcement of the available $1,100,000,000 limited the potential recipients to the claimants in the class actions. In my view, the pre-eminent cause of the recovery in the context of this discussion was the effort of class counsel, and it would not be proper to give them less than full credit for the result.

67 As already noted, Mr. Turriff argued that I must measure the relative contribution of class counsel in each province to the pan-Canadian settlement so that there will be no chance of counsel in one province being credited in fees for value contributed by counsel in other provinces. However, it is impossible in hindsight to unravel the many factors that influenced the ultimate outcome in this case. The efforts of counsel in the other provinces undoubtedly played a large role. As well, the voices of lobby groups and others heard through the media likely entered into the deliberations of the FPT Governments. It is not necessary to identify the discrete causal contributions and to measure their respective force. It is sufficient to ascertain whether the efforts of Mr. Camp and Mr. Lemer were a material cause of the result achieved to the extent that they should receive full credit in their fees for the outcome. I have concluded that they were.

68 In that regard, it should be noted that Mr. Camp and Mr. Lemer were the first to obtain class-action certification. Although the Quebec action had been commenced, it had not been certified at that time. The Ontario action had not yet even been commenced. The certification was no small accomplishment given the vigour with which the application was contested and the fact that the only previous Canadian attempt to obtain certification for a mass tort action involving infected blood had met with failure: see Sutherland v. Canadian Red Cross Society (1994), 17 O.R.

(3d) 645 (Gen. Div.). Whether the actions in the other provinces would have gone forward otherwise or not, it appears that the certification in British Columbia was the catalyst that gave them life.

69 The certification also energized plaintiffs' counsel nationally and Mr. Camp played a role in bringing approximately twenty of them together to form a coalition for the purpose of advancing their clients' claims. He made other significant contributions, as well. He was the chair of the coalition's first negotiating committee and, when that committee became unwieldy, he was one of three counsel delegated to negotiate for the transfused class, along with Mr. Strosberg of Ontario and Mr. Lavigne of Quebec. Mr. Camp was the first to bring representatives of the FPT Governments to the bargaining table when he met with Mr. Whitehall and Mr. Prowse, representing the federal and British Columbia governments respectively, on February 11, 1998. This meeting led to the further meetings that ultimately resulted in settlement. Mr. Camp and Ms. Tough, Ontario counsel for the haemophilic classes, were instrumental in bridging the differences between the transfused class members and the haemophilic class members. This accommodation resulted in their bargaining jointly with the FPT Governments, which was critical to the success of the negotiations. Mr. Camp's judgment and tactical decisions from time to time throughout the negotiations were important to their success.

70 Mr. Lemer and Ms. Mathews made significant contributions as well. Both served on the subcommittees formed by the coalition of lawyers for the purpose of facilitating negotiations and moving the lawsuits forward. I have already commented on Mr. Lemer's depth of knowledge and his value as a resource in relation to blood-related litigation.

71 I am satisfied that British Columbia class counsel made a substantial contribution to the result and that their efforts were at least as valuable as those of class counsel in the other provinces. It would not be proper in the circumstances to give them less than full credit for the result in the assessment of the reasonableness of their proposed fees.

(k) The integrity of the legal profession

72 Next, Mr. Turriff submitted that the fee proposed here is "simply too much". He suggested that a fee of this magnitude would "impair the integrity of the legal profession". That phrase appears in the remarks of McEachern C.J.B.C. in Commonwealth No. 2, supra, where, at p. 187, para. 47, in a passage that I have already quoted, he said:

> . . . With all this in mind, the court must then ask, as a matter of judgment, whether the fee fixed by the agreement is reasonable and maintains the integrity of the profession? . . .

73 Esson C.J. (as he then was) commented on this concept in Richardson (Guardian ad litem of) v. Low (1996), 23 B.C.L.R. (3d) 268 (S.C.) at paras. 29-30. I think that what he envisaged in using the phrase "integrity of the profession" was the decency, honour, and high-mindedness of the

profession, both in substance and in public perception. He referred, for example, to the willingness of lawyers to readily reduce the amount payable under a contingent fee agreement when circumstances are such that the agreed fee would be disproportionate to the amount of effort, risk, and cost involved; that the lawyer will be able to fill with other remunerative work the time set aside to try a case that was settled; and that the client needs the funds and cannot really afford to pay them to the lawyer despite the agreement.

74 Here, the fees proposed are very large. The total value of the time docketed by all plaintiffs' counsel for the transfused class, including those who acted for individual plaintiffs and who will be paid their fees by Mr. Camp, amounts to approximately $4,000,000. Accordingly, the proposed fee is roughly 3.75 times the value that they have ascribed to their work. However, that is not necessarily a reliable measure, as I have already noted. Moreover, it must be remembered that good counsel can often achieve with a minimal effort what it might take less skillful counsel a great deal of time to achieve, as was seen in Commonwealth No. 1 and Commonwealth No. 2. Good counsel should not be penalized for their acuity and efficiency by basing their fees only on the amount of time that it took them to accomplish their clients' objectives.

75 Mr. Camp and Mr. Lemer do not seek approval of a percentage fee in this case. However, percentage contingent fees have long been common in British Columbia and have been approved in class proceedings in this province: see Harrington v. Dow Corning Corp., supra, Campbell v. Flexwatt Corp. (22 February 1996), Victoria 2895/95 (B.C.S.C.), and Fischer v. Delgratia Mining Corporation, supra. A comparison between the proposed fees as a percentage of the settlement amount and percentage fees approved in previous class actions will therefore be informative, although I must not lose sight of the principle identified by Esson C.J. (as he then was) in Richardson (Guardian ad litem of) v. Low, supra at para. 35:

> The question "what is the reasonable fee?" must be answered, not as a percentage, but in dollars.

76 There is evidence that British Columbia has approximately 22% of the transfused HCV-infected cohort. On that basis, for purposes of rough estimation, approximately $352,000,000 of the $1,600,000,000 settlement can be notionally credited to the clients represented by Mr. Camp and Mr. Lemer, and their proposed fee of $15,000,000 is 4.26% of the recovery.

77 A contingent percentage fee of that magnitude in an action for damages for personal injuries is virtually unheard of in British Columbia. Rule 8-4(2) of the Law Society Rules permits a maximum percentage of 40% in cases such as this. The vast majority of percentage contingent fees in British Columbia range between 15% and 33 1/3%. In Harrington v. Dow Corning Corp., supra E.R.A. Edwards J. observed that class counsel fees in the United States commonly range between 15% and 50%, and that a "presumptively reasonable rate" is 30%. He approved a contingent fee of 15%, which produced a fee in the order of $6,000,000 for plaintiffs' class counsel. In Sawatzky, supra a contingent fee of 20% amounting to $760,000 was approved. In Fischer, supra a fee of 30% of

shares in a public company issued in settlement was approved, although the value of the fee in monetary terms is not apparent.

78 The fee proposed here compares favourably in percentage terms with contingent fees approved in Ontario and Quebec, as well. In Nantais, supra Brockenshire J. approved a percentage fee of 30%, which yielded a fee of approximately $6,000,000. In Doyer v. Dow Corning Corp. (1 September 1999), Montreal 500-06-000013-934 (Q.S.C.) a percentage of 20% was approved yielding a fee of $10,400,000. In Pelletier v. Baxter Health Care Corp., [1999] Q.J. No. 3038 (S.C.), a percentage of 16.9% yielding $3,648,000 in fees was approved.

79 I note, as well, the observation of McEachern C.J.B.C., speaking for the Court in Commonwealth No. 2, supra at p. 188, para. 49, that he saw nothing unreasonable or threatening to the integrity of the profession in a fee of 25% "for the skillful recovery of $6.5 million." Further, Mr. Giles, who is an experienced Vancouver barrister, as I have already noted, does not appear to consider that Mr. Camp's proposed fee is unseemly: he expressed the opinion that it is reasonable in all the circumstances.

80 I accept that a percentage fee should generally be lower where the recovery is higher. However, 4.26% is modest by any standard.

81 Another important factor in this connection is that the fees are not to be deducted from the compensation payable to the individual plaintiffs, as the settlement agreement provided for an allocation of $52,500,000 for legal fees in addition to that compensation. It could be said that this observation is illusory, as the $52,500,000 could have been allocated in part to plaintiffs' claims. However, two facts cannot be overlooked. First, the individual compensation awards provided for in the fund are full and generous and are available to the class members without further legal proceedings. Secondly, the FPT Governments tacitly agreed to fees up to this amount when they agreed upon the structure of the settlement fund.

82 Another perspective can be gained by considering the fee from the point of view of each member of the class. It appears that there are approximately 22,000 class members in British Columbia and the fee therefore works out to about $682 each. This is a modest fee for individual awards ranging from a minimum of $10,000 in non-pecuniary compensation to a maximum of $225,000 for non-pecuniary compensation plus loss of income, cost of care and home services, and other expenses, particularly when the fee is not deducted from the award.

83 It is also important to note that the representative plaintiff, Ms. Endean, considers the fee to be reasonable and urges the court to approve it.

84 While public perception is difficult to gauge, there is some interesting anecdotal evidence here. On July 11, 1999, Mr. Camp appeared on a "hot line" radio show in Vancouver, on a station that has coverage throughout the province, to discuss the $52,500,000 allocated for plaintiffs' lawyers' fees in this case. After Mr. Camp explained his justification of that amount, the host took

several calls from listeners. The majority of callers supported Mr. Camp's position and, of those who were not supportive, none were overly critical. I do not give this evidence any weight as a measure of public opinion on this matter, but it does suggest that at least some members of the public would not think less of the profession if the fee proposed in this case should be approved.

85 In my opinion, to say that the fee is "simply too much" invites a completely arbitrary assessment, one that depends upon the subjective opinions and whims of the particular judge hearing the application. If the proposed fees are to be reduced on the ground that they impair the integrity of the profession, some principled basis must be suggested for doing so. None has been suggested and I cannot agree that the proposed fee should be reduced by an arbitrary amount ostensibly to protect the integrity of the profession.

(l) Public policy

86 Mr. Turriff also advanced a public policy argument. He said that his clients want this Court to establish an upper limit for fees in class actions generally. One of his clients, the Province of British Columbia, enacted the Class Proceedings Act just a few years ago, in 1995, but did not impose any upper limit on fees at that time. Under our system of government, the introduction of a public policy of this nature is a matter for our elected representatives, not for this Court, and I decline Mr. Turriff's invitation to judicially legislate an upper limit.

87 There is, however, an aspect of public policy that is relevant. It was captured by Professor Garry D. Watson Q.C. in a paper entitled Class Actions: Uncharted Procedural Issues. In discussing the issue of compensation for plaintiffs' class counsel in the context of the Ontario statute, he said this:

> This is a vitally important subject, not just because it determines what will go into class counsel's pocket but because it will determine whether or not the legislation is successful. In the final analysis whether or not the Class Proceedings Act will achieve its noble objectives will largely depend upon whether or not there are plaintiff class lawyers who are prepared to act for the class and hence bring the actions. This in turn depends on two factors (a) the level of monetary reward given to class counsel, and (b) the predictability and reliability of the award. In the final analysis, both of these aspects are crucial. Class actions will simply not be brought if class counsel are not adequately remunerated for the time, effort and skill put into the litigation and the risk they assume (under contingency fee arrangements) of receiving nothing. Equally important is that such remuneration be reasonably predictable, i.e., that class counsel can take on class actions with a reasonable expectation that in the event of success they will receive reasonable remuneration. It is vital to the viability of class actions that class counsel not be met on "judgment day" with judicial pronouncements (issued with the "benefit" of hindsight) that class counsel "spent

> too much time, had hourly rates that were too high and in any event were conducting a case which was not really risky at all" and awarded a low base fee and a niggardly multiplier - except in very clear cases.

88 These comments flow from the objectives of the class action legislation, which include the improvement of access to the courts for those whose actions might have merit but who would not otherwise pursue them because the legal costs of proceeding are disproportionate to the amount of the individual claims: see Endean No. 1, supra at para. 23. Given that objective, the courts must ensure, first, that plaintiffs' lawyers who take on risky class actions on a contingent basis are adequately rewarded for their efforts and, second, that hindsight is not used unfairly in the assessment of the reasonableness of their fees.

89 On a consideration of all of the circumstances in this case, I am satisfied that the contingent fee contract was fair at the time it was made and that the fee of $15,000,000 proposed by Mr. Camp and Mr. Lemer is reasonable.

2. Fees in the haemophilic class action

90 I turn now to the fee proposed by Mr. Storrow in the haemophilic class action.

91 Actions were commenced on behalf of the haemophilic claimants in Ontario, Quebec, and British Columbia in 1998. The Ontario action was commenced by Ms. Tough, then of the firm of Blake, Cassels & Graydon, who coordinated and supervised the actions in Quebec and British Columbia as well. On May 1, 1998, the Vancouver office of that firm commenced the Mitchell action in this Court. The nature and extent of the work done in the Vancouver office of the firm is described in the following extract taken from Mr. Neaves' affidavit:

> 4. Blakes Vancouver delegated to Ms. Tough the responsibility of acting as national lead counsel on behalf of each plaintiffs' class in the British Columbia, Ontario and Quebec Hemophiliac Class Actions. However, I spent a considerable amount of time preparing for and participating in negotiation sessions with the FPT governments on behalf of the Representative Plaintiff in this action and in support of Ms. Tough's efforts. As a member of the Blakes Vancouver team, I provided advice to senior personnel in the Canadian Hemophilia Society and to members of the steering committee [of plaintiffs' class counsel]. I frequently consulted with and took instructions from the Representative Plaintiff. Mr. Gruber spent a considerable amount of time preparing for the hearing to approve the settlement that was ultimately reached and dealing with subsequent matters. Throughout our involvement, Mr. Storrow provided the Blakes Vancouver team with direction and advice and supported Ms. Tough in her national efforts.

92 Counsel for the haemophilic classes agreed to seek a collective fee of $7,500,000 and to share it in proportion to the amount of work done in each province. According to Mr. Neaves, the

$7,500,000 "primarily represents the work of Ms. Tough". In Mr. Neaves' words, the Vancouver office did "the least amount of work on its own." As lawyers in the Vancouver office spent most of their time assisting Ms. Tough, they agreed to seek $500,000 for their fees and Mr. Mitchell executed a contingent fee contract with Blake, Cassels & Graydon in that amount on June 2, 1999.

93 Counsel for this group ran similar risks to counsel for the transfused group, including the risks that for political reasons the FPT Governments would institute a no-fault compensation scheme and that negotiations would fail. These risks had heightened consequences for counsel for the haemophilic classes because of the greater litigation risk arising out of the grave difficulties they would necessarily encounter in attempting to prove causation. In the case of the transfused plaintiffs, it would be possible to identify a discrete transfusion as the source of the infection. However, haemophilic plaintiffs have been receiving blood and blood products regularly, many since before 1986, and the blood products were manufactured from pooled blood donations, making proof of causation at a trial very difficult if not impossible. The settlement was therefore particularly valuable for this group.

94 The compensation plan for these claimants is very similar to that agreed upon for the transfused class. However, haemophilic plaintiffs have a better result than transfused plaintiffs in some respects. First, haemophilic plaintiffs will not have to establish that their infection occurred within the class period. This is a critical provision because of the inability of most haemophiliacs to identify the source of their infection. Second, haemophiliacs will not be required to submit to liver biopsies for the purpose of identifying the relevant stage of their illness for compensation purposes. This is important because of the danger of uncontrollable bleeding from such an invasive procedure. Next, estates and family members of haemophiliacs who died prior to January 1, 1999, and who were infected with both HIV and HCV at the time of death may elect to receive a payment of $72,000 without proof that HCV was the cause of death. Finally, haemophilic plaintiffs infected with both HIV and HCV may avoid the stress and anxiety of participating in the long-term compensation program by electing to take a lump sum payment of $50,000.

95 It is apparent that, in comparison to Mr. Camp and his colleagues, British Columbia counsel for the hemophilic class made a smaller contribution to the outcome. The weight of the following factors accrues largely to Ms. Tough: the extent and character of the services rendered, the professional skills and experience called for, the character and standing of counsel, the results achieved, and the contribution of counsel to the result. On the other hand, although Ms. Tough deserves the lion's share of credit for the result, there is no doubt that the efforts of British Columbia counsel assisted her significantly in her efforts.

96 Other factors involved in the assessment of reasonableness are directly applicable to the claim by British Columbia counsel. The risks of failure of the action and of the negotiations were assumed by Mr. Storrow and his colleagues, though the consequences of failure were of a much lesser order of magnitude to them than to Mr. Camp and Mr. Lemer. As well, it must be remembered that the risk of failure in the litigation was far higher for this class than for the transfused class. The

litigation was profoundly important to the haemophilic class members, the amount recovered is generous, and the plaintiffs would not have been able to achieve the settlement without the assistance of class counsel acting on a contingent fee agreement. Moreover, the character and standing in the profession of Mr. Storrow and his colleagues is undisputed.

97 It must be noted that the Vancouver office of Blakes docketed no time on this matter until March 28, 1998, the day following the announcement on behalf of the FPT Governments that they would make $1,100,000,000 available to settle the actions. In pointing this out, Mr. Turriff suggested that there was no significant risk run by British Columbia counsel. There is an initial appeal to this assertion, but it does not tell the whole story. As I have already observed elsewhere in these reasons, the risk that negotiations might founder was a real and present risk until well after the judgments granting conditional approval of the settlement. Thus, the time invested by British Columbia counsel was at risk of being valueless. As well, the Toronto arm of the firm had invested substantial time and effort, through Ms. Tough, on behalf of haemophiliacs in the preceding years. The thoroughness and quality of Ms. Tough's work stands out clearly on the evidence. While her agreement to a fee of $500,000 for her Vancouver colleagues may seem generous, it is undoubtedly an expression of her view of the value of their work to the overall result and of the extent of the risk that they ran. As such, I consider it to be evidence supporting the reasonableness of the proposed fee.

98 Of the total amount of the settlement, it is estimated that approximately $150,300,000 should be allocated notionally to the haemophilic classes. Of the approximately 1,650 haemophilic plaintiffs nationally, approximately 180 are residents of British Columbia, or roughly 11%. If it is assumed that the total recovery for British Columbia haemophilic plaintiffs is 11% of the $150,300,000, that is, $16,533,000, the $500,000 share of the fee allocated to British Columbia counsel is 3% of the recovery. That is a manifestly reasonable percentage.

99 Assuming a cohort of 180 plaintiffs resident in British Columbia, the fee represents a charge of approximately $2,800 per plaintiff. While these are rough estimations, that is a reasonable amount for each claimant to pay in relation to the benefits recovered for them.

100 If the matter is examined from the base fee/multiplier approach, the proposed fee does not fare as well. A rough estimate of the value attributed to the time docketed by the Vancouver office of Blakes is $90,000. The proposed fee therefore represents a multiplier of 5.5, which is at the high end of the range of permissible multipliers using this approach.

101 The sorts of checks on reasonableness that I have just performed are useful as guides but, at bottom, the question is whether the proposed fee is reasonable having regard to all of the relevant circumstances. Having considered the circumstances, I conclude that this proposed fee of $500,000 meets the test for reasonableness.

3. Disbursements

102 As I understand it, Mr. Camp claims disbursements in the amount of $75,376 and Mr. Turriff, having scrutinized the items comprising that total, agrees that the amount claimed is reasonable and that the disbursements involved are properly payable. Accordingly, the claim for disbursements totalling that amount is approved.

103 Mr. Storrow advised during his submission that the disbursements for which he claims reimbursement total approximately $35,000. Mr. Turriff indicated that he wished to have some time to review the disbursements claimed and to make a written submission if he should think it necessary. I have not received anything further from counsel in this regard. Accordingly, if counsel can agree on the disbursements, they may insert the agreed amount in the order to be drawn up consequent on these reasons. There will be liberty to apply in the event that there are disbursement items requiring adjudication.

K.J. SMITH J.

cp/i/qldrk/qltlm

Case Name:

Helm v. Toronto Hydro-Electric System Ltd.

RE: Christian Helm, Plaintiff/Moving Party, and Toronto Hydro-Electric System Limited, Defendant/Respondent

[2012] O.J. No. 2081

2012 ONSC 2602

214 A.C.W.S. (3d) 352

40 C.P.C. (7th) 310

2012 CarswellOnt 5761

Court File No. CV-10-415780

Ontario Superior Court of Justice

G.R. Strathy J.

Heard: April 30, 2012.
Judgment: May 8, 2012.

(32 paras.)

Civil litigation -- Civil procedure -- Parties -- Class or representative actions -- Class counsel -- Fees -- Settlements -- Approval -- Motion by the plaintiff for approval of a settlement reached by the parties, approval of the fees of class counsel and approval of an honorarium of $2,500 to the representative plaintiff allowed in part -- Settlement and counsel fee were approved -- Settlement was a reasonable compromise -- Proceeding was conducted in an efficient, imaginative and cost-effective manner -- This was not an exceptional case justifying payment of honorarium to representative plaintiff.

Motion by the plaintiff for approval of a settlement reached by the parties, approval of the fees of class counsel and approval of an honorarium of $2,500 to the representative plaintiff. The plaintiff sued the defendant Hydro for breaching the Interest Act by failing to inform its customers of the

effective annual rate of interest it charged on overdue accounts. The settlement agreement resolved the claims of the Class Members for the total sum of $5,835,882. There had been no objections to the settlement. Class counsel fees were in the amount of $1,458,970. The plaintiff had entered into a retainer agreement that provided that Class Counsel's compensation should be 25 per cent of the recovery obtained in the action, plus disbursements and taxes.

HELD: Application allowed in part. Significant compromise was warranted, on both sides, and the resulting settlement was well within the zone of reasonable outcomes. The settlement, which included not only direct payments to the Refund-Eligible Class Members, but also the forgiveness of arrears and a cy prs distribution, was fair and reasonable. The counsel fee was approved. The proceeding was funded entirely by class counsel and no application to the class proceedings fund was required. There was significant risk to class counsel in taking on this case, in which liability was hotly contested and the outcome difficult to predict, and the proceeding was conducted in an efficient, imaginative and cost-effective manner. The plaintiff's honorarium was not approved since this was not an exceptional case.

Statutes, Regulations and Rules Cited:

Interest Act, R.S.C. 1985, c. I-15, s. 4

Counsel:

Charles Wright and Daniel Bach, for the Plaintiff/Moving Party.

Kelly Friedman, for the Defendant/Respondent.

ENDORSEMENT

(Settlement Approval and Fee Approval)

1 **G.R. STRATHY J.**:-- This is a motion for: (a) approval of a settlement reached by the parties; (b) approval of the fees of Class Counsel; and (c) approval of an "honorarium" of $2,500.00 to the representative plaintiff.

2 The plaintiff in this proposed class action alleges that Toronto Hydro-Electric System Limited ("Toronto Hydro") breached s. 4 of the *Interest Act*, R.S.C. 1985, c. I-15, by failing to inform its customers of the effective annual rate of interest it charged on overdue accounts.

3 Section 4 of the *Interest Act* states that where a written or printed contract provides for interest to be paid at a rate or percentage for any period less than a year, and does not express the equivalent annual rate, the collection of interest is limited to 5% per year. The rate actually charged by Toronto

Hydro was 19.56% per annum. This rate was set out in its tariff, which had been approved by the Ontario Energy Board ("OEB"). However, Toronto Hydro's invoices to its customers referred only to a 1.5% monthly late payment interest charge and made no reference to the effective annual rate of interest.

4 The plaintiff claims, among other things, that Toronto Hydro's invoice did not comply with the *Interest Act*. He alleges that he and other Class Members have been charged more than the limit permitted by law and that Toronto Hydro has thereby been unjustly enriched.

5 On June 16, 2011, I heard a summary judgment motion brought by Toronto Hydro and a cross motion for judgment brought by the plaintiff. While my decision was under reserve, I was advised that counsel were pursuing settlement discussions. I agreed that my decision would not be released if the parties were able to reach a settlement. Settlement discussions continued, with counsel keeping the court advised of their progress, in the hope of reaching a settlement that would form a proper framework for the resolution of the litigation.

(a) Settlement Approval

6 The parties have executed a Settlement Agreement that, subject to the approval of the court, resolves the claims of the Class Members for the total sum of CAD$5,835,882.00.

7 On February 8, 2012, there was a preliminary motion to certify this action as a class proceeding for the purposes of settlement and to establish a procedure for the dissemination of a notice of this settlement hearing and an opt-out form. The opt-out period expired on April 16, 2012 and there have been no opt outs. Nor have there been any objections to the proposed settlement.

8 The basic terms of the settlement are as follows:

(a) The Defendant will consent to certification of a class proceeding for the purposes of settlement. The Class will consist of:

> All persons that were customers (retail, commercial or otherwise) of the Defendant, who were billed at some time within the period from July 1, 2000 through to and including December 8, 2010, and who paid interest on an unpaid account billed during that period.

(b) The Common Issue will be:

> Did the Defendant breach the *Interest Act* by charging interest on unpaid customer accounts at a monthly rate which equated to more than 5% per

annum without disclosing the equivalent annual rate on its bills dated between July 1, 2000 and December 8, 2010, inclusive?

(c) The Defendant will provide CAD$5,835,882.00 in compensation to the Class, to be distributed as follows:

(i) The Defendant will make repayment, less applicable court-approved Class Counsel Fees, by mailed cheque or account credit, of interest paid in excess of 5% per annum ("Excess Interest") to Class Members who, between December 7, 2008 and June 29, 2011, paid an amount equal to or greater than $30.00 in Excess Interest in respect of a bill issued on or before December 8, 2010 ("Refund Eligible Class Members").

(ii) The Defendant will pay any residual funds, less Class Counsel Fees, to *cy près* recipient charities in proportions to be approved by the court.

(d) The Defendant will take all reasonable steps, including instructing third party collection agencies, within sixty (60) business days of the Approval Order to cancel all Excess Interest currently owed by Class Members that was assessed prior to December 9, 2010. The amount of accounts receivable to be cancelled and the benefit to the class in this regard is approximately $184,224.00. To the extent that any currently owed Excess Interest is collected before the *cy près* payment is made, and to the extent that such funds can reasonably be identified as Excess Interest, they will be paid to the *cy près* recipient charities in the same manner as the residual funds addressed above.

(e) The Defendant will achieve a final resolution of this matter and will not be required to admit liability for the allegations advanced in the Plaintiff's Claim. The action will be settled and dismissed on the merits with prejudice and without costs.

9 The Refund-Eligible group is limited to Class Members who, between December 7, 2008 and June 29, 2011, paid an amount equal to or greater than $30.00 in Excess Interest. This was done for two primary reasons.

10 First, Customer data for the portion of the Class Period prior to December 7, 2008 and after April 30, 2002, is stored on a different database than the one currently used by Toronto Hydro. It would have been disproportionately expensive and time-consuming to access this data. As well, Customer data for the beginning of the Class Period until April 30, 2002 is archived. Creating a

structure to access this data and to convert it to manageable form would have been expensive and time-consuming. Moreover, logistical difficulties would have been created due to difficulties in locating former Customers of the defendant who are no longer Customers.

11 Second, the estimated cost of distributing the Settlement Amount to Refund-Eligible Class Members is approximately $4.00 per Class Member. Nearly 60% of the Class Members paid less than $5.00 in Excess Interest. It would have been manifestly uneconomical to spend $4.00 to put $5.00 in the hands of a Class Member. By restricting refund entitlements to Class Members who paid at least $30.00 in Excess Interest, chronic late payers are compensated. Such chronic late payers have suffered the most from the alleged wrongdoing. It would further allow these individuals to benefit without compromising the parties' ability to achieve a meaningful settlement due to costs concerns.

12 The *Cy Près* recipients are listed below, and were selected for the following reasons:

(a) United Way Centraide Canada, was selected because of its dedication to community-building and poverty-relief initiatives, as well as its ability to distribute *cy près* funds to numerous meritorious projects;
(b) Second Harvest, was selected because of its work toward supplying fresh, nutritious food to low income communities in the Toronto region; and
(c) Red Door Family Shelter, was selected because of its efforts in assisting Toronto families in crisis by providing them with transitional housing facilities.

13 The plaintiff proposes, and I agree, that the *cy près* distribution ought to be split among the three recipients equally.

14 In order to approve a settlement, the court must be satisfied that it is fair, reasonable and in the best interests of the class. The leading authority is *Dabbs v. Sun Life Assurance Co. of Canada*, [1998] O.J. No. 1598 (Gen. Div.), which identifies the following factors that a court should take into account in approving a settlement;

(a) its likelihood of success;
(b) the amount and nature of discovery, evidence or investigation required to prosecute the action;
(c) its terms and conditions;
(d) the recommendation and experience of counsel;
(e) the future expense, and likely duration of litigation and risk;
(f) the recommendation of neutral parties, if any;
(g) the number of objectors and nature of objections;
(h) the presence of good faith, arms-length bargaining and the absence of collusion;
(i) information conveying to the court the dynamics of and the positions taken by the parties during the negotiation; and

(j) the degree and nature of communications by counsel and the representative plaintiff with Class Members during the litigation.

15 It is well understood, however, that these factors are only guides and that their relative importance will vary from case to case. In any particular case, some factors will have greater significance than others and weight should be attributed accordingly: *Parsons v. Canadian Red Cross Society*, 40 C.P.C. (4th) 151 (S.C.J.).

16 As a result of having heard the summary judgment motion on the merits, I am in a rather unique position. A judge on a settlement approval motion rarely has the benefit of such an intensive, merits-based analysis on agreed facts. Having had this benefit, I am able to form my own independent view of whether the settlement is fair, reasonable and in the best interests of the class.

17 In this case, having had that perspective, I am satisfied that significant compromise was warranted, on both sides, and that the resulting settlement is well within the zone of reasonable outcomes. I am also satisfied, from my own observations, that the settlement was the result of good faith, arm's length negotiations in which the parties were attempting to reach a resolution that was fair to Class Members, workable and reasonable. The settlement comes with the recommendation of experienced and highly reputable counsel, on both sides and I am fully satisfied that they have fulfilled their duties to their clients and to the court in the negotiation of the settlement and resolution of this litigation. It is of significance, as well, that there have been no objections to the settlement.

18 Every settlement involves compromise. This settlement is no exception. Some compromises had to be made as a practical matter to ensure that the costs of administration of the settlement did not become disproportionate to the amount actually paid to Class Members. I am satisfied, however, that the settlement, which includes not only direct payments to the Refund-Eligible Class Members, but also the forgiveness of arrears and the *cy près* distribution, is fair and reasonable.

19 For these reasons, the settlement is approved.

(b) Class Counsel Fee Approval

20 Class Counsel also move for an order: (a) approving the retainer agreement entered into with Christian Helm; and (b) approving Siskinds LLP's legal fees ("Class Counsel Fees") in the amount of $1,458,970.50, plus applicable taxes.

21 Class Counsel seeks a fee of 25% of the recovery, namely $1,458,970.50 plus HST in the amount of $189,666.16. Under the terms of the settlement, the defendant is responsible for paying the first $10,000.00 in "reasonable" disbursements. The parties have agreed to a payment of $7,678.29 (inclusive of taxes, as applicable). Class Counsel is writing off the balance of the disbursements as well as all disbursements incurred after April 19, 2012. I should also note that under the terms of the settlement, the defendant agreed to pay the costs of giving notice of the

settlement approval motion.

22 Mr. Helm entered into a retainer agreement that provided that Class Counsel's compensation should be 25% of the recovery obtained in the action, plus disbursements and taxes. This is a reasonably standard fee agreement in class proceedings litigation. Mr. Helm supports Class Counsel's legal fee request. The fee agreement complies with the requirements of the *Class Proceedings Act, 1992*, S.O. 1992, c. 6 (*C.P.A.*) and it is approved.

23 Since the commencement of the action, Class Counsel have financed disbursements totalling $10,741.37 (including taxes as applicable and as of April 19, 2012). In addition, as of April 19, 2012, Class Counsel had docketed time of $203,669.50.

24 There are some particular aspects of this case that should be taken into account in assessing whether the fee is fair and reasonable:

* the amount of the settlement is substantial, particularly having regard to the legal difficulties associated with recovery of the claim;
* leaving aside the monetary benefit to Refund Eligible Class Members, there are direct benefits to all Class Members through the cancellation of Excess Interest charges, there is a substantial *cy près* payment and actual behaviour modification has been achieved;
* the proceeding was funded entirely by Class Counsel and no application to the Class Proceedings Fund was required;
* there was significant risk to Class Counsel in taking on this case, in which liability was hotly contested and the outcome difficult to predict; and
* the proceeding was conducted in an efficient, imaginative and cost-effective manner.

25 The proposed fee represents a significant premium over what the fee would be based on time multiplied by standard hourly rates. Is that a reason to disallow it? If the settlement had only been achieved four years later, on the eve of trial, when over a million dollars in time had been expended, would the fee be any more or less appropriate? Should counsel not be rewarded for bringing this litigation to a timely and meritorious conclusion? Should counsel not be commended for taking an aggressive and innovative approach to summary judgment, ultimately causing the plaintiff to enter into serious and ultimately productive settlement discussions?

26 Plaintiff's counsel are serious, responsible, committed and effective class action counsel. They are entrepreneurial. They will likely take on some cases that they will lose, with significant financial consequences. They will take on other cases where they will not be paid for years. To my mind, they should be generously compensated when they produce excellent and timely results, as they have done here.

27 For those reasons, I approve the counsel fee.

(c) Honorarium for Representative Plaintiff

28 Counsel requests an honorarium of $2,500.00 for Mr. Helm, to be paid out of the settlement fund. They note that Mr. Helm carried out his responsibilities in a diligent and proper manner, providing assistance in the litigation leading to the settlement. They say that were it not for Mr. Helm's willingness to represent the class despite his small personal stake in the action, there would have been no settlement. Mr. Helm's efforts resulted in nearly immediate behaviour modification: the defendant brought its invoices into compliance with law shortly after the filing of the claim. Counsel says that Mr. Helm's accomplishments in this action far exceed his individual interest, which is only about $70.00, and that some modest payment is in order to recognize his accomplishment and to provide some indemnity for the time and effort he has put into the case.

29 I accept that I have jurisdiction to award an honorarium: *Wilson v. Servier Canada Inc,* 2005 CarswellOnt 1020 at para 95 (S.C.J.)*; Pysznyj v. Orsu Metals Corp,* [2010] O.J. No 1994 at para 31 (S.C.J.); *Farkas v. Sunnybrook & Women's College Health Sciences Centre*, 2009 CarswellOnt 4962 at paras 69-70 (S.C.J.); *Smith Estate v. National Money Mart Co,* 2011 ONCA 233 at paras 133-136.

30 I discussed the issue of compensation or honoraria for representative plaintiffs at some length in my settlement approval decision in *Robinson v. Rochester Financial Ltd.*, [2012] O.J. No. 534; 2012 ONSC 911. I noted in that case, at para. 43, that "compensation should be reserved to those cases, where, considering all the circumstances, the contribution of the plaintiff has been exceptional". In my view, this is not an exceptional case.

31 My decision not to award an honorarium should not be perceived by Mr. Helm as a lack of appreciation for what he has accomplished in commencing this action and in bringing it to a successful conclusion. Mr. Helm can take some satisfaction from the fact that this case, his case, *Helm v. Toronto Hydro-Electric System Limited,* has accomplished the goals of the *Class Proceedings Act, 1992* - it has brought access to justice to thousands of Toronto Hydro customers; it has actually achieved behaviour modification by causing Toronto Hydro to change its invoices; and it has resulted in judicial economy. The settlement puts real money into the hands of many Toronto Hydro customers and the *cy près* award will bring assistance to others in need. Mr. Helm can be justly proud of these accomplishments and he should be commended for them.

32 In closing, I express the court's appreciation to counsel on both sides for the efficient manner in which this action has proceeded and has been brought to a satisfactory conclusion.

G.R. STRATHY J.

cp/e/qljel/qlpmg/qljac

Case Name:

Griffin v. Dell Canada Inc.

RE: Thaddeus Griffin, 1339850 Ontario Limited (c.o.b. as Griffin Leasing) and Ian Andrews, Plaintiffs/Moving Parties, and Dell Canada Inc., Defendant/Respondent

[2011] O.J. No. 2487

2011 ONSC 3292

203 A.C.W.S. (3d) 37

38 C.P.C. (7th) 86

2011 CarswellOnt 4190

Court File No. 07-CV-325223

Ontario Superior Court of Justice

G.R. Strathy J.

Heard: April 26, 2011; written submissions and case conference, May 25, 2011.
Judgment: May 31, 2011.

(55 paras.)

Counsel:

Joel Rochon and Sakie Tambakos, for the Plaintiffs/Moving Parties.

Mahmud Jamal and Jean-Marc Leclerc, for the Defendant/Respondent.

REASONS FOR SETTLEMENT APPROVAL

1 **G.R. STRATHY J.**:-- This is a motion, pursuant to s. 29 of the *Class Proceedings Act, 1992,* S.O. 1992, c. 6 (the *C.P.A.)*, for the approval of a settlement between the plaintiffs and the defendant, Dell Canada Inc. ("Dell"). The plaintiffs also seek approval of class counsels fees and disbursements.

Background

2 This is a consumer class action involving five allegedly defective models of the Dell Inspiron computer, which was sold in Canada between March 2003 and May 2005. During that time, Dell sold approximately 118,629 Inspiron computers at an average price of about $2,000.

3 The plaintiffs allege that these computers were prone to overheating, power failure, an inability to "boot up" and unexpected shutdowns. They allege that the computers had an inadequate or defective cooling system, and a defective motherboard. The expert retained by class counsel expressed the opinion that the computers had improper circuit board soldering, a defect that was capable of being demonstrated on a class-wide basis.

4 Details of the allegations of the plaintiffs, and their specific experience, are set out in the decision of Lax J., certifying the proceeding as a class action: *Griffin v. Dell Canada Inc.,* [2009] O.J. No. 418, 72 C.P.C. (6th) 158.

5 The action has had a lengthy procedural history. There have been numerous motions and appeals. In response to the plaintiff's motion for certification, Dell brought a cross-motion to stay the action in favour of arbitration, based on a provision in Dell's standard terms and conditions which required that disputes be arbitrated in the State of Minnesota, in the U.S.A.

6 On February 3, 2009, Lax J. dismissed Dell's motion to stay and conditionally certified the action, subject to the plaintiffs producing a workable litigation plan.

7 Dells motion for leave to appeal the certification decision was dismissed by Wilson J.: [2009] O.J. No. 3438.

8 Dell moved, in March 2009, before Justice Lax for an order reconsidering the stay decision. That motion was dismissed: [2009] O.J. No. 1592.

9 Dell's appeal from the decision of Lax J. on the stay and reconsideration motions was dismissed by the Court of Appeal: [2010] O.J. No. 177. An application for leave to appeal was dismissed by the Supreme Court of Canada: [2010] S.C.C.A. No. 75.

10 As is so often the case, there was parallel class action litigation in the United States. Two U.S. class actions were settled in 2010 on the basis that purchasers of the 1150, 5100 and 5160 Inspiron models would receive compensation, in whole or in part, for "eligible repairs" - that is, repairs to

their computers that were performed by Dell or its authorized repair facilities. In the case of the Inspiron 5160 model, the compensation was "capped" at $150. There was no compensation provided to purchasers of the 1100 Inspiron model, because its repair record was better than the industry norm at the time. An earlier class action settlement had been concluded in 2006 with respect to the Inspiron 5150 model. That settlement provided reimbursement for certain out-of-pocket expenses and qualifying repairs and a new, limited warranty on the computer to cover qualifying repairs.

11 These developments encouraged the parties to discuss settlement of this proceeding and a two-day mediation was held in August 2010, with the Honourable Frank Iacobucci Q.C. as mediator. An agreement in principle was reached, and a settlement agreement was signed on January 9, 2011, subject to court approval.

The Settlement Agreement

12 Under the terms of the settlement, as in the U.S. settlements, class members (which Dell has agreed will include, for the purposes of settlement, persons who leased their computers directly from Dell) who paid for certain "reimbursable repairs" - that is, repairs of a specific kind that were made by Dell or one of Dell's authorized service providers - are entitled to receive a refund of all or a certain percentage of the repair cost. "Reimbursable repairs" include:

(a) repairs addressing clogged vents or restricted airflow, including fan repair or replacement;
(b) heat sink replacements;
(c) AC adaptor replacements;
(d) motherboard replacements addressing power failure, shutdown, failure to boot, and/or freezing situations; and
(e) battery replacements addressing failure to take a charge or to hold a charge.

13 The amount of the reimbursement depends on which model of computer is involved and how long the class member owned the computer prior to repair. In the case of the Inspiron 1150, 5100 and 5160 models, the refund will be equivalent to:

(a) 100% of the cost of repairs between 12 and 18 months of the purchase date;
(b) 75% of the cost of repairs between 18 and 24 months of the purchase date;
(c) 40% of the cost of repairs that occurred between 24 and 30 months of the purchase date; and
(d) 20% of the cost of repairs that occurred over 30 months after the purchase date and before the deadline for claims.

14 Unlike the settlement in the United States, there is no cap on eligible repairs to the Inspiron

5160 computer.

15 The payment of a different percentage of repair cost depending on the age of the computer is intended to reflect the fact that the consumer has obtained a greater use of the computer, there is greater likelihood that the need for repair is attributable to ordinary wear and tear, and the remaining working life of the computer is proportionately less.

16 Owners of the Inspiron 5150 will also receive a cash refund, on a sliding scale depending on when the repairs took place. The refund will be:

(a) 100% of the cost of repairs that occurred before September 30, 2007;
(b) 75% of the cost of repairs between October 1, 2007 and March 31, 2008;
(c) 40% of the cost of repairs that occurred between April 1, 2008 and September 30, 2008; and
(d) 20% of the cost of repairs that occurred between October 1, 2008 and the deadline for claims.

17 The following will not be covered under the settlement:

(a) as in the United States, owners of the Inspiron 1100 are not entitled to compensation under the settlement, as the failure rate for that computer was below the industry average. It was the experience of class counsel in Canada that the problems with this model were not as widespread as those affecting the other models - that said, some 70 of the 735 class members who contacted class counsel were model 1100 owners;
(b) repairs that were carried out by repairers other than Dell or its authorized repairers - if the owner found it more convenient, and perhaps less expensive, to have his or her computer repaired by a local repair shop, those costs will not qualify for reimbursement[1];
(c) computers that failed on one or more occasions, but were never repaired; and
(d) computers that were simply scrapped or replaced because they were unusable.

18 To reflect the fact that the settlement does not cover some of these claims, which in many cases would be difficult to prove and expensive to administer, Dell has agreed to contribute $200,000 worth of computers (at retail value) or, where that is not practical, to make equivalent cash donations, to various Canadian children's hospitals and other youth programs in Canada.

19 In addition, Dell will be responsible for payment of the costs of notice of the settlement to class members and the costs of administration of the settlement.

20 Dell has also agreed to pay the sum of $2 million, inclusive of taxes and disbursements, in full

satisfaction of the fees of class counsel. Class members will have no obligation to make any payment towards costs.

21 As Dell has an excellent customer database, it has been able to estimate, with some precision, the number of purchasers who are likely to qualify for reimbursement under the settlement. It estimates that there are approximately 435 customers who will automatically be eligible for settlement. Over 700 people have contacted class counsel with respect to the settlement, although a number of these may be ineligible. I was advised that the average repair cost was likely in the range of $400-$800. As noted above, only a portion of this cost will be recoverable in some cases.

Notice of Settlement and Objections

22 On January 11, 2011, I made an order giving notice of certification and of the proposed settlement. Analytics Inc. was appointed the notice and opt-out administrator. Class members were provided with an opportunity to file written objections to the settlement. There are approximately 118,000 class members and approximately 90% of those actually received direct written notice of certification and of the settlement approval motion. There was also a program for national newspaper advertisement and notice on class counsel's web site. There were six objections to the settlement. There were opt-out requests from 101 class members.

23 The primary concern of the six objectors is that the settlement only covers repairs carried out by Dell or its authorized service providers and that the compensation is confined to the reimbursement of repair costs. They complain that there is no compensation for owners who simply decided that they had had enough, and bought new computers and scrapped the old ones which were defective and had no trade-in or market value. One of the class members objected that class counsel received a large fee, whereas some class members were excluded from the settlement. I will discuss these objections below.

Discussion

24 In considering whether to approve a settlement, the court must ask whether the settlement is fair and reasonable and in the best interests of the class as a whole: *Dabbs v. Sun Life Assurance Co. of Canada* (1998), 40 O.R. (3d) 429, [1998] O.J. No. 2811 (Gen. Div.) at paras. 30-46, aff'd (1998), 41 O.R. (3d) 97, [1998] O.J. No. 3622 (C.A.), leave to appeal refused [1998] S.C.C.A. No. 372 (*Dabbs*).

25 Consideration must be given to all the circumstances, including the factual context of the proceedings, the legal issues, the claims made and defences raised, as well as any objections to the proposed settlement. The relevant factors, which will vary from case to case, were summarized by Perell, J. in *Corless v. KPMG LLP*, [2008] O.J. No. 3092, 170 A.C.W.S. (3d) 464 at para. 30 (S.C.J.) at para. 38:

> When considering the approval of negotiated settlements, the court may consider,

> among other things: likelihood of recovery or likelihood of success; amount and nature of discovery, evidence or investigation; settlement terms and conditions; recommendation and experience of counsel; future expense and likely duration of litigation and risk; recommendation of neutral parties, if any; number of objectors and nature of objections; the presence of good faith, arms length bargaining and the absence of collusion; the degree and nature of communications by counsel and the representative plaintiffs with class members during the litigation; and information conveying to the court the dynamics of and the positions taken by the parties during the negotiation: *Dabbs v. Sun Life Assurance Company of Canada* (1998), 40 O.R. (3d) 429 (Gen. Div.) at 440-44, aff'd (1998), 41 O.R. (3d) 97 (C.A.), leave to appeal to S.C.C. refused Oct.22, 1998, [1998] S.C.C.A. No. 372; *Parsons v. The Canadian Red Cross Society*, [1999] O.J. No. 3572 (S.C.J.) at paras. 71-72.; *Frohlinger v. Nortel Networks Corp.*, [2007] O.J. No. 148 (S.C.J.) at para. 8; *Kelman v. Goodyear Tire and Rubber Co.*, [2005] O.J. No. 175 (S.C.J.) at paras. 12-13; *Vitapharm Canada Ltd. v. F. Hoffmann-La Roche Ltd.* (2005), 74 O.R. (3d) 758 (S.C.J.) at para. 117; *Sutherland v. Boots Pharmaceutical plc*, [2002] O.J. No. 1361 (S.C.J.) at para. 10.

26 The test is easy to state. It is more difficult to apply. It is particularly difficult to apply because the adversary process is generally absent from the settlement approval motion. Both parties support the settlement and neither party is inclined to highlight its deficiencies. The Court of Appeal has recently noted that in appropriate cases, the motion judge may appoint an *amicus* or monitor to investigate and comment on a proposed settlement: *Smith Estate v. National Money Mart Co.*, [2011] O.J. No. 1321, 2011 ONCA 233 at paras. 23-41.

27 Settlement approval is all the more difficult because in many cases, including this one, the risk of the settlement not being approved falls disproportionately on class counsel. If the settlement is not approved, and the case goes to trial and the plaintiff loses, the loss to each class member is a few hundred dollars, which they would not have recovered in any event without the class action. Class counsel stands to lose not only the substantial time and and disbursements invested in the file to date, but also is at risk of the considerable costs of taking the case to trial and, potentially, the risk of an adverse costs award.

28 Mr. Rochon properly acknowledges that no settlement is perfect and that this settlement is not perfect. It clearly is not perfect as far as the six objectors are concerned. Some class members are being left out of the settlement. On the other hand, as was noted in *Dabbs* at para. 30, "[A] less than perfect settlement may be in the best interests of those affected by it when compared to the alternative of the risks and costs of litigation."

29 I propose to briefly summarize my conclusions with respect to the factors mentioned in *Dabbs.*

30 *Likelihood of success:* It has been my experience on settlement approval motions, particularly where the settlement reflects a significant compromise, that the parties are reluctant to make detailed submissions about the likelihood of success. This is probably because neither party wants to admit to weaknesses in its case, in the event the action does not settle. In this case, one could say that the plaintiff has a good arguable case, but the defendant has some weighty potential defences, including absence of negligence, contractual exclusions and the limited nature of the purchasers warranty. This is definitely a case in which a prudent plaintiff would accept a significant discount in order to avoid the litigation risks associated with trial.

31 *Amount and nature of discovery:* There has been no discovery, but the plaintiffs counsel has had the benefit of information gleaned from the proceedings in the United States and has also, as I have noted, retained an expert witness. I am satisfied that class counsel has a full appreciation of the strengths and weaknesses of the case.

32 *Settlement terms and conditions:* I have set out the settlement terms above. There is a rational basis for the exclusion of certain claims based on difficulties of proof.

33 *Recommendations and experience of counsel:* The settlement comes with the recommendation of experienced and highly reputable class counsel.

34 *Future expense and likely duration of litigation:* There is absolutely no question that if this action is not settled, the plaintiffs will be faced with an adversary with deep pockets, which is strongly motivated to resist any attack on its brand. Dell has shown a willingness to engage in costly litigation, using experienced, hard-nosed and well-nourished counsel, to defeat these claims. With the litigation in the United States settled, the plaintiff in Canada would have to go it alone. There is no question that taking this action to trial will be an expensive and time-consuming process. It will likely cost at least another $1 million in unbilled fees and three or more years to take this action through discovery and to trial. These are circumstances that militate strongly in favour of settlement and are factors that any fee-paying litigant would take into account in assessing the value of an immediate settlement against the possibility of a future recovery.

35 *Recommendations of neutral parties:* The mediator has not, quite properly, expressed an opinion on the settlement. He has, however, confirmed that the negotiations were adversarial, lengthy and hard fought. I am satisfied that the settlement was the product of a true adversarial process and that class counsel sought to achieve a settlement that was in the best interests of all class members.

36 *Number and nature of objections:* The objections come from six individuals who will be excluded from the settlement class. Their objections are fair, reasonable and principled. Their main complaint is that the settlement does not include purchasers who had their computers repaired by someone other than Dell or its authorized service providers or who simply scrapped their computers without having them repaired.

37 This issue was addressed in the plaintiffs motion for settlement approval and also by way of supplementary submissions, at my request. The issue was raised in the settlement negotiations and Dell took the position that any settlement in Canada would have to be modelled on the settlements in the U.S., which did not include compensation for anything other than eligible repairs. In addition to this position, which appears to have been a "deal breaker", there was a genuine concern about the ability to identify claimants for non-eligible repairs and the administrative costs of verifying their claims. Ultimately, the proposed cy-près payment was put forward, and agreed upon, as a means of making some acknowledgment of these claims.

38 As well, of course, class members not included in the settlement have the right to opt-out, and it appears that approximately 100 class members have decided to do so.

39 Having considered this issue, I have concluded that although the objectors concerns are legitimate, and the settlement can be described as less than perfect to that extent, this settlement, like all settlements, is the product of compromise. While the court might prefer a more inclusive compromise, I am not prepared to say that the compromise was not a reasonable one.

40 *Good faith and absence of collusion:* I am satisfied that the settlement is made in good faith and that there was no collusion.

41 *Communication between class counsel and class members:* Class counsel has been in communication with the class through its web site.

42 *The dynamics of the negotiations:* As described above, the negotiations were adversarial and took place over two days. It is noteworthy that class counsel was given the opportunity to participate in the settlement negotiations involving the U.S. litigation. He declined to do so, based on the assessment that an independent settlement was in the best interests of the class. The settlement in Canada is a modest improvement on the settlement achieved in the United States.

The Cy-Près Component

43 Sub-section 26(4) of the *C.P.A.* provides:

> The court may order that all or a part of an award under section 24 [an aggregate assessment of damages] that has not been distributed within a time set by the court be applied in any manner that may reasonably be expected to benefit class members, even though the order does not provide for monetary relief to individual class members, if the court is satisfied that a reasonable number of class members who would not otherwise receive monetary relief would benefit from the order.

44 Subsection 26(6) provides that the court may make such an order even if the order would benefit persons who are not class members.

45 The proposed award in this case is set out above. Considering that the contribution of computers can be made in kind, and is calculated at retail value, the cost to Dell is quite modest. I assume that the contributions will also have a goodwill element that benefits Dell.

46 The cy près distribution will provide children in hospitals and in youth programs with Dell computers for their education, training and recreational use. To that extent, it can reasonably be expected to benefit certain members of the proposed class. Further, to the extent the contribution represents additional damages payable by Dell, it may be regarded as accomplishing the goal of behaviour modification, and thus advances the goals of the *C.P.A.*

Conclusion on Settlement Approval

47 For the foregoing reasons, I approve the settlement.

Class Counsel Fees

48 The settlement includes a payment of $2 million for the fees and disbursements, together with taxes, of class counsel. That fee was negotiated after agreement in principle had been reached on the main terms and structure of the settlement with class members.

49 The fee component is approximately $1.7 million which represents a multiple of approximately 1.3 on the base time of class counsel. The retainer between class counsel and the representative plaintiffs calls for a fee based on the higher of 25% of the total amount recovered or a multiple of three times the time spent. The proposed fee falls well within the latter.

50 Class counsel requests approval of the fee. It is the responsibility of the court to determine whether the fee is "fair and reasonable", having regard to the factors usually considered in the approval of a lawyers fee, as well as the goals of the *C.P.A.*

51 The factors to be considered include:

(a) the time expended by the lawyer
(b) the complexity of the matter;
(c) the responsibility assumed by the lawyer;
(d) the monetary value of the matter;
(e) the importance of the matter to the client;
(f) the degree of skill and competence demonstrated;
(g) the results achieved;
(h) the ability of the client to pay;
(i) the client's expectation as to the amount of the fee.

52 A fee of $2 million is undoubtedly large. It may well exceed the total compensation payable to class members under the settlement. In considering this fee, I keep in mind the following:

(a) the fee is consistent with the retainer agreement and with the expectations of the representative plaintiffs;
(b) no portion of the fee falls on class members - they are entitled to compensation without deduction for fees;
(c) this was a complicated class action, both procedurally and substantively - Dell was a sophisticated and tough-minded opponent and it put up an aggressive defence;
(d) the result achieved for the class is reasonable; and
(e) a very substantial amount of time was expended on this matter by class counsel, over a period of more than four years, without any compensation and with no assurance of compensation unless the action was successful.

53 Class action legislation in Ontario was prompted, in part, by a concern that consumer claims could not be economically advanced on an individual basis. The costs of individual action, against large corporations, is simply too high. Consumer class actions simply will not be undertaken by first rate lawyers, such as class counsel in this proceeding, unless they are assured of receiving fair - and I would add "generous" - compensation in appropriate cases. That compensation must take into account the risks they undertake - including the real risk of no payment at all, the risk of exposure to costs, and the cost of deferred recovery of compensation. Plaintiffs class action work is not for the faint-hearted. The defendants are frequently represented by large firms, with substantial hourly rates, which deploy teams of partners and associates who are able to mount an aggressive defence and no doubt endeavour to wear down plaintiffs counsel. Unless there are generous rewards for cases that are won, the number and quality of plaintiffs' counsel will inevitably decline.

54 Considering the foregoing, I approve class counsel's fee and disbursements.

Claims Administration and Reporting

55 The court will continue to exercise supervisory jurisdiction over the claims administration process until its conclusion. Class counsel will also remain involved. I wish to arrange a case conference with the claims administrator and counsel at an early date to discuss the claims administration protocol. This should include a provision to ensure that disallowed claims are subject to review by class counsel and ultimately by the court. The court should be copied on all reports from the claims administrator to counsel.

G.R. STRATHY J.

cp/e/qllqs/qlvxw/qlana/qljac

1 No doubt Dell's warranty would be voided if repairs were carried out by anyone other than an authorized repairer.

Case Name:

Andersen v. St. Jude Medical Inc.

PROCEEDING UNDER the Class Proceedings Act, 1992
Between
Yvonne Andersen on her own behalf and as Executrix of the Estate of Erik Andersen, Sharon Frost and Her Majesty the Queen in Right of the Province of Alberta, as represented by the Minister of Health and Wellness, Plaintiffs, and St. Jude Medical Inc. and St. Jude Medical Canada Inc., Defendants

[2012] O.J. No. 2921

2012 ONSC 3660

Toronto Court File No. 00-CV-195906CV

Ontario Superior Court of Justice

J.L. Lax J.

Heard: February 8, 2010; March 8, 2011 (138 days) (Evidence); May-August 2011 (by written submissions); September 12-15, 20-23, 2011 (oral submissions).
Judgment: June 26, 2012.

(595 paras.)

Tort law -- Negligence -- Duty and standard of care -- Duty of care -- Standard of care -- Causation -- Causal connection -- Class action based on medical device product liability claim dismissed -- Defendants designed, manufactured and sold Silzone heart valves and rings -- Family and patient classes of plaintiffs alleged defendants failed to reasonably evaluate safety and utility of product prior to entry to market and subsequently failed in duty to warn of risks -- Evidence established material risk in increase of paravalvular leak, but did not establish explanation for increase -- Evidence did not establish material increase in other complications at issue -- Plaintiffs failed to establish breach of duty regarding pre-market testing and post-market surveillance of products.

Tort law -- Suppliers of goods -- Product liability -- Duty to warn (product labeling) -- Duty to test

-- Manufacturers -- Class action based on medical device product liability claim dismissed -- Defendants designed, manufactured and sold Silzone heart valves and rings -- Family and patient classes of plaintiffs alleged defendants failed to reasonably evaluate safety and utility of product prior to entry to market and subsequently failed in duty to warn of risks -- Evidence established material risk in increase of paravalvular leak, but did not establish explanation for increase -- Evidence did not establish material increase in other complications at issue -- Plaintiffs failed to establish breach of duty regarding pre-market testing and post-market surveillance of products.

Class action by the plaintiffs against the St. Jude Medical defendants for damages for a medical device products liability claim. The defendants designed, manufactured and sold Silzone mechanical prosthetic heart valves and annuloplasty rings. Silzone was a coating designed to inhibit growth of infective bacteria that could cause serious complications in heart valve surgery. Prior to use of Silzone, the devices made by the defendants were favoured by cardiac surgeons due to their reliable performance and low complication rate. The devices were implanted in Canadian patients between 1997 and 2000, at which time a worldwide recall of all Silzone-coated products was issued by the defendants. An ongoing randomized clinical trial had revealed a statistically significant increase in a medical complication known as a paravalvular leak (PVL) in patients who had received a Silzone implant. The plaintiffs were comprised of a family and patient class. They alleged that the defendants failed to reasonably evaluate the utility and safety of Silzone before introducing it to the market and then failed in their duty to warn of its risks. They sought damages for negligence based on 11 common issues primarily related to design, testing, marketing and the relative risk of complications posed by Silzone valves. The plaintiffs advanced the theory that Silzone was a toxic substance that interfered with tissue healing and impaired the body's ability to properly incorporate the Silzone device into the heart, thereby causing or contributing to a variety of serious medical complications for Silzone patients.

HELD: Action dismissed. There was sufficient evidence to find that Silzone probably materially increased the risk of PVL for some patients for some period of time post-implant. The explanation for such increase was unclear. There was insufficient evidence to conclude that Silzone probably increased the risk of the other medical complications that were in issue. The plaintiffs did not succeed in proving that Silzone had an adverse effect on tissue healing. Therefore, no breach of the duty to warn arose. Although there was a high duty of care imposed on a medical device manufacturer, the plaintiffs did not establish that the defendants failed to exercise a reasonable degree of care in the pre-market design and testing or in the post-market surveillance of Silzone-coated products that would be expected of a reasonable and prudent prosthetic heart valve manufacturer in similar circumstances.

Statutes, Regulations and Rules Cited:

Class Proceedings Act, S.O. 1992, c. 6, s. 5(1)(a)

Medical Devices Regulations, C.R.C., c. 871, s. 38(a)

Counsel:

Angus T. McKinnon, Peter W. Kryworuk, Russell Raikes and *James M. Newland*, for the Plaintiffs.

S. Gordon McKee and *Jill M. Lawrie*, for the Defendants.

Additional Plaintiffs' Lawyers: Ed Morgan, Sandra Barton, Stephanie Montgomery, Rebecca Case, Brian P.F. Moher, Yola S. Ventresca, Louise F. Moher, Paul Hendrikx, Andrea D'Silva, Mark Hines.

Additional Defendants' Lawyers: Tony S.K. Wong, Marcy T. McKee, Robin L. Reinertson, Ashley P. Richards, Karin J. McCaig, Nicole D. Henderson, Robin D. Linley.

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Judgment

J.L. LAX J.:--

SYNOPSIS

1 This is a medical device products liability claim that was certified as a class proceeding by Mr. Justice Cullity in 2003 on behalf of a patient class and a family class and continued on to a trial of common issues before me in 2010 and 2011. The trial was about the safety of the mechanical

prosthetic heart valves and annuloplasty rings with Silzone (R) that were designed and manufactured by the defendants and approved for sale in Canada in the late 1990s. They were implanted in Canadian patients between September 1997 and January 21, 2000, when the defendants issued a worldwide recall of all Silzone-coated products. At that time, an ongoing randomized clinical trial called 'AVERT' revealed a small, but statistically significant increase in explants due to a medical complication known as paravalvular leak (PVL) in patients who had received a Silzone implant. As a result, enrolment of patients in the AVERT study was terminated.

2 Silzone is a proprietary term for a coating comprising layers of titanium, palladium and an outer layer of metallic silver. This was applied to the polyester (Dacron (R)) sewing cuff that surgeons use to attach a prosthetic heart valve to heart tissue. Silver is known as an antimicrobial in medicine and the Silzone coating was designed to inhibit the growth of the bacteria that can cause endocarditis, an infection that is a serious complication of heart valve surgery. In some forms and concentrations, silver can be cytotoxic to cells, but at the time that Silzone was developed, silver had been shown to be effective against bacteria and safe to use in applications such as wound dressings, sutures and catheters. Apart from the application of the Silzone coating to the Dacron sewing cuff, the Silzone valves were of the same design as the conventional mechanical valves that the defendants had manufactured for many years. These valves were considered to be the "gold standard" in mechanical heart valves and were favoured by many cardiac surgeons due to their reliable performance and low complication rate.

3 The Silzone valve also enjoyed widespread use during the time it was on the market even though a few Canadian hospitals stopped using Silzone-coated devices in the year preceding the recall and in November 1999, the United Kingdom Medical Devices Agency (MDA) issued an Advice Notice to physicians warning about possible thromboembolic complications (TE events).The MDA took no other action, but within days of this notice, Australian and New Zealand regulators withdrew approvals for Silzone products in those countries. Health Canada and the United States Food and Drug Administration (FDA), as well as the Data Safety Monitoring Board (DSMB) for the AVERT clinical trial, were well-informed about this, but they did not express concerns about the safety of the valve or take any action. The Silzone devices continued to be marketed in Canada and in the United States as well as in the United Kingdom and Europe until the recall. At the time of recall, about 36,000 valves had been sold in markets around the world.

4 There are nine common issues to be answered, but at its core (although on a grand scale), this is a negligence claim and the evidence focused on two of its major elements: breach of duty causing injury and cause. The trial examined the defendants' conduct in designing, testing and marketing the Silzone valve (Common Issue 1) and considered questions of general causation - whether Silzone has an adverse effect on tissue healing (Common Issue 2) and whether the risk of medical complications is greater for patients with Silzone valves (Common Issue 3). The preponderance of the evidence that was adduced at trial addressed these common issues. The remaining common issues are largely concerned with entitlement to the remedies the plaintiffs seek: medical monitoring (Common Issues 4 and 5), spoliation (Common Issue 6), disgorgement of profits or 'waiver of tort'

(Common Issues 7 and 8) and punitive damages (Common Issue 10(a)).[1] The trial was concerned only with liability and Common Issues 9 and 10(b) on quantum of damages were bifurcated to the end of the trial of common issues.

5 The plaintiffs needed to establish on a balance of probabilities a "but for" negligent act or omission linking the defendants' conduct to a class-wide injury in order to move the claims of each class member forward to individual hearings. They tried to show that the defendants failed to reasonably evaluate the utility and safety of Silzone before introducing it to the market and then failed in their duty to warn of its risks. A theme was that the Silzone valve was rushed to market in view of the pending expiry of the patent for the defendants' successful bileaflet valve. The plaintiffs advanced the theory that Silzone is a toxic substance that interferes with the cells involved in tissue healing and impairs the body's ability to properly incorporate the Silzone device into the heart, thereby causing or contributing to a variety of serious medical complications for Silzone patients. As medical complications can occur with all prosthetic heart valves, a key inquiry in this trial was whether a Silzone coating on a mechanical heart valve puts patients at a *materially increased risk* of experiencing one or more of these complications.[2]

6 There is sufficient evidence to find (and the defendants do not dispute) that Silzone probably materially increased the risk of PVL for some patients for some period of time post implant. The explanation for this is unclear. There is insufficient evidence to conclude that Silzone probably increased the risk of the other medical complications that are in issue and the plaintiffs did not succeed in proving that Silzone has an adverse effect on tissue healing. Although there is a high duty of care imposed on a medical device manufacturer, the plaintiffs did not establish that the defendants failed to exercise a reasonable degree of care in the pre-market design and testing or in the post-market surveillance of Silzone-coated products that would be expected of a reasonable and prudent prosthetic heart valve manufacturer in similar circumstances.

7 These findings lead to the conclusion that the action must be dismissed.

INTRODUCTION

The Trial

8 The trial was lengthy and complex. Some 2,293 documents were introduced into evidence as exhibits in electronic format with many exhibits running to hundreds of pages. The court heard testimony for 138 days from 40 witnesses, including 23 expert witnesses from 14 different disciplines in science and medicine. At the conclusion of the evidence, the parties delivered voluminous written submissions over a period of several months and 18 months after the trial had commenced, it concluded in late September 2011 with eight days of closing submissions.

9 There is a vast and challenging evidentiary record to consider and opposing expert opinions to resolve in order to arrive at the answers to those issues that the certification judge determined could be tried as common issues. To assist me, the parties provided their written submissions in electronic

format with hyperlinks to the transcripts of witness testimony, the exhibits, and numerous legal authorities. Their submissions alone comprise more than 2,000 pages.

10 The parties left no stone unturned in presenting this important case to the court and I have reviewed the extensive record many times and given careful consideration to all of it. However, if I were to discuss every argument and every detail of the evidence, this judgment would also run to thousands of pages, which I do not believe is necessary or desirable. Instead, I have tried to select the key arguments and evidence that the parties rely upon and explain how this has led to the conclusions that I have reached. Although I will not discuss everything, I hope to demonstrate that I have given careful consideration to all issues that are truly of substance. In parts of these reasons, I have used a narrative format. Unless I indicate otherwise, these are findings of fact.

11 In preparing these reasons, I have borrowed liberally from the parties' written submissions. I have incorporated portions as my own where I considered it appropriate to do so. Without their roadmaps through 138 days of evidence as well as the additional written material that was prepared for closing submissions, my task would have been considerably more difficult. I am grateful to counsel for the invaluable assistance provided to the court at each phase of the trial process. I am also indebted to them for the exemplary manner in which they conducted the trial.

The Parties

12 St. Jude Medical, Inc. is a global manufacturer of medical devices with its headquarters in St. Paul, Minnesota. St. Jude Medical Canada, Inc. is its wholly-owned subsidiary. St. Jude manufactured and distributed three Silzone-coated products in Canada - the St. Jude Medical Mechanical Heart Valve SJM Masters series with Silzone (Silzone valve), the St. Jude Medical Mechanical Heart Valve SJM Regent Valve with Silzone (Regent valve) and the Sequin Annuloplasty Ring with Silzone (Sequin Ring).[3] The SJM Tailor Annuloplasty Ring with Silzone coating and the Epic valve with Silzone were also manufactured by the defendants, but they were not sold in Canada.

13 In May 1997, St. Jude submitted applications for regulatory approval to distribute and sell the Silzone valve to Health Canada, the FDA and regulatory agencies in Europe. The application was filed as a Supplementary Notice of Compliance (SNOC) in Canada and as a Pre-Market Application Supplement (PMA Supplement) in the United States. It was approved in both countries as a modification to the Masters series valve.[4]

14 The patient class consists of approximately 1100 Canadian residents other than residents of Quebec and British Columbia whose native aortic or mitral heart valves, or both, were replaced with a Silzone valve. At the time of certification, the plaintiff class was represented by Sharon Frost and Erik Andersen. Sharon Frost received a Silzone valve in the mitral position on April 13, 1998 that was explanted and replaced with another Silzone valve on August 20, 1998. That valve remains in place and Ms. Frost was the first witness to testify at trial in February 2010. Erik Andersen received a Silzone valve in the mitral position on May 28, 1998 that was explanted on July 27, 1998 and

replaced with a second Silzone mitral valve. At the same time, Mr. Andersen's native aortic valve was replaced with a Silzone valve. Mr. Andersen died on January 15, 2005 with both Silzone valves still implanted. His widow, Yvonne Andersen, replaced him as class representative in her personal capacity and in her capacity as executrix of his estate. Mrs. Andersen was the second witness to testify at trial.

15 The evidence of the representative plaintiffs occupied less than a day of the trial. In the section that follows, I introduce the other fact witnesses who were involved in the Silzone story in the 1995 - 2000 timeframe and whose evidence contributed to my understanding of Silzone from product development to recall.

The Fact Witnesses

Plaintiffs' Witnesses

16 In 1997, Dr. Keith Butler and Dr. William Freeland held positions in the Health Protection Branch of Health Canada. Dr. Butler has a Ph.D. in physiology and was a scientific reviewer in the cardiovascular division who was assigned to the application submitted by St. Jude for Canadian regulatory approval for the Silzone valve. Dr. Freeland is a medical doctor and was the Chief, Device Evaluation Division, Medical Device Bureau. Their evidence addressed the Canadian regulatory regime for a medical device and the approval process for the Silzone valve.

17 Jagdish Butany and Eric Butchart are physicians and were among the first to raise concerns about the Silzone valve. Dr. Butany is an internationally recognized cardiovascular pathologist at the Toronto Hospital, University Health Network (TGH) who was summoned to testify. Mr. Butchart is a senior cardiovascular surgeon at University Hospital of Wales, Cardiff, Wales and is an internationally recognized cardiothoracic surgeon, specializing in thromboembolic complications of heart valve surgery.[5]

18 All heart valves have thrombogenic potential in that thrombus may form on the leaflets or sewing cuff that can cause a blockage either at the valve site or elsewhere in the body after breaking away and travelling through the bloodstream. In the 1990s, Mr. Butchart was conducting an ongoing study known as 'CERFS' at his Cardiff hospital to evaluate the risks of thromboembolic complications (TE events) in patients following valve surgery.[6] Patients with Silzone valves were enrolled in the study between October 1997 and July 1998. He concluded that there was an increased incidence of TE events in these patients. His study findings strongly influenced the MDA to issue its Advice Notice to U.K. physicians in November 1999 and this, in turn, influenced the decisions of the Australian and New Zealand regulators to cancel the registration of Silzone products in these countries. Mr. Butchart was also a key expert witness for the plaintiffs, particularly on questions of thrombogenicity and TE events.

19 Drs. George Christakis, Ghopal Bhatnagar and Hugh Scully are cardiovascular surgeons who held staff positions at teaching hospitals in Toronto at the relevant time. They testified about their

experience with the Silzone valve in their respective hospitals. Dr. Christakis was also qualified as an expert witness, mainly on the issue of medical monitoring for Silzone patients.

20 Through the read-in process, the plaintiffs adduced evidence given at U.S. depositions or Canadian discovery from a number of St. Jude employees or former employees.

Defendants' Witnesses

21 Dr. Katherine Tweden, Mr. William Holmberg and Dr. Alan Flory were the main fact witnesses for the defendants. Dr. Tweden holds a Ph.D. in biomedical engineering with a focus on biomaterials and was the senior scientist on the Silzone project. She conducted the initial investigations on the antibacterial potential of a silver-coated sewing cuff, evaluated the *in vitro* efficacy and safety testing, and participated in many aspects of the *in vivo* sheep studies that assessed tissue healing. William Holmberg is a mechanical engineer and was the Silzone project team leader. Among other things, he was responsible for co-ordinating the work of the team members, facilitating Design Review meetings where key aspects of the project were discussed, and reporting periodically about the status of the project to the executive group at 'goaltending' sessions. Dr. Flory is a doctor of veterinary medicine and was Vice President of Corporate, Clinical and Regulatory Affairs. He and his staff were involved in the pre-market regulatory approval process, the AVERT study design and implementation, and post-market surveillance and recall.

22 Other St. Jude employee witnesses were Terry Shepherd, President of the Heart Valve Division until 1999 and later, Chief Executive Officer of the company, and Dr. Wenda Carlyle, a research scientist at the company between 1997 and 2000. Dr. Robert Frater is a cardiothoracic surgeon who served as Medical Director of the company from 1999.

23 At the time that Silzone was developed, St. Jude was known as a very good company with a reputation for producing very good products. The St. Jude employee witnesses who testified struck me as very able people who individually reflected the attributes that had earned St. Jude that reputation. They demonstrated professionalism and concern for their work and I was favourably impressed with their testimony. I found each of them to be credible, forthright and honest witnesses.

24 Spire Corporation developed the technology for the Spi-Argent coating that ultimately became Silzone. Eric Tobin is Vice-President and Chief Operating Officer of Spire Biomedical Inc., a division of Spire Corporation. During the relevant time period, he was a research scientist who worked on the development of the Spi-Argent coating.

25 Dr. Hartzell Schaff is a cardiothoracic surgeon and Chair, Cardiothoracic Surgery Division at the Mayo Clinic in Rochester, Minnesota. Dr. Schaff was the AVERT Principal Investigator for North American sites. Dr. Lisa Kennard was a member of the Department of Epidemiology at the University of Pittsburgh. Dr. Kennard was the AVERT Study Coordinator between 1998 and 2002 when she became AVERT's co-Principal Investigator, a position she continues to occupy.

AVERT

26 As the AVERT study figures so prominently in the trial, and in particular, in the causation analysis in Common Issue 3, I will introduce it briefly here. AVERT was a randomized control trial (RCT) sponsored and funded by St. Jude and is an acronym for Artificial Valve Endocarditis Reduction Trial. Its purpose was to study whether Silzone was clinically effective in reducing prosthetic valve endocarditis, but its protocol included the collection of data on adverse events that are complications of valve surgery. The protocol specified that the study would take four years to complete.

27 RCTs comparing mechanical heart valves are uncommon, but during its development of the Silzone coating, St. Jude began planning for a post-approval clinical trial to establish that the Silzone coating would reduce the incidence of prosthetic valve endocarditis in patients implanted with a Silzone valve. Until this was demonstrated, the FDA did not permit St. Jude to make efficacy claims in its product labelling or marketing. AVERT was designed as a large, multi-centre, study with the study population coming from 17 centres in North America and in Europe and with patients randomized into two groups - those who received a Silzone valve and those who received a conventional St. Jude valve. Dr. Schaff was to serve as Principal Investigator in North America and Dr. Thierry Carrel, a cardiac surgeon in Bern, Switzerland, was to serve as Principal Investigator in Europe.

28 The Epidemiology Data Coordinating Center (DCC) at the University of Pittsburgh was selected to receive reports from the various clinical centres and maintain a database. The DCC, in turn, was to recruit members from the medical community to serve on a Data Safety Monitoring Board (DSMB). Its role was to review the AVERT data and make recommendations as to the conduct of the study having regard to the safety of enrolled patients. Its membership included specialists in cardiology, cardiac surgery, infectious disease and statistics. The DSMB was to operate independently from St. Jude as study sponsor and funder, from Drs. Schaff and Carrel as investigators, and from the DCC.

29 The design of the AVERT study was well underway by early 1998 at a time when the Silzone valve was undergoing the regulatory review process at the FDA. The Silzone valve was not approved for sale in the United States until March 1998, some eight months after it was approved for sale in Canada. A study sample size of 4400 patients - 2200 patients in each of the Silzone and non-Silzone arms of the study - had been calculated by Dr. Gary Grunkemeier, statistical consultant for AVERT. The study was launched in the summer of 1998 with the first implant taking place in August of that year.

30 When the DSMB recommended in January 2000 that patient enrolment in AVERT be suspended, there were a total of 807 patients enrolled - 403 in the Silzone arm and 404 who had received non-Silzone valves. It is these patient populations who continue to be comparatively followed in the AVERT study for risk of medical complications to find out whether these risks are

greater for patients with Silzone valves than they are for those with the conventional St. Jude valve.

Adverse Inferences

31 The plaintiffs provided the court with a list of individuals whom they say are material witnesses that the defendants failed to call. An adverse inference may be drawn in circumstances where a party fails to call a witness who would have knowledge of the facts and would be assumed to be willing to assist the party. It also may be drawn against a party who does not call a material witness over whom he or she has exclusive control and does not explain it away.[7] An adverse inference is not justified where the issue has been adequately covered by another witness, or by other evidence.[8] The fundamental condition for the operation of the rule is that it applies only to issues material to the determination of a case and only where the case made against the party is of such strength that it calls for a reply.

32 The first group of witnesses the plaintiffs say should have been called includes scientists or physicians who were involved in aspects of the AVERT study - Dr. Holubkov, Dr. Grunkemeier, Dr. Davila-Roman and Dr. de la Rivière. There is no evidence that the defendants exercised exclusive control over these individuals, nor can it be assumed that they would have been willing to assist the defendants merely because they were participants in AVERT. The defendants adduced evidence from Dr. Schaff and Dr. Kennard - two key participants in the design and conduct of the AVERT study - as well as from Dr. Flory. All of the material AVERT issues were addressed by these witnesses and none of the proposed witnesses had evidence material to the determination of the case.

33 The second group, Connie Roos, Monica Schultz and Barbara Illingworth, were St. Jude employees between 1995 and 2000.[9] There is no evidence they were employees at the time of trial and there is no reason to assume that they would have been willing to assist the defendants by reason only of their employment more than a decade earlier. The plaintiffs had access to the deposition evidence of these witnesses and by agreement, the ability to adduce the evidence of Ms. Schultz and Ms. Illingworth through the read-in process.[10] If the plaintiffs considered the evidence of Ms. Roos necessary, they could have taken their own steps to adduce her evidence. While each of these potential witnesses are out of the jurisdiction and would only be compellable to give evidence by Letters of Request, the plaintiffs had equal ability to use that process.

34 Richard Bianco and Dr. Douglas Cameron were consultants to St. Jude and involved in the pre-market animal studies. The plaintiffs' read-in discovery evidence shows that while Dr. Cameron initially provided some information to the defendants for responses to undertakings during the Ontario discovery process, he did not continue to do this. If he would not assist the defendants during the discovery process, it is unlikely he would be willing to assist them at trial. Mr. Bianco did appear on the defendants' witness list, but months before the trial process was completed, the plaintiffs were advised that they did not propose to call him as a witness. As part of the plaintiffs' consent to resolve two outstanding motions related to Mr. Bianco, the defendants paid the plaintiffs'

costs of the motions and agreed not to call him at any future time. There is no justification for drawing an adverse inference in circumstances where the defendants do not call a witness in compliance with an undertaking.

35 Dr. Tirone David is a world renowned cardiac surgeon at TGH who was conducting a prospective, randomized comparison of the St. Jude bileaflet valve to the bileaflet valve of a competitor valve manufacturer. Silzone patients were added to the study in 1997. The plaintiffs submit that Dr. David's evidence ought to have been adduced in relation to "the Toronto experience" with the Silzone valve. Dr. David was a treating surgeon for one or more class members and he is not a witness who was in the exclusive control of St. Jude. His evidence was equally available to the plaintiffs. Like Dr. Butany, he could have been summoned to testify.

36 There are many reasons why a party may not call witnesses and drawing an adverse inference is an increasingly rare finding and one that should be exercised with "the greatest of caution".[11] This is, in part, due to the increased access to pre-trial discovery. As there is a freer exchange of documents and discovery of witnesses, it is the rare case that only one party is able to bring a witness before the court. In this proceeding, the plaintiffs also had access to deposition evidence from the U.S. Silzone litigation. This significantly broadened the scope of the discovery. The fairness considerations for drawing adverse inferences that might apply in some circumstances do not apply here.

37 In each of the cases relied on by the plaintiffs, the missing evidence was considered of crucial importance to a key element of the case.[12] In this instance, the plaintiffs failed to identify except in the most general way the inferences that they wished the court to draw. I am hard pressed to identify any evidentiary gaps on material issues that demanded a response from the defendants. Consequently, I decline to draw any adverse inferences.

The Expert Witnesses

38 Expert evidence is essential to resolve the standard of care question in Common Issue 1 on the adequacy of the pre-market testing as well as the general causation questions in Common Issues 2 and 3 which require an understanding of the process of tissue healing, the mechanism of action of silver and epidemiological and statistical evidence of risk. The court was privileged to hear evidence from many distinguished physicians and scientists. Schedule II is a chart listing the expert witnesses who testified at trial and their respective areas of expertise.

39 For the most part, the defendants' experts were the more qualified experts on the issues that are before the court. Dr. Schoen is an internationally recognized cardiac pathologist who also holds a Ph.D. in materials science and has extensive experience performing pathological analysis of prosthetic heart valves. Dr. Williams, the defendants' biomaterials expert, is an internationally recognized expert in biomaterials and tissue response to biomaterials, especially the biocompatibility of silver, with extensive research and experience with animal studies. He has also been involved in the design and testing of prosthetic heart valves since the mid 1990s. While Dr.

Rodricks, the defendants' toxicologist, lacked experience with prosthetic heart valves, he was expert on the toxicity of metals and evaluating the safety of medical devices for toxicity.

40 Dr. Williams and Dr. Rodricks concluded that St. Jude's testing was reasonable and in accordance with industry standards. They testified that the results of the testing as well as the scientific literature gave no indication that Silzone would cause adverse reactions in patients. Dr. Williams' opinion on the adequacy of the safety testing was supported by Diane Johnson, a former lead reviewer at the FDA of prosthetic heart valve submissions for regulatory approval. Ms. Johnson was personally involved in the drafting of the FDA's 1994 Draft Heart Valve Guidance and the ISO 5840 standard, the documents that were looked to by industry and regulators at the time when considering what testing should be done for prosthetic heart valves. Dr. Williams' interpretation of the results of the sheep studies was supported by Dr. Factor, a cardiac pathologist with recognized expertise in prosthetic heart valves, healing in heart valves implanted in sheep, and the pathology of endocarditis.

41 On the other hand, the plaintiffs' expert, Dr. Healy, a biomaterials scientist with otherwise impressive qualifications, had no experience with silver or cardiac devices in terms of pre-market testing. The major background of Dr. McLean, one of the plaintiffs' toxicologists, was in pharmaceutical medicines rather than medical devices. Dr. Olson had done some testing of silver-coated wound dressings, but the plaintiffs called him to testify about the adequacy of the two sheep studies. He had experience with sheep studies, but no experience with sheep studies involving implanted cardiac devices, particularly prosthetic heart valves. Dr. Wilson, the plaintiffs' expert in pathology, lacked experience in sheep studies and in valve disease in adult patients.

Assessment of Scientific Evidence

42 The plaintiffs sought to prove a causal relationship between Silzone and medical complications on the basis of a theory of silver toxicity that they supported through the evidence of their expert witnesses, principally, Drs. Healy, Wilson, Madigan Sackett and Mr. Butchart. Dr. Madigan is a statistician. Dr. Sackett is an epidemiologist. Both are highly qualified. The reliability of this evidence is central to the plaintiffs' burden of proof of causation. That burden is described by Justice Osler in *Rothwell* and I adopt his language:

> ... it cannot be forgotten that the onus does lie upon the plaintiffs to establish, if only by the slimmest balance of probability, that a named cause is likely. To demonstrate a possibility is not enough; probability must be established.[13]

43 The reliability of expert opinion evidence is considered both at the stage of assessing its admissibility (threshold reliability) and at the stage of determining what weight, if any, should be given to that evidence (ultimate reliability). The assessment of threshold reliability is an assessment of the principles and methodology underlying an expert's opinion to determine if they are of sufficient reliability that the opinions based upon those methods ought to be admitted into evidence. Where a scientific theory or technique is "novel", the Supreme Court of Canada held in *R. v. Mohan*

that it must be subjected to special scrutiny to determine whether it meets a basic threshold of reliability.[14]

44 In *Daubert*, the court considered a number of factors to assist it in determining whether a theory or a technique constitutes scientific knowledge and has sufficient reliability. These include: (1) whether the theory or technique has been tested, (2) whether it has been subject to peer review and publication, (3) its known or potential error rate and the existence and maintenance of standards controlling its operation, and (4) whether the theory or technique has received general acceptance.[15] These criteria were adopted by the Supreme Court of Canada in *R. v. J.-L.J.* and discussed by Justice Goudge as Commissioner in the Inquiry into Pediatric Forensic Pathology in Ontario.[16]

45 A scientific theory, method or technique that is generally accepted for some purpose, may be novel when used for a different purpose, and as such, fail to satisfy reliability criteria. For example, at issue in *J.-L.J.* was a technology that had been generally recognized by the scientific community to monitor the result of treatment for sexual pathologies. The Supreme Court of Canada found that the trial judge properly excluded opinion evidence of an expert who was using the technology as a forensic rather than therapeutic tool. The techniques the expert had employed were not novel and may have been useful in therapy to obtain information about a course of treatment for a patient, but they were not sufficiently reliable to be used in a court of law to identify or exclude the accused as a potential perpetrator of an offence.[17]

46 The need for special scrutiny of novel science was first identified in *Mohan* to ensure that only reliable evidence would be heard by a jury, but this concern has gradually broadened. Justice Goudge observed that reliability is a fundamental organizing principle in the law of evidence and must be a constant concern of judges in their gatekeeper role, whether or not the science is novel. He also noted that the jurisprudence has been moving in the direction of recognizing the importance of reliability standards for all expert evidence, if not all evidence.[18] In assigning weight to the opinions of experts, there is no reason for a court to relax its scrutiny of the evidence even though the evidence has passed through the threshold reliability gate. This demands a rigorous evaluation of the experts' theories and methodologies (including the kind and quality of studies relied on), their application to the conclusions that the expert reached, and an understanding of the purpose for which those conclusions are advanced. As to why this is needed, Judge Richard Posner is quoted as saying, "the court is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it".[19]

47 While the court must determine the answers to the common issues before it on a balance of probabilities and scientific certainty is not the standard of proof, the underlying message of *J.-L. J.*, echoed in The Goudge Report, is that in assigning weight to individual pieces of scientific evidence, the court must pay attention to its purpose and underlying methodology and be guided by the methods and principles generally accepted and applied in the relevant scientific communities. A level of reliability that may be useful to formulate a plausible hypothesis may not be sufficiently reliable to prove causation and ascribe fault.

48 For example, there is a generally accepted hierarchy within the scientific community of different kinds of epidemiological studies that may be helpful in investigating relationships of cause and effect.[20] At the top of the hierarchy is a RCT such as AVERT. Lower down in the hierarchy are cohort studies, case studies and case reports. There is consensus within the scientific community that a RCT, if well done, is the most reliable scientific evidence to support conclusions about causation. Studies below this in the hierarchy are generally not regarded as capable of generating evidence to support a causal relationship, although they may be useful for other purposes. As Justice Osler said in *Rothwell*:

> It is important to remember that the plaintiffs must prove their case and in medical and scientific matters it is not sufficient to show that a cause and effect sequence is theoretically possible. For the plaintiffs to discharge their onus they must show, on the balance of probability, that a cause and effect relationship does exist.[21]

49 In this case, the methodology applied by some of the plaintiffs' experts called into question the reliability of their opinions on causation. Examples include Dr. Wilson's use of a clinico-pathological correlation of 18 valves in 14 patients (14 patient study) to support his causation opinions on Silzone toxicity, Mr. Butchart's CERFS study to support his opinions on increased TE events in Silzone patients, Dr. Madigan's cohort analysis of the AVERT data to support his opinion on when risk is present and Dr. Sackett's two-part test to support his opinion on continuing harm. I will later explain why these are unreliable methodologies to support the opinions for which they were advanced.

50 I will explain in Common Issue 2 why the plaintiffs failed to demonstrate on a balance of probabilities that abnormal tissue healing is the mechanism by which (or how) Silzone causes medical complications. In Common Issue 3, I will explain why the evidence does not support an inference on causation, upon which the plaintiffs relied heavily to assist their burden of proof of causation. As I point out there, I recognize that the plaintiffs do not have to demonstrate *how* Silzone causes medical complications in order to prove *that* it does. However, reliable evidence as to how Silzone would cause medical complications would be able to support an inference that it does. That evidence was lacking.

51 As one would expect in a trial dominated by scientific evidence, there were numerous articles from the scientific literature that were introduced into evidence as exhibits. The question arises as to their evidentiary value. Justice Osler in *Rothwell* again provides guidance:

> The principal value of the studies, and of the various articles and learned papers to which reference was made in the course of the trial, is to act as touchstones which may be used to test the opinions of the witnesses who gave *viva voce* evidence and filed their reports before the court. While my conclusions must be based upon the evidence, and that of course means that I must assess and choose

> between the evidence of the experts where they are not in agreement, I may use the articles and reports as one of my means of assessment. While in most cases the reports are not evidence of the truth of the facts or the validity of the opinions stated therein, they are evidence, when such is acknowledged by the appropriate witnesses, of the fact that they were published, they were circulated and they were part of what has been referred to as "... the general corpus of medical and scientific learning on the subject and can be relied upon and adopted by suitably qualified experts": *Loveday v. Renton and Wellcome Foundation Ltd.*, unreported but delivered by Stuart-Smith L.J., in the Queen's Bench Division, High Court of Justice, England, March 29, 1988.[22]

52 As the excerpt explains, there are three principal uses: (1) to act as "touchstones" to assess opinion evidence; (2) to establish the fact of publication as part of the general body of scientific learning on the subject; and (3) to form part of the opinion of the witness, but only if the witness adopts passages or relies on study data from the article. During the course of these reasons, the scientific articles I refer to are footnoted with a brief reference. A bibliography of the articles with a fuller citation is found in Schedule III. A Glossary of Medical Terms is found in Schedule IV.

Order of Determination of the Common Issues

53 It is the defendants' position that the court's determination as to what, if any, risks materially increased as a result of the addition of the Silzone coating will have a fundamental impact on what has to be determined in respect of the other common issues. They argue that as a person who acts without reasonable care commits no tort unless his lack of care causes damage, the defendants' conduct need only be considered under Common Issue 1 on standard of care to the extent it relates to a medical complication found to be at a materially increased risk under Common Issue 3. Accordingly, they submit that the first issue the court should determine is Common Issue 3 together with Common Issue 2 on tissue healing, which they describe as a sub-question of Common Issue 3 because any effect on tissue healing would be of no consequence if it is not proven to materially increase the risk of one or more medical complications.

54 I agree that Common Issues 2 and 3 are related to one another, but it is not clear to me that addressing causation first will allow the court to narrow its standard of care analysis. The only assistance to be derived from the authorities the parties referred to is that the court must carefully consider the interaction between standard of care and causation and that to fail to consider causation may, in some circumstances, constitute legal error.[23] There are cases such as

Rothwell and *Buchan* where the court has chosen to address causation before standard of care,[24] but the cases do not establish a requirement that the parties are "entitled" to findings with respect to causation before standard of care is addressed. This is a matter for the court's discretion.

55 As I will discuss in Common Issue 3, there is insufficient evidence to conclude that Silzone patients are at a materially increased risk of experiencing medical complications with the exception

of the complication known as PVL. Although I agree with the defendants that the company's conduct need only be considered under Common Issue 1 to the extent it relates to this complication, I have not found it easy to isolate the standard of care evidence for only this complication. As a result, there is no efficiency to be gained by addressing causation first. As well, I believe that addressing standard of care first will yield a more coherent narrative of the story of Silzone. I therefore propose to review the first three common issues in order.

COMMON ISSUE 1

Did the defendants breach a duty of care owed to class members by reason of the design, pre-market testing, regulatory compliance, manufacture, sale, marketing, distribution and recall of Silzone-coated mechanical heart valves and annuloplasty rings implanted in such members?

56 The parties addressed Common Issue 1 in two parts as Common Issue 1a - pre-market design, manufacture and testing; and Common Issue 1b - post-market surveillance, warning and recall. The defendants acknowledge that St. Jude owed a duty of care to patient class members to take reasonable care in the design and testing of its products and in its post-market surveillance. What is at issue is whether there was a breach of that duty.

57 The existence of a duty of care is a question of law: the standard of care that applies is a factual inquiry and defines the content of the duty that is owed.[25] To establish a breach of duty, a plaintiff must demonstrate, without the benefit of hindsight, some act or omission of the defendant in the present circumstances that was inconsistent with the conduct to be expected of alike-situated party, that is, the conduct of an ordinary, reasonable and prudent prosthetic heart valve manufacturer in similar circumstances. The measure of what is reasonable was described by the Supreme Court in *Ryan v. Victoria*:

> ... what is reasonable depends on the facts of each case, including the likelihood of a known or foreseeable harm, the gravity of that harm, and the burden of costs which would be incurred to prevent the injury. In addition, one may look to external indicators of reasonable conduct, such as custom, industry practice, and statutory or regulatory standards.[26]

Common Issue 1a - Design and Testing

58 The plaintiffs do not contest their burden to show that if Silzone materially increased the risk of any medical complication, such increased risk was attributable to some act or omission by the defendants that fell below the standard of care. The plaintiffs contend that St. Jude's testing was inadequate and did not provide a proper scientific basis to support either the efficacy of Silzone or its safety and that as a result, St. Jude did not exercise reasonable care in analyzing the risks and benefits of adding the Silzone coating to its conventional valve. The plaintiffs do not clearly articulate what level of testing they allege was required by the requisite standard of care, but suggest that different and more extensive animal and pre-market clinical studies were required before the

valve was marketed.

59 It is the defendants' position that the nature and extent of the testing they performed satisfied the standard of care as informed by industry standards and the regulatory environment, and that, in any event, the plaintiffs have failed to adduce evidence to demonstrate that, if the standard of care required further testing, this would have affected the risk utility analysis and the reasonableness of St. Jude's decision to introduce Silzone-coated products.

Risk Utility Assessment

60 The parties agree that the standard of care applicable to St. Jude as a medical device manufacturer required it to perform a risk utility assessment and to exercise reasonable care in doing so. They disagree on (i) the degree of certainty the defendants were required to have about the benefits of Silzone before distributing the product, (ii) the reasonableness of the product development process including the testing undertaken and the manner in which the testing results were interpreted and, (iii) the role and impact of industry and regulatory standards and practices and regulatory approval.

61 A risk utility assessment is a concept adopted from United States jurisprudence that is used to determine whether a manufacturer has been negligent in the design of a product.[27] It requires a balancing or weighing of foreseeable risk against the foreseeable utility of the product based on information available to the manufacturer at the time of distribution of the product and without the benefit of hindsight. Health Canada and the FDA both apply a risk benefit analysis when reviewing submissions to approve new prosthetic heart valves or modifications in order to determine whether they are safe and effective. The Health Canada witnesses both testified that this involves weighing the known and potential risks of a device against the known and potential benefits and determining whether the benefits outweigh the risks. Ms. Johnson described this in the FDA process as being reasonably assured that the probable benefits to health outweigh the probable risks.

62 In *Rentway*, the court provides a list of seven factors to consider (only a few are relevant factors in this case) but offers little guidance on how to apply these in order to assess the reasonableness of the risk utility assessment of the manufacturer. The defendants, relying on American case law, submit that a manufacturer is required to weigh the likelihood of both the benefit and the risk offered by a product as well as the value of the potential benefit and the seriousness of the potential risks. Based on the American case law cited by the defendants as well the U.S. case law referred to by Mr. Justice Cumming in *Ragoonanan*, I find that this is the assessment that the defendants were required to undertake. Put another way, St. Jude was required to weigh both the gravity and the likelihood of the reasonably foreseeable risks posed by the Silzone valve relative to the potential extent of its utility and the likelihood that the potential utility could be realized.

Initial Investigations

63 The Spi-Argent technology that ultimately became Silzone was developed in the 1990s by Dr. Piran Sioshansi, a physicist at Spire Corporation in Bedford, Massachusetts. In June 1995, Dr. Sioshansi made a presentation to St. Jude employees about Spi-Argent. Bill Holmberg, the Silzone project leader, first became involved in the early fall of 1995 when St. Jude's Director of Research and Development for mechanical valves asked Mr. Holmberg to investigate the Spi-Argent technology. Dr. Katherine Tweden had attended Dr. Sioshansi's presentation and Mr. Holmberg asked her to assist him. Initially, Dr. Tweden was a consultant to the Silzone project while working on other projects within the company, but apart from a three month maternity leave commencing mid-November, 1995, she was actively involved during the initial stages of investigation and later, during the testing phase. Her participation was formalized in early December 1996 as a member of the 'AB Cuff Team'.

64 Through her educational and work experience, Dr. Tweden had acquired specialized knowledge in tissue healing research and had conducted animal studies, including sheep studies, working with leading surgeons, pathologists, and animal study investigators in the scientific community. Mr. Holmberg was a project engineer with the company. He was not a research scientist, but he had led or been a member of several heart device projects at St. Jude and had some training in experiment design and failure modes effects analysis. They were impressive witnesses who were both deposed as part of the Silzone litigation in the United States. Neither was successfully impeached during their many days of testimony at this trial.

65 Dr. Tweden agreed in cross-examination that it would have been better to have had a toxicologist on the team, but the plaintiffs' own toxicology expert, Dr. McLean, volunteered that he thought Dr. Tweden did "some very competent and thorough work". Although the plaintiffs suggested otherwise, I find that Mr. Holmberg and Dr. Tweden brought relevant knowledge, training and experience to the Silzone project and approached their work in a thoroughly competent and professional manner. As the Silzone project went forward, the team was also able to draw on the experience and knowledge of other St. Jude scientists, the Medical Director, reputable testing laboratories and medical and surgical consultants as well as the experience and knowledge of Spire and those using the Spi-Argent technology. The plaintiffs' criticisms of Dr. Tweden and Mr. Holmberg are unfounded.

66 The initial investigations of Spi-Argent occurred in the fall of 1995 when Dr. Tweden began a preliminary literature review and consulted with external experts about the types of testing to be considered. She spoke with Mr. Bianco, Director of Experimental Surgery at the University of Minnesota and with Dr. Schoen and Dr. Fortune, who were medical consultants to St. Jude. Her note records that Dr. Schoen recommended she look into the research by Dr. Anderson and Dr. Durack on animal models for endocarditis. This led to further reading. She also became aware of the work of Dr. Rolf Bambauer who was using the Spi-Argent coating on catheters. She reviewed his articles and spoke to him personally about the results of his work.[28]

67 Sims Deltec, a manufacturer of medical products, was also using the Spi-Argent coating on

catheters. Dr. Tweden, Mr. Holmberg and Jonas Runquist spoke with Dr. Harry Puryear, a scientist at the company. Dr. Tweden's testimony, confirmed by a note made at the time, describes some of the difficulties that it encountered with testing and some of their concerns about the coating coming off, but the note also records that "it appeared to be an effective technology". Sims Deltec used a silicone rubber substrate and Dr. Tweden and Mr. Holmberg satisfactorily explained why they did not believe that the adherence concerns described by Dr. Puryear would apply to the Dacron cuff. This was confirmed by Spire's testing which showed excellent adherence of the Spi-Argent coating on Dacron.

68 Dr. Tweden concluded that Dr. Bambauer's work assessing the Spi-Argent coating on hemodialysis catheters and catheter cuffs was particularly relevant and positive. These early enquiries were followed by a conference call with Dr. Sioshansi and Mr. Barry of Spire about the Spi-Argent coating as there were two possibilities: Spi-Argent I and Spi-Argent II. At the end of November, Mr. Holmberg and several other St. Jude employees travelled to the Spire facility in Massachusetts to look at the feasibility of the Spire technology for the Silzone project and to make a "go/no go" decision about moving forward. Before this, no decision had been made to form a project team or proceed with testing, but the information obtained from these investigations was favourable. Spire made a positive impression during the visit and the technology looked promising. I am satisfied that St. Jude conducted reasonable investigations of Spire, the Spi-Argent coating and the coating process before deciding to pursue the Silzone project.

69 Spi-Argent I that ultimately became Silzone is composed of three layers beginning with titanium which is applied to the substrate (the polyester fabric) to provide adhesion; then, palladium, which acts as an oxygen barrier; and finally, silver. The Spi-Argent I coating was selected because Spire had greater experience with it, specifically on the polyester fabric that St. Jude used on its valves. It also had higher levels of antimicrobial activity and had been the subject of the majority of Spire's biocompatibility testing. The results of that testing are found in the Spire Master File and some of it was later relied on in the regulatory submissions. It was discussed at the November meeting at Spire and reviewed at other times during the project.

70 The Spi-Argent coating is applied using an ion beam assisted deposition or IBAD process that Mr. Holmberg and others observed during the trip to the Spire facility. Mr. Holmberg and Mr. Tobin described the process and Dr. Williams explained the advantages of the IBAD process for the Silzone coating. I attach little weight to Dr. Wilson's criticisms of the uniformity of the coating from his examination of one unimplanted valve as his opinions are based on a faulty understanding of the coating and cuff construction process. The uniformity of the coating can be observed in the high magnification photographs of the fabric and was confirmed by the evidence of Dr. Williams.[29] I am satisfied that the IBAD process produced a relatively uniform and firmly adherent coating and was an appropriate technology to use for its intended purpose. The coating was applied in conformity to St. Jude's specifications. There is nothing to criticize in St. Jude's quality assurance inspection of the fabric both before and during the assembly of the valves. When problems arose - for example, the discolouration of gloves observed by workers assembling test valves - they were appropriately

investigated and resolved to ensure that the coating was adherent.

The Silzone Project Moves Ahead

71 Following the Spire visit, a team was formed and the Silzone project did move forward. Its development was characterized by a similar approach of reasonable investigation and assessment as the project proceeded. I do not accept the plaintiffs' description of a rushed process, implying a lack of reasonable care. It is true that Mr. Holmberg as project leader, and Mr. Shepherd as the executive leading the heart valve division, frequently stressed the importance of making progress and not getting behind schedule. At times, they conveyed a sense of urgency to team members, but there is no evidence that the timelines or goals for the Silzone project were unusual from a development perspective or that it proceeded at a pace that was at the expense of completing appropriate tasks, tests and evaluation.

72 In forming this opinion, I have considered the evidence the plaintiffs rely on, including the request to the FDA for an expedited review (the FDA refused this), the shortening of the 20 week sheep study to 10 weeks (the FDA approved this), an early strategy to release the Silzone products first in unregulated countries (the strategy was abandoned), and references to patent expiry in various marketing documents. I agree that Mr. Runquist's May 14, 1997 letter to the FDA requesting an expedited review exaggerated the demand for the Silzone product, but as the FDA refused this request, nothing turns on this.

73 While it would be naïve to think that the company was unconcerned about profits or protecting its intellectual property, no valve manufacturer would be in business very long if it neglected patient safety and marketed products that didn't work. It also seems unlikely that a company that didn't have a real belief in the potential benefit of Silzone, both for patients and for its shareholders, would license the Spire technology as it did in February 1996; pursue a multi-million dollar project to acquire the IBAD technology from Spire that was ongoing at the time of the recall (despite the publications of Dr. Butany and Mr. Butchart raising concerns about the safety of the valve); or put the Silzone valve into a "gold standard" RCT like AVERT. At the time, this would have been considered a bold step as there had been few RCTs comparing two mechanical heart valves and clinical efficacy data could have been obtained in other ways. The plaintiffs contend that St. Jude carried on with AVERT only to assist it with the litigation that followed the recall. As the company had no way of knowing if AVERT would show that Silzone patients were at increased risk for other medical complications, I do not find this argument persuasive.

74 Dr. Flory, Mr. Shepherd, and the other St. Jude witnesses who testified on this point did not dispute that patent expiry was a consideration in the development of the Silzone valve, but the evidence satisfies me that it was not a consideration that affected the amount of testing that was done or the analysis of that testing. Evidence that a business is motivated by profit cannot, without more, be treated as evidence that it fell below the standard of care. At most, the evidence demonstrates that St. Jude behaved as would be expected of a commercially-motivated party.

75 I am also satisfied that St. Jude thoroughly investigated problems when they arose, for example, the corrosion and leaching concerns that were the subject of Mr. Holmberg's August 21, 1996 letter to Dr. Sioshansi and the excess pannus observed on two valves in the Long Term Sheep Study. Mr. Holmberg sought advice from Dr. Roger Stahle, an external corrosion specialist and consulted the fabric supplier and fabric consultants. Dr. Tweden sent the valves to Dr. Schoen to be reviewed. Mr. Holmberg understood that unless these issues were addressed satisfactorily, it would slow down or stop the project and he acted reasonably in seeking advice and finding solutions, as did Dr. Tweden. I accept that the company wanted to get the product to market quickly, but the evidence as a whole satisfies me that this was not at the expense of product safety.

76 All of the safety issues raised in the trial - including excess pannus, dehiscence and paravalvular leak, systemic and local toxicity, increased thrombogenicity, and adherence of the coating - were formally identified as potential risks during the Failure Mode Effects and Criticality Analysis (FMECA) in December 1996 and in July 1997. The FMECA provided a structured format for the analysis of the relative risks of each potential failure and recorded the results of the testing that had been done or was ongoing that provided assurance that the addition of the Silzone coating did not create these additional risks. In order to bring a variety of perspectives to the discussion, participants included not only members of the project team, but also managers and scientists involved in other projects and from other divisions. A similar format was used for the Design Review Meetings that Mr. Holmberg led.

77 The plaintiffs criticize FMECA as coming too late in the development process, but I accept Dr. Tweden's evidence that the identification of potential failure modes formed a part of the design and testing process and the project team began brainstorming potential failure modes informally from the beginning of the project. This is corroborated by the company's Regulatory Assessment signed April 10, 1996, which identified at an early time inadequate tissue ingrowth - one of the plaintiffs' main contentions - as a possible risk of the Silzone coating.

78 I also accept the evidence of Dr. Tweden that over the course of the project she reviewed hundreds of articles and abstracts in the scientific literature on the biocompatibility of silver. From her review of the literature, Dr. Tweden concluded that cytotoxicity was directly related to the concentration of silver ions available. Each sewing cuff contained only a tiny amount of silver - between 17 and 50 mg - depending on the size of the valve. As silver ions from metallic silver ionize much less readily than from silver salts, she concluded that cytotoxicity would be at an acceptable level as there would be fewer silver ions available. Dr. Tweden's conclusions were confirmed by the results of the pre-market safety testing and are consistent with the published literature on the toxicity profile of silver. In Common Issue 2, I will review the scientific literature and explain why it supports Dr. Tweden's conclusions.

The Utility Assessment

Potential Utility/Benefit of Silzone

79 The Silzone valve was designed and manufactured to directly reduce infection while having no adverse effect on tissue healing when compared to the uncoated Dacron cuff. The coating was applied to the specific area where infection often started, the sewing cuff. A starting point is to consider whether there was a reasonable basis for the company to pursue a technology to reduce the incidence of post-operative infectious endocarditis, specifically, prosthetic valve endocarditis (PVE) in St. Jude's conventional valve sewing cuffs. Experts called by both the plaintiffs and the defendants gave evidence as to the rate or incidence of endocarditis among prosthetic heart valve recipients and as to its morbidity and mortality. While varying numbers were provided, the conclusion to be drawn from the evidence from both sides is that, while PVE is relatively rare, its potential consequences are very serious. Mr. Butchart, the plaintiffs' expert,agreed that "prosthetic valve endocarditis is the most feared complication after valve replacement surgery." Dr. Sexton, the defendants' expert and a leading authority on endocarditis, described it as a "terrible disease".

80 Dr. Sexton testified that there are different rates of morbidity and mortality at different medical centres, but that a blended average would be that about half of patients who have PVE require reoperation and roughly one third die as a consequence of the infection. In the late 1990s, approximately 70,000 of the defendants' valves were implanted each year. Applying a PVE rate of 1% per patient year, approximately 2800 patients would contract PVE. Of these, approximately 1400 would require reoperations and 930 would die over the anticipated four year period of the AVERT trial that was to assess the clinical efficacy of Silzone. Although these numbers are not large, PVE was a serious enough issue that some surgeons, including those at the Mayo Clinic, were dipping valve sewing rings in antibiotics prior to implantation in an attempt to minimize the risk of PVE without any evidence that this was effective.

81 PVE is treated with a heavy course of antibiotics. The expert testimony confirmed that in the 1995-1997 timeframe, the medical and scientific communities were increasingly concerned about antibiotic resistance, and at the same time, silver was gaining popularity as an antimicrobial agent. Device infection is often caused by biofilms which are more resistant to commonly used antibiotics and very difficult to treat with systemic antibiotics. Silver has the unique ability to stop the initial phase of bacterial attachment that leads to formation of a biofilm. As well, endocarditis is caused by a number of different organisms and there is no single antibiotic with as broad a spectrum of activity against microbes as silver. Dr. Williams, the most knowledgeable expert on the biocompatibility of silver, testified that there was a reasonable scientific basis to use the Silzone coating for the purpose of reducing endocarditis. Dr. Hancock, a microbiologist and the most knowledgeable expert on infectious organisms and the behaviour of bacterial cells, agreed.

82 Dr. Christakis downplayed the desire of the medical community for a heart valve with antimicrobial properties stating that there was no "clamour" for such a product, but St. Jude was not alone in investigating the use of antimicrobial coatings. Dr. Butany recalled that at the time, "everybody was trying to develop sewing cuffs which would prevent endocarditis". Dr. Errett, Chief of Cardiovascular and Thoracic Surgery at St. Michael's Hospital in Toronto, described the efforts of two competitors who were also investigating impregnating sewing cuffs with antimicrobial

agents, including a project similar to Silzone that applied silver to the pledgets in addition to the sewing cuff.

83 It seems unlikely that St. Jude and its competitors would be interested in developing a product that the medical community was not going to use. In fact, all of the surgeon witnesses called by the plaintiffs, including Dr. Christakis, used the Silzone valve when it became available. It was used by leading medical centres in Canada, the United States and Europe, including the 17 centres participating in AVERT. Mr. Butchart, who later was extremely critical of the valve's performance, felt at the time that it had potential benefits for patients and agreed to include it in CERFS, the study he was conducting at his hospital in Cardiff, Wales. In my view, this is strong evidence that a mechanical heart valve with antimicrobial properties did meet a perceived need and corroborates the testimony of Mr. Shepherd and Mr. Holmberg that they understood there was support within the medical community for St. Jude to develop a product that had the ability to reduce the risk of PVE. That other manufacturers were also interested in developing a similar product is further corroboration of their evidence.

84 The conclusion to be drawn from the evidence is that a mechanical heart valve with antimicrobial properties did meet an important need and the potential utility of Silzone was considerable for this group of patients. Although the risk of developing endocarditis was very small, the consequences were very serious. As discussed in Common Issue 2, the state of knowledge at the time was supportive of the use of silver in medical products to reduce the incidence of infection and promote healing. There was a reasonable basis for St. Jude to pursue a technology using silver to reduce the incidence of PVE.

The Efficacy Testing Program Animal Efficacy Studies

85 As I have already mentioned, at an early stage in the Silzone project, Dr. Tweden began to consult with external experts, including Mr. Bianco and Dr. Schoen about the type of testing they might recommend. Her note of September 13, 1995, records a conversation with Mr. Bianco who was highly regarded by Dr. Tweden for the work he had done in development of animal models for testing prosthetic heart valves. Based on these discussions and her reading, Dr. Tweden concluded that there was no established animal challenge model for PVE that could be used. She became aware of an animal model for native valve endocarditis, but I accept her explanation that this model was not suitable for a prosthetic heart valve.

86 The challenges involved in performing an animal efficacy study were outlined in St. Jude's letter to the FDA on December 29, 1995 when Mr. Runquist notified the FDA of the proposed mechanical heart valve project with Silzone and explained why the company did not plan to pursue pre-market animal efficacy studies. Instead, St, Jude proposed to the FDA that it submit relatively limited labelling claims based on Spire's *in vitro* data and then pursue post-approval efficacy studies over several years. The FDA's agreement with this approach is consistent with Dr. Wustenberg's opinion that in the 1995-2000 timeframe, the FDA wanted animal data for antimicrobial devices if it

could get it, but allowed approval of devices without this data. In that event, it did not allow manufacturers to claim clinical efficacy. As a result, the FDA approved a label for Silzone products that was also reviewed by Health Canada and read: "The Silzone coating has been shown *in vitro* to reduce attachment and colonization of microorganisms frequently associated with endocarditis". That the Silzone valve enjoyed widespread use based only on *in vitro* efficacy claims is further evidence that the medical community supported the development of this product and believed it had potential benefit for patients even though clinical efficacy had not been shown.

87 The challenges of an animal efficacy study that St. Jude described in the letter to the FDA were confirmed by the expert testimony of Dr. Hancock and by Dr. Wustenberg, the defendants' expert on industry standards for animal testing. Their opinions support the conclusion of Dr. Tweden and the project team not to pursue pre-market animal efficacy studies. Dr. Hancock testified that he had reviewed the literature and had been unable to find any previous studies using an endocarditis model in a large animal. Among other issues, such a study would have required large numbers of animals, raising ethical concerns, and it was questionable whether the animal data would apply to humans. Dr. Hancock explained that even if a challenge model could be developed, it would still be of doubtful validity to the clinical situation because these models cannot recreate the conditions of endocarditis infection found in people with replacement heart valves. St. Jude's post-submission attempt to inoculate the sewing rings of valves with bacteria before they were implanted in sheep did not proceed past the method development stage. A systemic inoculation large animal model was also proposed but the institution where the study was to be conducted rejected it due to animal welfare concerns.

88 Dr. Wustenberg described the technical difficulties manufacturers encountered at that time in obtaining reliable and repeatable results for antimicrobial coatings on long-term implantable devices. Virtually all of the testing was done by implanting materials infected with various infectious agents under the skin of small animals. St. Jude ultimately experienced all of these difficulties in their post-submission attempts to develop *in vivo* efficacy models in rabbits and guinea pigs. These failed attempts support the opinion of the defendants' experts that there was no animal model available at that time for testing antimicrobial coatings that would provide repeatable results that could be extrapolated to humans. Neither Health Canada nor the FDA raised any concern that an animal efficacy study had not been conducted. I find that St. Jude's decision not to pursue pre-market animal efficacy testing was reasonable and in accordance with industry standards at the time.

In Vitro Testing

89 The evidence that bears on this comes from Dr. Tweden and Dr. Hancock. Although the plaintiffs' expert, Dr. Olson, is also a microbiologist, the plaintiffs did not seek to qualify him to give opinion evidence on this subject. Dr. Hancock was the only microbiologist to testify at trial. He is Professor of Microbiology and Immunology at the University of British Columbia, the Director of the Centre for Microbial Diseases and Immunity Research, and a Canada Research Chair in

Microbiology.

90 St. Jude relied on tests that were performed using the Dow Corning Flask and NYS63 methods of testing. Dr. Hancock confirmed that these were standard efficacy tests and that the four microorganisms that were tested are major causes of endocarditis. The results showed that Silzone was effective against all four endocarditis-causing infectious agents. Dr. Hancock also explained and put into context some of the inconsistent test results such as the Dow assay on April 10, 1996 that the plaintiffs emphasize in their submissions. He agreed that this was a flawed result corroborating Dr. Tweden's conclusion that there were problems in the laboratory on that experimental day and that it was appropriate to repeat the test.

91 After reviewing all of the results, including the inconsistent data, Dr. Hancock concluded that these tests demonstrated that Silzone had the potential for clinical efficacy to reduce endocarditis in patients. No expert criticized the company for not having a "pass/fail" criterion for the microorganism reduction tests and the plaintiffs did not cross-examine Dr. Hancock on this issue. Dr. Hancock's uncontradicted evidence that these tests provided strong evidence of Silzone's ability to kill the bacteria that cause endocarditis and prevent bacterial colony formation corroborates Dr. Tweden's view that the results of the testing were promising. Dr. Hancocks' opinions addressed each of the plaintiffs' arguments about the efficacy testing and support the defendants' position that there was a reasonable scientific basis for the company's belief that Silzone had the potential to reduce the incidence of endocarditis.

92 St. Jude also performed parallel streak tests on the Silzone fabric and obtained inconsistent results. While the parallel streak test is a standard efficacy test, Dr. Tweden concluded that it was not appropriate for the Dacron fabric due to the fabric's three-dimensional nature. In order to have a meaningful test, organisms needed to be seated on the interstices of the fibres. Mr. Tobin testified that Spire had reached a similar conclusion because the silver did not come off the surface at high enough rates to set large zones of inhibition and, therefore, did not have that much sensitivity or usefulness for the Spi-Argent coating. Dr. Hancock agreed that it would have been inappropriate for St. Jude to draw conclusions about the antimicrobial activity of Silzone based on these tests because it was not an appropriate assay to test a surface-associated substance that does not diffuse rapidly. However, the results did confirm the low rate of ionization of the silver ions.

93 The plaintiffs rely on the fact that that these tests, and also those done by Spire, showed that Silzone set a zone of inhibition, or "kill-zone", against certain microorganisms demonstrating that Silzone "leached" from the fabric. They suggest that this showed that Silzone was capable of inhibiting cellular growth and destroying cells not in direct contact with the fabric. Dr. Hancock reviewed the zone of inhibition testing reported in the Spire Master file as well as the testing performed on behalf of St. Jude by NAmSA, a reputable testing laboratory. He confirmed that there was an indication of a small zone of inhibition in a couple of test results for one particular organism and none against other organisms, but he agreed with St. Jude's conclusions that the most that could be concluded from these tests was that not much silver was diffusing away from the surface of the

fabric. In response to the plaintiffs' argument on cell destruction, he testified that whether or not there was a zone of inhibition, the results of this kind of testing with bacteria and fungi do not provide useful information about the effects on human cells as zone of inhibition testing is not a standard assay for measuring the killing of human cells as opposed to bacterial cells. Dr. Hancock was the most qualified to discuss this and his testimony on this point was not challenged.

94 At the time the valve was distributed, St. Jude had not established that an antimicrobial coating would be clinically effective against PVE. Instead, St. Jude decided to seek regulatory approval for the valve with limited labelling claims as to efficacy based on *in vitro* testing, relying on AVERT to subsequently demonstrate clinical efficacy. It is the plaintiffs' position that St. Jude could not establish the efficacy of Silzone with the appropriate degree of certainty through *in vitro* testing and should have delayed introducing the Silzone valve until it had completed a pre-market clinical trial. The main reason they advance is that Silzone was an unproven modification to St. Jude's "gold standard", low complication rate, conventional valve. Their argument appears to be that as the conventional valve was a safer alternative, the standard of care required the defendants to show that Silzone was effective in patients and posed no additional risk in order to be able to conclude that the Silzone valve truly represented a benefit over the conventional valve that outweighed its risks.

95 The availability of safer products to meet the same need is a factor in the risk utility analysis, but the plaintiffs' argument ignores that PVE was a known risk with the conventional valve that the Silzone valve had the potential to address. Every heart valve patient who received a conventional St. Jude valve was at a small but serious risk of experiencing this complication that is difficult to treat and associated with high morbidity and mortality. This was the need that was being addressed. The risk utility analysis did not require St. Jude to assess whether the benefits of the Silzone valve outweighed the benefits of the conventional valve relative to their risks. Rather, it was required to consider whether the potential benefits associated with the addition of Silzone outweighed the potential risks of Silzone.

96 As well, the plaintiffs' argument is premised on the assumption that there was an increased risk with the Silzone valve over the conventional valve. In January 2000, the AVERT data showed that some Silzone valve recipients were at an increased risk of explant due to PVL, but this was not known or foreseeable at the time the valve was distributed. While in some cases the existence of a safer alternative to meet the same need can be a relevant factor in the risk utility analysis, in the circumstances of this case, this reasoning imports a hindsight analysis. In any event, the conventional valve did not meet the same need as the Silzone valve because it did not address the risk of PVE.

Regulatory Submissions

97 Although the plaintiffs' experts did not criticize the efficacy testing or the reporting of the test results, the plaintiffs contend that St. Jude did not fairly report the efficacy testing results in the

regulatory submissions and, as a result, the FDA and Health Canada were not in a position to adequately assess the test results. The essence of the evidence from Dr. Butler and Dr. Freeland was that, while Health Canada was relying on the information received from a medical device company, they expected the manufacturer to exercise judgment about what to include in a submission and did not expect information that was not scientifically relevant or reliable. If there was difficulty replicating results, Dr. Butler expected contradictory information to be resolved. In my view, this is what St. Jude did. Dr. Hancock testified that St. Jude's submission included a fair representation of the test results and fairly and accurately summarized the testing and the company's interpretation of the results. This evidence was uncontested and I agree with it.

98 The plaintiffs also allege that the SNOC submission was misleading with respect to the sufficiency of the pre-market efficacy testing as it failed to disclose St. Jude's plans to conduct a post-market clinical efficacy study or an animal challenge study "and thereby cast doubt upon the regulators' ability to weigh the respective risks and benefits of the Silzone product". I must say I have difficulty understanding this argument. However, it was clear from the submission that a clinical trial to demonstrate efficacy had not yet been conducted. While the *in vitro* efficacy testing supported the potential benefits of Silzone, Health Canada understood the limitations of that evidence. As Dr. Butler said:

> [St. Jude Medical] did prove efficacy in the fact that this valve worked in animals. The animals would have died if this valve wasn't effective ... you know, as a valve, it was effective. That - the animal study proved it. The valve could be implanted, the valve worked, it didn't leak. So in other words the valve was proven to be effective as a valve. But they did not prove that the Silzone coating prevented infection.

99 The plaintiffs point to the uncontradicted evidence from AVERT that Silzone was not effective in reducing the incidence of infective endocarditis as evidence that St. Jude's claims that Silzone would be beneficial "were proven false". Clinical efficacy was not proven in AVERT, but as the trial was stopped prematurely, it may never be known whether a study of 4400 patients rather than 800 patients would have shown a reduction in the rate of infectious endocarditis.

100 The evidence as a whole shows that St. Jude's view of the potential efficacy of Silzone was reasonable at the time. The *in vitro* efficacy testing demonstrated that Silzone was effective against infectious agents that commonly cause endocarditis. Products on the market at that time, such as treatments for wounds and burns, showed silver to be effective against bacteria and promote healing. Dr. Bambauer's experience with the Spi-Argent coating on catheter devices in a blood-contacting environment showed that it reduced infection in patients. The scientific literature (to be discussed in Common Issue 2) reported the effectiveness of silver in killing bacteria and preventing them from attaching to surfaces. It was reasonable for the defendants to conclude that a Silzone coating had potential benefits and could be clinically effective in reducing the incidence of PVE.

The Risk Assessment

Industry Standards for Safety Testing

101 Compliance with regulatory and industry standards can be useful evidence of reasonable conduct, although this is not necessarily co-extensive with the standard of care.[30] As manufacturers often play a role in setting the industry standards that they are required to meet, the court must consider whether the industry standard is one that requires an appropriate degree of care and, if met, will discharge the manufacturer's duty of care. Industry standards can be reflected in commonly accepted industry guidelines and also by the steps that other companies in the same industry take in designing and testing similar products in order to address reasonably foreseeable risks associated with the use of these products.

102 It is common ground that at the time the Silzone valve was developed, the industry standards for pre-market testing of a modification to an approved prosthetic heart valve included reference to written standards for pre-market testing in the FDA's Draft Heart Valve Guidance and ISO 5840 and ISO 10993, which are standards published by the International Standards Organization (ISO). The drafting of the Heart Valve Guidance was a collective effort between the FDA, heart valve manufacturers, the medical community, academics, and public stakeholders. The ISO publishes consensus standards which are developed from committees composed of industry participants, academics and representatives from regulatory agencies from around the world.

103 Dr. Butler of Health Canada identified the Heart Valve Guidance and ISO 10993 as standards that Health Canada reviewers consult when reviewing Notices of Compliance (NOCs) and SNOCs for heart valves. The plaintiffs led no evidence at trial of Canada-specific industry standards and they acknowledge that the FDA's Guidance document and ISO standards are relevant in determining whether St. Jude met industry standards.

104 Neither the Heart Valve Guidance nor ISO standards prescribe mandatory testing. Instead, they outline recommended testing and suggest the kinds of tests that might be done. The Heart Valve Guidance specifically contemplates that manufacturers may achieve the same testing objectives by other means, or may justify not performing the recommended tests where a justification or explanation is provided to the FDA. The plaintiffs' toxicology expert, Dr. McLean, testified that "[ISO standards] give guidance to people who are doing safety testing ... by giving them advice which comes from experienced toxicologists and with very large input from industry. ... [b]ut it is up to experienced, knowledgeable investigators to decide which tests are applicable for the particular device, material and site of implantation".

105 As the Heart Valve Guidance and ISO standards were intended for new prosthetic valves, their application to modifications of existing valves required some interpretation on the part of the manufacturer as to the sections of the written standards that applied and, if they applied, the extent to which they needed to be followed to perform adequate safety testing for the modification in issue. Ms. Johnson testified that a manufacturer's assessment of how the written standards would be

applied was frequently reached through informal communication with the FDA prior to submission for approval. St. Jude's proposal to shorten the 20 week sheep study recommended in the Heart Valve Guidance to 10 weeks is an example. A December 15, 1997 conference call among Mr. Runquist, Dr. Flory and FDA personnel to discuss the FDA's request for further information following the FDA's non-approvable letter is another example.

106 While the plaintiffs acknowledge the relevance of the Heart Valve Guidance and ISO standards, they dispute that there is any industry standard or practice to measure the defendants' conduct against because it is left to the manufacturer to determine which guidelines apply and the manner in which to comply with these guidelines. In the circumstances of the introduction of a completely new medical device or the modification of an existing device incorporating a never before used material, the plaintiffs argue that it is difficult, if not impossible, to identify a recognized industry standard. I do not agree. If this were the case, industry practice would be irrelevant for every new product.

107 The prosthetic valve industry was well-established at the time the Silzone valve was developed. Industry and regulators had acquired considerable experience in addressing modifications to previously approved valves. In fact, the predicate device - the Masters series mechanical heart valve without Silzone - itself had been approved in 1995 by way of a submission for a SNOC. The Masters series valve modified the St. Jude standard valve by adding a rotatable cuff feature. The St. Jude standard valve had originally been approved by way of a Notice of Compliance and itself received a number of SNOCs for modifications prior to the development and approval of the Masters series. While it is true that the specific tests manufacturers perform may vary depending on the nature of the modification, the experts on both sides considered industry practice in reaching conclusions about how to measure the defendants' conduct in regard to the Silzone modification.

Expert Witnesses

108 The most probative evidence on industry standards comes from the expert witnesses. As I mentioned earlier, Ms. Johnson was the drafter of the FDA's 1994 Heart Valve Guidance, a former FDA lead reviewer of regulatory submissions for prosthetic heart valves from 1990 to 1995, and the voting member from the FDA for the 1996 version of ISO 5840. She had worked with and/or trained the reviewers at the FDA who later evaluated St. Jude's PMA Supplement. She was clearly the most knowledgeable witness about the Heart Valve Guidance and the FDA's process for approval of a new heart valve or a modification. Ms. Johnson's testimony on industry practice was based largely on her experience at the FDA in the period immediately before the development of the Silzone valve. While she conceded there was no specific industry standard for pre-market testing of a valve with a silver-coated cuff, she described the industry standards for testing of prosthetic valves generally, and specifically for modifications to prosthetic heart valves, and provided her opinion that St. Jude met those standards.

109 I also touched on the qualifications of Dr. Williams earlier. He has carried out many studies investigating the cytotoxicity of metallic materials, particularly silver. He has extensive experience investigating the effects of biomaterials in animal models and specific experience with prosthetic heart valves. I expand on this and review the qualifications of Dr. Rodricks, the defendants' toxicologist, in Common Issue 2.

110 The defendants' experts provided clear and unequivocal opinions that the pre-market testing to assess the safety of applying Silzone to the sewing cuff was reasonable and in accordance with industry standards. The plaintiffs sought to neutralize the impact of their evidence by arguing that none of the defendants' witnesses had any experience in the pre-market testing of a silver-coated permanently implantable medical device that required adequate tissue healing to function safely. This is merely a variation of the argument that there can never be an industry standard for the testing of a heart valve or modification because there is no other device that is identical. Collectively, these witnesses have relevant and extensive knowledge and experience in biomaterials, biocompatibility and toxicity testing, and in the written standards and industry practices that apply to testing of modifications to prosthetic heart valves.

111 Dr. McLean, the plaintiffs' toxicologist, was certainly qualified to discuss the toxicity testing. In fact, Dr. McLean evaluated the same testing protocols that are now in issue in the trial in 1999 in his role as a consultant to the MDA in the United Kingdom. He prepared a report to the MDA on the sufficiency of the defendants' testing and the potential toxicology issues concerning the Silzone valve.[31] He described the kinds of tests that were appropriate for devices containing blood and tissue, and concluded:

> ... It is therefore noted that SJM have sponsored all of the aforementioned standard studies except for carcinogenicity bioassays and that all of these appear to have been performed satisfactorily to GLP standards.

112 In contrast, Dr. McLean in his testimony at trial criticized the fibroblast and hemolysis tests as well as a washout study that assessed the potential loss of silver ions from the coating. His explanation in cross-examination was that he had not made it clear in his report to the MDA that St. Jude conducted "the wrong tests". If the testing methodology he proposed at trial was important to obtaining reliable test results, it is reasonable to think that this would have been discussed in his report to the MDA. His testimony is also inconsistent with his evidence that ISO standards allow discretion on the tests and methodology that can be used. His failure to satisfactorily explain these inconsistencies impaired the credibility of his evidence.

113 His evidence was further weakened by his admission that he had read only the regulatory submissions and had not reviewed internal company documents that discussed the reasons for the selection of tests that were used to evaluate the biocompatibility of Silzone. Finally, he admitted that he had no experience with the Dacron fabric and was therefore not in a position to know if the alternative tests he proposed would be suitable for a woven fabric. In view of these shortcomings in

his testimony, where the opinions of Dr. McLean conflict with those of Dr. Rodricks and Dr. Williams, I prefer their evidence.

114 The plaintiffs tendered Dr. Olson as an expert on industry standards for the animal testing. He offered opinions on the use of power calculations to determine the number of animals to be included in an animal study, the role of Good Laboratory Practices (GLP) in the conduct of animal studies, and whether the defendants' study complied with ISO 5840. Dr. Olson had designed and conducted numerous animal studies, including sheep studies, but prior to this litigation, Dr. Olson had never worked with the Heart Valve Guidance or done a study using ISO 5840. Over the objections of the defendants, I ruled his evidence admissible, but I attach less weight to it.[32]

The Safety Testing

115 The nature and quality of the testing a manufacturer performs will normally satisfy the standard of care so long as it meets industry standards and those standards are reasonable. The plaintiffs do not claim that the industry standards are unreasonable. They submit that Silzone valve patients were exposed to unnecessary risk as a result of a poorly designed and poorly executed pre-market testing strategy that was "inadequate and rushed". I have said earlier that I am not persuaded that the pre-market testing program was rushed at the expense of safety. Inadequate testing may be the basis for finding a breach of the standard of care if testing would have resulted in a reasonable decision not to manufacture the product in light of its inherent hazard. Otherwise, the failure to test will not normally result in liability because the failure does not cause the loss.[33]

116 The plaintiffs allege that St. Jude conducted only the minimum *in vitro* tests, abbreviated the sheep studies, and conducted a limited clinical study (LIMRA), and that this amounted to inadequate testing. They referred me to two Superior Court decisions in which the court found the defendants' testing to be inadequate.[34] In *Willis*, the court held that one year of testing was insufficient, but provided no guidance in determining the measure of adequate testing. In *Alie*, the industry had established guidelines that recommended that before fly-ash supplemented cement was poured, it had to be sampled and tested. In that case, the defendant manufacturer, Lafarge, did not carry out these tests or arrange for the concrete mixer to do so. The court concluded that the defendant's protocol for testing did not meet the requirements of the standard.

117 A failure to meet industry guidelines for testing is a relevant factor in the standard of care analysis, but in this case, the evidence shows that standard tests were performed that met the testing recommended by the Heart Valve Guidance and ISO standards. The essence of the plaintiffs' position is that St. Jude should have performed different tests or used alternative methods of testing or performed more tests, but there is no direct evidence that this testing was necessary or that it would have changed anything. It is not sufficient to claim that the defendants should have done more testing without also showing (a) that such tests were possible, and (b) that this would have affected the risk utility assessment and made it unreasonable for St. Jude to manufacture and market Silzone products. This evidence was lacking on both counts.

118 Dr. Williams concluded that the pre-market testing was reasonable and performed in accordance with the Heart Valve Guidance and industry standards. Ms. Johnson concluded that the testing, as described in the regulatory submissions, met industry standards. Dr. Rodricks evaluated the toxicity testing and concluded that St. Jude had exercised a thorough and reasonable approach and conducted reasonable and appropriate testing. A review of the testing supports their opinions.

In Vitro and Small Animal Studies

119 The potential for toxicity or cytotoxicity was evaluated in a series of laboratory tests and small animal studies with mice and rabbits that Spire had performed on the Spi-Argent I fabric as well as in additional fibroblast tests that St. Jude conducted. Fibroblasts are a type of cell involved in tissue healing. The toxicity testing investigated local and systemic toxicity, including differences in tissue reactions, direct cellular changes and cell death. St. Jude also conducted a washout study as well as testing for fabric performance and corrosion.

120 The defendants acknowledge that generally, it is preferable that all testing for medical devices be performed on the finished product, but the ISO standards - which are umbrella standards for biocompatibility testing - do not preclude testing on representative samples from the final product or material. The testing performed for Spire was done in reputable laboratories using standard protocols and no expert criticized St. Jude for relying on Spire's test results. The FDA asked St. Jude to justify this and St. Jude's rationale for using the Spire testing was explained in a December 1997 Amendment to the PMA Supplement that the FDA accepted.

121 St. Jude performed testing to assess the potential loss of silver ions from the cuff in the form of galvanic corrosion testing and a washout study. Galvanic corrosion is a standardized test appropriate for evaluating a valve with metal components and is referenced in both the Heart Valve Guidance and ISO 5840. The first results showed very high values, but once the surface area of the fabric was correctly estimated, the corrosion rates were very low: 5 to 95 angstroms per year.

122 In the washout study, two samples of the fabric and two assembled valves were tested. The washout study performed on the valve showed a larger release of silver in the first few days, which then dropped over time. Dr. McLean testified that the test solution in the washout study became saturated and only showed a levelling off in the amount of silver in serum. Dr. Rodricks researched the saturation point for silver salts and found that it was far above the concentrations seen in the washout study. Dr. Williams agreed with the conclusions of St. Jude that the washout study showed that silver ions would be released from the Silzone coating at a very low rate and at rates far lower than the silver concentrations seen in the literature where patients experienced toxic effects. He testified that neither test raised any safety concerns.

123 St. Jude conducted fibroblast testing in accordance with methods recommended in ISO 10993 and also developed a human fibroblast test using a technique called a "Live Dead" assay. This test measured the potential for a toxic effect by observing fibroblasts exposed to the Silzone fabric for cell changes and for whether they remained alive or died. The results were published in an

article co-authored by Dr. Tweden in the *Journal of Heart Valve Disease*.[35] Dr. Williams and Dr. Rodricks analyzed the human fibroblast testing performed by St. Jude. Dr. Williams testified that the results were consistent with what was known about silver ions (i.e. that they can produce toxicity at some level). He opined that the lack of toxicity seen until the concentration of the solution reached 1200 ppb indicated that it was unlikely that Silzone would exert any "consequences as far as healing and performance of tissues" adjacent to the coating was concerned.

124 Dr. McLean and Dr. Healy each criticized the indirect method of fibroblast testing used by St. Jude, although for different reasons, but neither offered a clear opinion that St. Jude's testing did not meet industry standards. Dr. Williams testified that while a direct contact test was possible, it would be more difficult to derive meaningful data due to the complex weave of the Dacron fabric. Dr. McLean acknowledged he had no experience with the Dacron fabric. Further, both Drs. Williams and Rodricks testified that there was no benefit or scientific reason to employ a direct contact method, that industry standards permitted both methods, and that the defendants' choice of an elution or indirect method was appropriate.

125 Dr. McLean also criticized the hemolysis testing performed on the Silzone-coated fabric. This was a standard screening test to determine if red blood cells would be 'lysed' or ruptured. An indirect hemolysis method was used and the fabric was found to be non-hemolytic. After the valve was approved in Canada, it was retested using a direct *in vitro* hemolysis method and some of the values were found to be elevated. This testing was done because of the results seen in the testing of the Epic valve which passed the indirect, but not the direct test.

126 Dr. Williams pointed out that all mechanical heart valves cause some hemolysis and the factor that St. Jude wanted to measure was whether there was any additional hemolysis for the silver ions released from the coating. In his opinion, the most appropriate way to measure this was with the indirect method, although industry standards permit either method. No hemolytic effect was seen in the sheep implanted with the Epic valve and St. Jude concluded that based on all of the data, the Silzone-coated fabric was not hemolytic. Dr. Hirsh, an internist and haematologist, reviewed the results of the hemolysis testing and agreed with the company's conclusion. I conclude that the hemolysis testing was appropriately performed.

127 Dr. McLean testified that the lysis seen in the Epic study is indicative of damage that could occur to fibroblasts or other cells involved in tissue healing, although the three fibroblast tests showed no significant toxic effect. The only study he could think of to support his opinion that silver metal might lyse fibroblasts was the work of Dr. Williams published in a 1989 paper that I will discuss in Common Issue 2. Dr. Williams explained that Dr. McLean's conclusions were incorrect because he wrongly assumed that the form of silver used in Silzone was sintered silver, which is a different material. Further, as Dr. Rodricks testified, if hemolysis testing could be predictive of toxicity to other types of cells, the scientific community would be using the test for this purpose. Dr. Rodricks was not aware of any toxicology textbook that listed hemolysis testing as a screen for cell toxicity. He testified that the only inference that can be drawn from a positive *in*

vitro hemolysis test is to follow up with *in vivo* testing in animals. To the extent that Dr. McLean concluded that broken red blood cells would alter the tissue healing process, his opinion is not well-founded and I reject it.

Sheep Studies

128 St. Jude considered the most important safety issues to be whether the addition of the Silzone coating would negatively affect healing as well as the amount of silver that would be released from the cuff when implanted. The sheep studies were of great significance in evaluating both.

129 St. Jude conducted two *in vivo* implant studies using the sheep model. The Short Term, or 4 to 5 week sheep study, was conducted between June and October 1996 and was a study with implants of valves that were half coated with Silzone and half uncoated. Five of the sheep had valves with Dacron cuffs and two of the sheep had valves with Teflon cuffs. The Long Term or 10 week sheep study commenced in November 1996 and was completed in April 1997. There were six sheep implanted with Silzone-coated valves and three sheep implanted with conventional valves as controls.

130 Dr. Tweden was responsible for the design and oversight of both sheep studies. The examination of gross pathology and histopathology was carried out by Dr. Douglas Cameron, a board-certified pathologist and Adjunct Professor at the University of Minnesota who had some training with Dr. Jack Titus, a pre-eminent cardiovascular pathologist. Dr. Tweden had previously worked with Dr. Cameron in regard to another heart valve research project and was satisfied with the quality of his work. She participated with Dr. Cameron in the gross and microscopic pathology on the explanted specimens. Mr. Holmberg was also present at times. Dr. Cameron did not testify but his pathology reports were admitted as business records.

131 The plaintiffs criticize the sheep studies for being conducted with too few animals and for too short a period of time. They contend that these studies showed that of the 13 sheep implanted with partially or wholly-coated Silzone cuffs, two developed such abnormal healing that one died (KTMV-2) and the other (SJII-8) would not have survived to 20 weeks. They allege that an early death from an unknown cause (KTMV-2), an excessive pannus formation obstructing a valve leaflet (SJII-8), discoloured tissue, spalled silver fragments and discernable tissue healing differences all pointed to Silzone adversely affecting critical tissue healing. I will review the expert evidence from Dr. Factor and Dr. Wilson in Common Issue 2 in considering the effect, if any, that Silzone has on tissue healing. The issues to be considered here are whether the Silzone sheep studies were conducted in a reasonable manner and whether they raised serious safety concerns, as the plaintiffs allege, or provided a reliable basis for St. Jude to conclude that the Silzone-coated Dacron cuff was safe and effective.

Short Term or 4 to 5 Week Study

132 The Short Term Sheep Study was conducted partly at the University of Minnesota and partly

at Loma Linda University in California. Its purpose was to assess tissue ingrowth into a Silzone-coated Dacron sewing cuff at an intermediate stage of healing (30 days) to see if there was any difference compared to uncoated polyester. A valve with a half coated and half uncoated sewing cuff was implanted in each sheep. The sheep implanted at the University of Minnesota were identified as KTMV and were sacrificed at different times during the study. They were given sequential numbers at the time of implantation. KTMV-1 was the first sheep to be implanted. When KTMV-2 died at 10 or 11 days post implantation, it was replaced by KTMV-3. The sheep implanted at Loma Linda with half-coated Dacron sewing cuffs were LL-1 and LL-3. There were two sheep implanted with half-coated Teflon sewing cuffs known as LL-2 and LL-4.

133 Dr. Tweden had used the 'half and half' model in another project and the weight of the evidence establishes that this method provides the advantage of having a control within the same animal. This minimizes variability from animal to animal as well as variation in surgical procedures. St. Jude considered this study to be a feasibility study that was not intended for regulatory submission, but it was described in summary form in the narrative portion of the submission to Health Canada and Dr. Cameron's pathology reports were included as an attachment to the SNOC submission. In them, he described findings of particulate material and discolouration in several sheep, but he reported good healing and comparable tissue growth on both coated and uncoated portions of the six sheep that survived to planned sacrifice.

134 The most contentious issue in the 4 to 5 week study is the early death of KTMV-2 whose valve dehisced or ruptured and developed a paravalvular leak. The cause of the dehiscence was not determined.[36] The plaintiffs submit that the defendants failed to adequately investigate the cause of the animal's death.

135 Dr. Tweden testified that she and Mr. Holmberg examined the explanted valve and observed the PVL/dehiscence on both the coated and uncoated sides of the sewing cuff of KTMV-2 and that they also observed missing sutures where the PVL/dehiscence appeared. The plaintiffs submit that Dr. Tweden's evidence is not credible or reliable since Dr. Tweden acknowledged that Dr. Cameron made no notes about the missing sutures, came to no conclusion about the cause of death of KTMV-2, and there are no records documenting these observations. While initially, I thought it unlikely that either Dr. Tweden or Mr. Holmberg would recall their observations of the explanted valve from one sheep, I have since changed my mind.

136 The early death of an animal in an animal study is not uncommon, but the death of this animal was a significant event in the context of this study. The 4 to 5 week study was the first opportunity to evaluate the Silzone coating *in vivo*. KTMV-2 was the second animal to be implanted, but the first to have its valve explanted and examined. Dr. Tweden was the senior scientist on the project and the individual who had developed and proposed the 'half and half' method for this study. She had prior experience with this and it was important for her to determine where the dehiscence was located in order to understand if the Silzone coating was implicated. I have concluded that these are circumstances that make it likely she would remember whether the

dehiscence was on the Silzone side of the cuff or on both sides. Mr. Holmberg would have been equally concerned. He regarded this study as an opportunity to make a "go/no go" decision on the project. If the death of KTMV-2 was device-related, this could have terminated the project. As they were both looking for an explanation for the early death of this sheep, I find that their recollections are credible.

137 By the time of the Design Review meeting on October 24, 1996, all of the sheep had been sacrificed. Dr. Tweden testified that "part of the design review is you are starting to put together your failure modes and effect analysis, and it is a group of not only the team but outside people who are brainstorming on all the possible failure modes. So it is important to bring up any possibility". The meeting was attended by eighteen St. Jude employees including Dr. Flory, Darin Bergman, Director of Mechanical Valve Research and Development, and Bill Mirsch, Director of Tissue Valve Research and Development. Many of those in attendance would have been knowledgeable about sheep studies as this is a common animal model used for testing prosthetic heart valves. At the meeting, Dr. Tweden discussed the results of the 4 to 5 week study, including the early death of KTMV-2. Dr. Tweden did not recall anyone expressing concern or suggesting that further work be done to evaluate the death of this sheep.

138 A cross-functional group was also brought together in December 1996 for the FMECA process to brainstorm failure modes and participants there were also made aware of KTMV-2. The possibility of dehiscence and paravalvular leak was addressed as an effect of the potential failure mode, "Silver coating results in inadequate tissue ingrowth". Thus, there were numerous experienced individuals at the company who knew about KTMV-2, who were familiar with sheep studies and who had the opportunity to suggest that further investigation was necessary.

139 Dr. Cameron's pathology report for KTMV-2 did not mention anything about missing sutures, but he reported on the tissue development and found it to be comparable on both sides. His pathology reports for the six other animals described good healing on both sides of the cuff with a similar degree of tissue growth. After reviewing the pathology with Dr. Cameron for KTMV-2 and for all the other animals in the study, Dr. Tweden concluded that the death of KTMV-2 was not device-related. In my view, this was a reasonable conclusion to reach.

140 I also find it significant that the Short Term study results were described in a peer-reviewed article (the ASAIO article) co-authored by Dr. Tweden, Dr. Cameron, Mr. Bianco, Dr. Razzouk, Mr. Holmberg, John Barry, Ray Bricault and Eric Tobin.[37] All were aware of the study results, including the death of KTMV-2. It is reasonable to think that if any of the authors believed the PVL/dehiscence to be related to the Silzone coating, they would have suggested further investigation before publishing the article. Neither KTMV-2 nor the two sheep implanted with Teflon valves were described in this article, as the focus of the article was the evaluation of the Silzone coating on Dacron. In the case of KTMV-2, it died too soon after implantation to give meaningful information one way or the other on tissue healing.

141 The ASAIO article described comparable tissue ingrowth of coated and uncoated fabric with "a more organized thinner pannus formed on silver coated fabric." A more organized pannus indicates better or more advanced healing. Dr. Tweden considered the thinner pannus to be a more ideal pannus because a thinner cuff is compatible with a milder thrombotic response to the cuff. The histopathology also described signs of immature or less organized pannus only on the uncoated sides of the cuff and a "lamellar pattern" of cell organization in tissue in the coated halves, indicating advanced maturity in the pannus. Dr. Cherian, the plaintiffs' toxicologist, testified that he would not expect to see more organized pannus if the thinner pannus was under toxic stress.

142 Finally, the study analyzed blood samples taken from the sheep during the course of the study. They revealed an increase of silver levels after implantation with a slight peak after two weeks, never exceeding 50 ppb and then declining to below quantitation levels at the time of sacrifice. This data suggests that there was only a small amount of released silver from the cuff that declined over time.

Long Term or 10 Week Study

143 The recommendation of the Heart Valve Guidance for conducting preclinical animal studies on new heart valves is that a minimum of six animals must survive an implantation period of 20 weeks with at least two additional animals to serve as controls. Mr. Runquist wrote to the FDA on August 30, 1996 to propose that St. Jude shorten its animal study from 20 weeks to 10 weeks based on previous studies (including the Short Term study then underway) that showed that healing in the sheep model was complete by six weeks. There was no evidence from the Short Term study to support this statement, but Dr. Tweden had been involved in other projects where she had studied the time course of healing in sheep. She informed Mr. Runquist that based on her experience, sheep would be completely healed in terms of tissue ingrowth by six weeks. While the plaintiffs criticize the length of the study (and the "misleading" letter to the FDA), none of the plaintiffs' expert witnesses challenged Dr. Tweden's conclusion that tissue healing in sheep is complete by six weeks.

144 Dr. Williams testified that if healing is complete by six weeks, differences in healing response would be observed by that time and that extending the study to 20 weeks would not provide any additional information on the healing response, which was the purpose of the study. Both the FDA and Health Canada were aware of the rationale for shortening the study to 10 weeks and neither took issue with its length. Dr. Hilbert of the FDA was a pathologist who reviewed all of the animal studies for prosthetic heart valves and it can be inferred that he was capable of assessing the length of the study. I find that the study was of sufficient length to assess the tissue healing response of the Silzone valve.

145 The six test animals and three controls that St. Jude used in the Long Term Sheep Study met what was recommended by the Heart Valve Guidance for a new valve and was consistent with ISO standards, including the principle in ISO 10993-2 to minimize, where possible, the number of animals used for testing. Dr. Olson's opinion that industry standards required the use of power

calculations to determine the number of animals in the study, and that this required 25 Silzone animals and 25 controls, is contradicted by the written standards and by the experience of all other witnesses familiar with pre-market testing of prosthetic heart valves.

146 I do not find it necessary to review Dr. Olson's evidence on deficiencies in the design and conduct of the Long Term Sheep Study at Loma Linda University, such as lack of GLP compliance. There is no evidence that any of his criticisms, assuming they are valid, compromised the reliability of the data or the study objectives of assessing the healing of the Silzone-coated valve and quantifying the release of silver from the cuff into the bloodstream over time. At the time, it was consistent with both industry and regulatory standards to conduct large animal studies without full GLP compliance.

147 The Silzone sheep in this study were SJII-1, SJII-2, SJII-3, SJII-4, SJII-5 and SJII-8. The sheep with uncoated valves were SJII-6, SJII-7 and SJII-9. The surgical staff at Loma Linda performed necropsy and gross examination of the animals at the time of sacrifice. They reported that all animals "seemed to be in healthy condition at the time of sacrifice". With the exception of SJII-8, the surgical notes indicate that the sewing rings for both control and coated valves were epithelialized, with no thrombus or vegetation.

148 Dr. Cameron evaluated the gross and microscopic pathology and recorded that none of the sheep had unhealed areas. He wrote, "[a]ll cardiac specimens appeared to exhibit a similar degree of epicardial reaction to the surgical procedure which had occurred 10 weeks earlier". There was no evidence of thrombus formation. There were variable differences in areas of thin and thick pannus, but the degree of variability was similar in Silzone cuffs to controls and Dr. Tweden testified that the variability was similar to what she had observed in valves in other projects. Dr. Tweden agreed with Dr. Cameron's assessment and concluded, based on the gross pathology, that the healing was comparable.

149 Dr. Cameron also conducted a microscopic evaluation to evaluate tissue healing and potential toxicity, including pannus measurements, foreign body response and macrophage incorporation of the coating material.[38] He recorded his results on a chart. Using an evaluation system for pannus formation developed by Dr. Schoen, the Silzone valves showed equal or greater tissue growth into the sewing cuff than controls. There was comparable foreign body response, indicating that Silzone permits healing without causing an undue inflammatory response. The macrophage assessment showed that the accumulation of silver in the macrophages was not having an adverse effect on tissue formation and growth. This is an indication that the material is biocompatible and is not having a toxic effect.

150 Dr. Cameron concluded: "There was no apparent differences [sic] in the parameters of granulomatous inflammatory infiltrate (giant cell formation) or degree of fibrous tissue integration into the sewing cuff fibres of the coated and uncoated specimens. There appeared to be a greater degree of pannus formation in the sections available in the uncoated specimens relative to the

coated specimens although the number of observations is small." His summary comment was: "The tissue reaction to coated and uncoated synthetic materials appears to be similar by the parameters available for study."

151 The pannus measurements were the basis for Dr. Tweden and Dr. Cameron's conclusions in the JHVD article that there was "a suggestion" that the pannus formed on the coated cuff was thinner. Dr. Tweden said that word was deliberately chosen as they were unable to show a statistically significant difference. The plaintiffs allege that testing should have been performed to determine the effect of thinner pannus on tissue ingrowth. Dr. Tweden was not aware of a test to assess this and there is no expert evidence regarding a testing method or whether such a test was possible. Neither is there evidence that the thickness of pannus affects tissue ingrowth into the cuff.

152 Two valves in this study - SJII-8, a coated valve and SJII-9, an uncoated valve -exhibited excess pannus. As I mentioned earlier, Dr. Tweden forwarded them to Dr. Schoen for gross evaluation. Dr. Schoen did not think the excess pannus on SJII-9 was unusual. In Common Issue 2, I discuss the conflicting expert evidence from Dr. Factor and Dr. Wilson on this valve. It is sufficient to note here that Dr. Schoen informed Dr. Tweden that there were two prominent suture knots adjacent to the pivot guards and while their relationship to the excess pannus was uncertain, he could find no other apparent cause for the excessive pannus. Dr. Cameron's gross and microscopic pathological examination of SJII-8 did not indicate any underlying problem.

153 Dr. Tweden and Dr. Cameron both came to the reasonable conclusion that the 10 week study showed that Silzone did not inhibit, delay or impair tissue healing. It confirmed the pattern of good healing seen in the 4 to 5 week study. Dr. Tweden wrote in the JHVD article: "The ten-week study showed that both the uncoated standard cuff and the silver-coated cuff reached the same endpoint of fully healed, functional pannus." The paper was co-authored by Drs. Cameron and Razouk and Mr. Bianco. While the paper is not admissible as proof of the truth of the opinions in it, it is admissible as corroboration of Dr. Factor's opinion, and to contradict Dr. Wilson's opinion where they differ as discussed in Common Issue 2. It is also corroboration of Dr. Williams' opinion, which I accept, that the Short and Long Term Studies provided a reasonable assurance of the safety of the Silzone valve.

Was a clinical trial required?

154 The plaintiffs submit that the failure to conduct a clinical trial to assess the safety of the Silzone valve fell below the standard of care. At times, their submissions suggest that the standard of care required the defendants to delay the introduction of the Silzone valve and conduct a pre-market clinical trial such as AVERT in order to show that Silzone was effective in patients and posed no additional risk. At other times, they refer to clinical data, but they do not describe the kind of clinical data that was necessary to meet the standard of care. In their submissions, they refer to a paper by Dr. Grunkemeier as evidence that "a much smaller OPC (Objective Performance Criteria) study, with 800 patient-years, would have been sufficient to identify the increased risk of major leak."[39]

155 I agree with the defendants that the OPC paper is not admissible as evidence of its contents or for the truth of the authors' opinions. Not only did the plaintiffs fail to call any of the authors at trial, they failed to put the paper to any witness or attempt to establish through their own witnesses or cross-examination of the defendants' witnesses that the Silzone valve would not have met the OPC criteria in the Heart Valve Guidance. I therefore place no weight on this paper. This leaves a RCT such as AVERT or the LIMRA (discussed below) as there is no other evidence on the kind of clinical study or clinical data that might be required to meet the standard of care.

156 In the context of determining the appropriate requirements for studies generating human clinical data for a new mechanical heart valve, the FDA, with input from many industry participants, rejected a requirement that data be derived from RCTs for valve related morbid events that occurred at very low rates. As the Heart Valve Guidance states, there was a concern that "... requiring such a study would essentially eliminate the possibility of introducing an improvement in technology to the market before the improvement itself was obsolete".[40] It recognized the need to strike a compromise "... between knowing before the product is marketed whether it was safe and effective for the intended use and keeping these new, innovative valves out of the hands of the surgeons and preventing treatment of patients". Thus, the document that reflects industry standards strikes a balance between innovation and risk and did not require a RCT such as AVERT before introducing a new prosthetic heart valve to the market, much less a modification. Instead, event rates could be compared against pre-established acceptance criteria for clinical performance called objective performance criteria, even though RCTs provide the most scientifically valid information.

157 In the FDA's initial communication to St. Jude in February 1996, it stated that it wished to have some pre-market clinical data and suggested several options for providing this, including "a clinical study via IDE or other available means, European clinical data and/or clinical data in the Spire Master File." St. Jude responded in two ways. The Limited Initial Market Release Authorization or LIMRA was a limited release of the Silzone valve to two European centres before the Silzone product was released to a more general market. It provided clinical data on silver serum levels in a small number of patients implanted with Silzone valves and monitored short-term complications. As well, part of the Spire Master file discussing Dr. Bambauer's clinical work and his related papers were included as part of the regulatory submissions.

158 Although the plaintiffs criticize the LIMRA as being too small to assess the safety of the valve and the tissue healing response to Silzone, Health Canada and the FDA approved the Silzone valve without a clinical trial beyond the LIMRA study. At the time of the submission to Health Canada in May 1997, there was limited data on the LIMRA patients. This was updated for Health Canada in July and December while the FDA review process was ongoing. The FDA requested an additional summary report of the 38 patients in the study, but at no time did it require clinical data beyond the LIMRA, let alone a more comprehensive clinical trial.

159 The Heart Valve Guidance provides that modifications to the sewing ring material require clinical data. The plaintiffs ask me to find "on the totality of the evidence" that Silzone is

"chemically fundamentally different" from Dacron or Teflon, to reject Ms. Johnson's evidence that the addition of Silzone to the sewing cuff was not considered to be a change of fabric, and to find that industry standards required clinical data beyond the LIMRA. The plaintiffs do not point to any expert evidence that Silzone-coated Dacron is chemically different from uncoated Dacron or to any evidence of the kind of clinical data that industry standards would require if the provision applied. The only evidence on this point comes from Ms. Johnson who testified that the provision does not apply.

160 The FDA reviewers of the Silzone modification included, as I have mentioned, Dr. Hilbert, a pathologist experienced in valve implant studies in sheep, as well as several engineers, a cardiac surgeon and a biomaterials expert. All had input into the drafting of the Heart Valve Guidance. The internal FDA documents show that they considered many of the issues raised at trial in their review of the PMA Supplement, but the record contains no evidence that any FDA reviewer (or Dr. Butler) thought that the addition of Silzone was a change of fabric, implicitly corroborating Ms. Johnson's opinion that it was not.

161 The FDA and Health Canada were clearly aware that no clinical trial beyond the LIMRA had been conducted. Dr. Williams and Ms. Johnson opined that industry standards did not require this. The plaintiffs' position is not supported by the expectations of the regulators or by industry standards. All of the evidence supports the conclusion that the industry and regulatory standards for evaluating the safety of the Silzone modification did not require a clinical trial or clinical data beyond the LIMRA. The plaintiffs' assertion that a pre-market clinical trial was necessary in this case to meet the standard of care is not supported by any of the evidence led at trial.

Regulatory Approval

162 The PMA Supplement was submitted to the FDA on May 14, 1997 and the SNOC was submitted to Health Canada on May 23, 1997. They were not identical, but they were substantially similar. Health Canada completed its review and issued the SNOC in less than sixty days on July 16, 1997, but the FDA did not approve the valve until March 1998, and only after St. Jude submitted two Amendments to the PMA Supplement that addressed the FDA's queries. This included: (i) providing complete pathology reports and microphotographs from the sheep studies; (ii) justifying why biocompatibility testing relied on Spire data rather than testing on the finished sterilized product; (iii) addressing issues related to corrosion testing; (iv) substantiating the hypothesis that endocarditis is attributable to colonization of bacteria on the sewing cuff; (v) revising the labelling and promotional material; and, (vi) revising the proposed efficacy study.

163 The FDA and Health Canada both concluded, based on the materials they each reviewed, that there was sufficient evidence of safety and effectiveness to warrant approval of the valve. The defendants submit that Health Canada's approval of the submission and issuance of the SNOC indicates that it agreed that the testing that St. Jude described in the submission was adequate and met Heart Valve Guidance and ISO standards as required, and that the results included in the

submission showed that the Masters series valve with Silzone would continue to be as safe and effective as the conventional valve. The defendants do not contend that regulatory approval displaces the common law standard of care, but rather that it is corroborative evidence of the defendants' experts' opinions that St. Jude conducted adequate testing in accordance with industry standards and interpreted the results of the testing in a reasonable manner.

164 Health Canada's mandate requires it to strike a balance between innovation and patient safety, but Health Canada is largely dependent on manufacturers of medical devices for information regarding the safety of their products.[41] As regulatory approval is based on the information provided by the manufacturer, the plaintiffs argue that it cannot be seen as strong evidence that the defendants met the standard of care. They suggest that Dr. Butler lacked the appropriate qualifications and specialized knowledge relevant to a review of the SNOC submission and that he performed only a cursory review as he was under pressure to complete his review within the 60 day timeline set out in Part V of the *Medical Devices Regulations* promulgated under the *Food and Drugs Act* (the legislation that was the statutory framework for the regulation of medical devices in Canada at the time).[42] While the plaintiffs acknowledge that compliance with industry standards and the fact of regulatory approval can be useful evidence of reasonable conduct and the standard of care, they deny that it is of value in this case because St. Jude's regulatory applications, contained "a series of contradictory statements, material misrepresentations, misstatements and omissions concerning the company's pre-market efficacy and safety testing".

165 Neither regulator was in a position to conduct any independent testing of the Silzone valve and St. Jude possessed vastly greater resources than either did, but the FDA process shows a group of experienced technical experts in biomaterials, engineering, corrosion, cardiac surgery and experimental pathology reviewing the PMA Supplement and Amendments for compliance with industry standards and FDA expectations before granting approval. It is clear that Health Canada did a much lesser review than the FDA and less weight attaches to its analysis, but the same test data was used to show safety and effectiveness for both the Health Canada and FDA submission. As well, although Health Canada conducted an independent review of medical devices, Dr. Butler testified that Health Canada placed considerable importance on the FDA's approval or rejection of a device because of their greater experience with medical devices. To the extent that the FDA reviewed additional material and still approved the valve, this is some evidence that Health Canada would have also approved the valve if it had reviewed the additional information provided to the FDA.

166 This is also borne out by Dr. Butler's responses to questions posed by plaintiffs' counsel during direct examination about whether he would have wanted to know or whether he would have expected St. Jude to disclose specific types of information. At no time did Dr. Butler testify that he would have refused to recommend approval of the SNOC if he had known any of the additional information that plaintiffs' counsel put to him. As well, while Dr. Butler testified that "we accept the word of the company", both he and Dr. Freeland gave evidence that a reviewer could request additional information, or clarification, including that a manufacturer conduct a clinical trial. The

conclusion to be drawn from their evidence is that unless a submission was hopeless, before rejecting an application, a manufacturer was given every opportunity to provide the information that was necessary to satisfy the reviewer of the safety and efficacy of the product. Thus, if Health Canada had raised the same queries as the FDA, it is likely that St. Jude would have responded in a similar fashion and approval of the valve would have followed as it did in the United States.

167 Dr. Butler's background was in physiology. His Ph.D. from Duke University related to cell membrane biology and transport processes, which involves the study of the structure of cellular membranes and the transport of ions across membranes. He also had training in statistics and had been involved in the design of animal studies and *in vitro* studies. While he was at Health Canada, and before that at the National Research Council, there were frequent seminars led by outside experts on a wide variety of topics. Also, he attended annual meetings of the American Heart Society and the Canadian Cardiovascular Society.

168 Dr. Freeland testified that the Health Protection Bureau had many sources of scientific information available to it, including access to experts in the fields of cardiac surgery, toxicology, biomaterials, microbiology and statistics and a large scientific body of information. Dr. Butler testified that he spoke with physicians in the department about silver toxicity and discussed the submission with the reviewer of the Masters series valve application and reviewed the submission report coming out of that review. He contacted Mr. Runquist in July 1997 seeking further information on biocompatibility. While Dr. Butler could not recall conducting an independent literature review, his report shows that he obtained a copy of the US Public Health Service's Toxicological Profile for Silver. He was therefore alive to the issue of silver toxicity. In my opinion, Dr. Butler had sufficient expertise and resources to evaluate the SNOC.

169 Dr. Freeland testified that while every attempt was made to process applications for a SNOC within 60 days, there were procedures in place to extend the period if it was necessary. Dr. Butler testified that he felt pressure in general to meet this deadline if possible, but it is clear from his evidence that whether or not the deadline was in fact met was largely due to chance:

> Well, it's one of these things like, the line in the grocery store. I mean, if you happen to get in the line right behind somebody with two carts full, you're going to be a while. If you happen to get ahead of them, you grease through. So sometimes there was a big load, sometimes there wasn't. It was irregular.

170 The evidence is insufficient to conclude that Dr. Butler rushed his review of the St. Jude submission as there is no evidence one way or the other as to the line in which the application for the SNOC ended up. However, it is apparent that it received far less scrutiny than the comparable application submitted to the FDA, and that Health Canada was far more reliant on the veracity of the assertions contained in the submission and the data that was provided to support the claims that were made.

171 I am satisfied by the evidence that the submissions did not misrepresent, misstate or fail to

disclose the results of the pre-market efficacy and safety testing in any material way. The only serious omission was the failure to mention the early death of KTMV-2 (discussed below). Otherwise, I attach little weight to the plaintiffs' submissions. In some cases, they are simply wrong as St. Jude did disclose the tissue discolouration observed in the sheep studies and accurately described the parallel streak test results. I have found that the disclosure of the *in vitro* test results was fair and accurate. Further, as I have said, it was apparent from the submission that no clinical trial had been conducted and Dr. Butler gave evidence that, at the time he reviewed the SNOC submission, he knew that St. Jude had not been able to prove that Silzone prevented infection. There was no need for St. Jude to disclose that it was aware that it would be unable to establish Silzone's efficacy in humans without conducting a clinical trial as this was evident from the submission.

172 The plaintiffs criticize Dr. Tweden's literature summary on silver toxicity. I attach no weight to Dr. Healy's opinion that it was inadequate as he admitted that he looked at "only 50 to 60 percent" of the articles she referenced. Dr. Williams testified that the summary was not comprehensive and did not contain the totality of the literature that existed, but he concluded that she had done a good job and presented a balanced review of the matters in issue. All witnesses agreed that the most significant characteristic of a literature summary for regulatory submission is that it be balanced.

173 I am also satisfied that St. Jude made no misleading statements in describing the results of the washout studies, corrosion testing, blood silver studies and tissue silver studies. They consistently showed that the coating was minimally leaching. No confusion would have been created by the reference in one part of the submissions to "non-leaching" and in other parts to "minimally leaching". Both Health Canada and the FDA were aware that some silver ions would be released from the Silzone coating once the valve was implanted. It was apparent from the submission that some silver would be present in annular tissue.

174 The plaintiffs allege that St. Jude "grossly exaggerated" reported PVE rates "for the purpose of justifying the approval of its unproven Silzone valve". The PVE rates given in the submission ("less than 5%") and in Dr. Tweden's Literature Review on Infective Endocarditis ("reported to range from 1 to 4%/patient-year") are quite a bit higher than those referred to by the plaintiffs in the two published articles they rely on, although the article by Grunkemeier et al. was not published until after the valve was approved.[43]

175 Dr. Sexton testified that there were a number of reasons for the range in rates and that "there are all kinds of numbers in the literature", including those provided by the defendants in their submissions. Even if the plaintiffs are correct that the rates are exaggerated, they were not exaggerated to a degree that it would likely have affected Health Canada's decision to approve the valve. The submission makes clear that the disease affects only a small number of patients, but with serious consequences.

176 The defendants acknowledge that it would have been preferable for the early death of

KTMV-2 to have been mentioned in the Health Canada submission as it was later mentioned in the FDA review process. The FDA approved the Silzone valve with knowledge only of the early death of KTMV-2 and that the cause of death was unknown. The FDA did not have Dr. Cameron's pathology report or Dr. Tweden's report on the 4 to 5 week study which the plaintiffs allege should have been disclosed to Health Canada. The FDA did not request further information about the early death of KTMV-2. This is some evidence that this was not of concern to them.

177 In direct examination, Dr. Butler was asked about his expectations in the circumstances of the early death of an animal in a study. He testified that he expected the company to "come clean and say: We had this one sheep who died early. We did the pathology. This is why it died. This is why we don't think it is relevant to our study. We did replace it with another". Dr. Butler was aware that it was not uncommon for animals to die early in a cardiovascular implant study and he agreed that if the early death of a sheep was disclosed and he was satisfied that it didn't reflect any toxicity with respect to Silzone, he would still have approved the SNOC for the Silzone valve. As St. Jude had concluded that the death of this animal was not device-related and Dr. Cameron's pathology report described comparable tissue healing on both coated and uncoated sides of the cuff, I believe that Health Canada would have approved the Silzone valve if St. Jude had provided this information.

178 The plaintiffs argue that the submission to Health Canada should have proceeded as a NOC rather than as a SNOC. Whether a SNOC or a NOC was required was ultimately Health Canada's decision. Dr. Butler testified that it would have been appropriate for a manufacturer to proceed by way of SNOC instead of NOC "[w]henever most of the characteristics of the device are unchanged". However, he also explained that whether a device was submitted for approval as a NOC or a SNOC made no difference to the regulatory approval process:

> This was a perpetual issue, but really, it doesn't make a major different [*sic*] because the reviewer has the flexibility of reviewing what is necessary. The company has to convince the reviewer, and hence the rest of the Bureau, that the device continues - that the device is safe and effective. And it really doesn't matter whether it's a SNOC or NOC that comes in, as long as there is sufficient evidence from previously notified devices and testing on the new device that it is safe and effective.

179 The plaintiffs' Health Canada witnesses each agreed that no implanted device is without risk and neither the regulations nor Health Canada require that an implantable device be 100% safe prior to approval. As the Court of Appeal explained in *Attis* in considering whether to impose a duty of care on Health Canada:

> ... In making decisions about whether medical devices should be available in Canada, Health Canada must weigh the need of some individuals to obtain relief from suffering (and sometimes death), despite the risks of a particular device,

> with the desire of others to avoid all risk, no matter the consequences. In doing so, Health Canada is obliged to consider the needs of the public at large in determining whether a device meets the minimum requirements for sale and/or distribution in Canada. ...[44]

180 A device known to have significant risks, even greater risks than similar devices of the same type, may still be found to be "safe and effective" for the purposes of approval under the regulations, depending on the benefits associated with that device. In response to a series of questions from plaintiffs' counsel relating to whether he would approve the SNOC if the device under consideration was worse than the predicate device, Dr. Butler testified that, "if there was a device that was -- hypothetically a device that was worse in several aspects but was life-saving for a small group of people, we would almost definitely approve it".

181 The disclosure issues that the plaintiffs raise are not significant, but even if they were, the FDA's more thorough review and approval of the valve shows that it is unlikely that the lack of disclosure would have affected Health Canada's approval of the Silzone valve. The plaintiffs presented no evidence that the information the plaintiffs allege should have been disclosed would have changed Health Canada's decision to approve the valve. I find that regulatory approval corroborates the opinions of Drs. Hancock, Williams and Rodricks that St. Jude conducted appropriate and sufficient testing that met industry and regulatory standards.

Conclusion on Common Issue 1a

182 The evidence satisfies me that St. Jude's pre-market testing to develop Silzone was reasonable and in accordance with the standard of care. St. Jude identified the appropriate issues for testing and performed standardized approved tests which showed that Silzone had a low potential for causing a toxic reaction, especially *in vivo*. *In vitro* efficacy testing demonstrated that Silzone was effective against infectious agents that cause endocarditis. The sheep studies showed that the Silzone valve was comparable to the conventional valve from a safety and healing perspective. The pattern of release of silver was also evaluated in the LIMRA study with results that showed values to be well below toxic levels.

183 The testing results were reviewed by a broader group within the company. St. Jude reasonably interpreted the results and reasonably concluded that the testing was consistent with the scientific literature, which showed silver had low toxicity to human cells but was effective against bacteria. Products on the market at the time also demonstrated this. There was no indication that Silzone inhibited tissue growth, caused an abnormal inflammatory response or toxic effect, or that the inflammatory reaction seen with Silzone was any different than uncoated Dacron. The FDA and Health Canada reviewed and approved the distribution of the Silzone valve, implicitly concluding that the design and testing met industry and regulatory standards. Although there are serious risks associated with the implantation of a mechanical heart valve, the likelihood of risk for both conventional and Silzone valves was low. It is only with the benefit of hindsight that it can be

argued that Silzone patients were put at greater risk. In weighing the potential benefits and likely risks, St. Jude conducted an appropriate assessment and reasonably concluded that the benefits to health for heart valve patients outweighed the risks of the Silzone valve. Accordingly, this portion of Common Issue 1a is answered in the negative.

Common Issue 1b - Post-Market Surveillance, Warning and Recall

184 In *Hollis v. Dow Corning Corp.*,[45] La Forest J., for the majority, provided a thorough overview of tort law in the context of the duties imposed on medical device manufacturers:

> 20 It is well established in Canadian law that a manufacturer of a product has a duty in tort to warn consumers of dangers inherent in the use of its product of which it has knowledge or ought to have knowledge. This principle was enunciated by Laskin J. (as he then was), for the Court, in *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569, at p. 574, where he stated:
>
> > Manufacturers owe a duty to consumers of their products to see that there are no defects in manufacture which are likely to give rise to injury in the ordinary course of use. Their duty does not, however, end if the product, although suitable for the purpose for which it is manufactured and marketed, is at the same time dangerous to use; and if they are aware of its dangerous character they cannot, without more, pass the risk of injury to the consumer.
>
> The duty to warn is a continuing duty, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered; see *Rivtow Marine Ltd. v. Washington Iron Works*, [1974] S.C.R. 1189, at p. 1200, per Ritchie J. All warnings must be reasonably communicated, and must clearly describe any specific dangers that arise from the ordinary use of the product; see, for example, *Setrakov Construction Ltd. v. Winder's Storage & Distributors Ltd.* (1981), 11 Sask. R. 286 (C.A.); *Meilleur v. U.N.I.-Crete Canada Ltd.* (1985), 32 C.C.L.T. 126 (Ont. H.C.); *Skelhorn v. Remington Arms Co.* (1989), 69 Alta. L.R. (2d) 298 (C.A.); *McCain Foods Ltd. v. Grand Falls Industries Ltd.* (1991), 116 N.B.R. (2d) 22 (C.A.).
>
> 21 The rationale for the manufacturer's duty to warn can be traced to the "neighbour principle", which lies at the heart of the law of negligence, and was set down in its classic form by Lord Atkin in *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.). When manufacturers place products into the flow of commerce,

they create a relationship of reliance with consumers, who have far less knowledge than the manufacturers concerning the dangers inherent in the use of the products, and are therefore put at risk if the product is not safe. The duty to warn serves to

correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.

22 The nature and scope of the manufacturer's duty to warn varies with the level of danger entailed by the ordinary use of the product. Where significant dangers are entailed by the ordinary use of the product, it will rarely be sufficient for manufacturers to give general warnings concerning those dangers; the warnings must be sufficiently detailed to give the consumer a full indication of each of the specific dangers arising from the use of the product. This was made clear by Laskin J. in Lambert, supra, where this Court imposed liability on the manufacturer of a fast-drying lacquer sealer who failed to warn of the danger of using the highly explosive product in the vicinity of a furnace pilot light. The manufacturer in Lambert had placed three different labels on its containers warning of the danger of inflammability. The plaintiff, an engineer, had read the warnings before he began to lacquer his basement floor and, in accordance with the warnings, had turned down the thermostat to prevent the furnace from turning on. However, he did not turn off the pilot light, which caused the resulting fire and explosion. Laskin J. found the manufacturer liable for failing to provide an adequate warning, deciding that none of the three warnings was sufficient in that none of them warned specifically against leaving pilot lights on near the working area. At pages 574-75, he stated:

> Where manufactured products are put on the market for ultimate purchase and use by the general public and carry danger (in this case, by reason of high inflammability), although put to the use for which they are intended, the manufacturer, knowing of their hazardous nature, has a duty to specify the attendant dangers, which it must be taken to appreciate in a detail not known to the ordinary consumer or user. A general warning, as for example, that the product is inflammable, will not suffice where the likelihood of fire may be increased according to the surroundings in which it may reasonably be expected that the product will be used. The required explicitness of the warning will, of course, vary with the danger likely to be encountered in the ordinary use of the product.

> 23 In the case of medical products such as the breast implants at issue in this appeal, the standard of care to be met by manufacturers in ensuring that consumers are properly warned is necessarily high. Medical products are often designed for bodily ingestion or implantation, and the risks created by their improper use are obviously substantial. The courts in this country have long recognized that manufacturers of products that are ingested, consumed or otherwise placed in the body, and thereby have a great capacity to cause injury to consumers, are subject to a correspondingly high standard of care under the law of negligence; see *Shandloff v. City Dairy*, [1936] 4 D.L.R. 712 (Ont. C.A.), at p. 719; *Arendale v. Canada Bread Co.*, [1941] 2 D.L.R. 41 (Ont. C.A.), at pp. 41-42; *Zeppa v. Coca-Cola Ltd.*, [1955] 5 D.L.R. 187 (Ont. C.A.), at pp. 191-93; *Rae and Rae v. T. Eaton Co. (Maritimes) Ltd.* (1961), 28 D.L.R. (2d) 522 (N.S.S.C.), at p. 535; *Heimler v. Calvert Caterers Ltd.* (1975), 8 O.R. (2d) 1 (C.A.), at p. 2. Given the intimate relationship between medical products and the consumer's body, and the resulting risk created to the consumer, there will almost always be a heavy onus on manufacturers of medical products to provide clear, complete and current information concerning the dangers inherent in the ordinary use of their product.

185 While the above excerpt is lengthy, the standard is really quite simple. The underlying question is always "what was reasonable under the circumstances?" As a manufacturer occupies the position of an expert in the field, it is under a continuing duty to inform physicians when additional dangerous side-effects are discovered.[46] It must therefore assess the information that it receives regarding the performance of its product to determine whether or not it reasonably indicates an additional risk that requires an updated warning or other action. In *Hollis*, Dow Corning had received between 48 and 61 field experience reports (FERs) prior to the implant rupture that the plaintiff experienced. These were categorized as "unexplained". The court concluded that as these were not attributable to any known cause for which a warning had been provided, the manufacturer had notice of an additional or new risk that was not disclosed in its warnings for the product.

186 In the present case, all of the adverse events that were observed and the FERs that were received between the time that the Silzone valve went to market and its recall, were of a type that St. Jude had already warned about in the labelling and in the physicians' manual. The question under Common Issue 1b, then, must be whether at any point during that period, sufficient evidence of an increased risk of one or more of the complications already warned of arose, such that a reasonable manufacturer of heart valves in the position of St. Jude would have either (a) issued an additional warning, or (b) recalled the Silzone valve. Since St. Jude did eventually recall the Silzone valve, this question can be reframed as: did the timing of St. Jude's recall of the Silzone valve fall within the timeframe that could be considered reasonable in the circumstances?

187 With respect to these two questions, I propose to discuss the most persuasive evidence and arguments adduced by the plaintiffs as well as the defendants' response. Broadly speaking, I believe the strongest evidence for the plaintiffs relates to the concerns raised by Mr. Butchart and Dr. Butany prior to recall, the MDA Advice Notice, and the Australia/New Zealand regulatory action. Strictly speaking, I do not need to consider the evidence of Mr. Butchart as I have found that the Silzone valve did not materially increase the risk of thromboembolism (discussed in Common Issue 3). Thus, the failure to warn of an increase in risk of this complication cannot result in liability. However, for completeness, I will review this evidence.

Mr. Butchart

188 Mr. Butchart contacted St. Jude in the fall of 1998 about high rates of thromboembolism in Silzone patients at his hospital in Cardiff, Wales. On November 11, 1998, he met with key personnel from St. Jude and with Dr. Schoen who attended by videoconference to present his findings. An action plan was developed at the meeting and the evidence shows that St. Jude followed up on each of the items. This included a survey of three of its earliest implanting centres, a review of explanted Silzone cuffs returned to the company to that point in time, and pathological reviews of two of Mr. Butchart's explants. Efforts were also made to conduct a comparative valve review of explanted Silzone and conventional valves and this was discussed with Mr. Butchart in a conference call on December 15, 1998.

189 The plaintiffs are critical because Mr. Butchart was told that he was the only surgeon who had reported a *pattern of thromboembolic events*, but this in fact was true. He was reporting five or six TE events in a fairly small group of patients and no other centres had reported a similar experience at that time. The plaintiffs also allege that St. Jude discouraged Mr. Butchart from reporting his findings to regulators, but this is not so. Mr. Butchart was simply asked not to *publish* his findings until the company had an opportunity to gather further information. Mr. Butchart, in fact, agreed to this request: "[w]ell, at that stage, I was, I suppose, prepared to give them the benefit of the doubt because they told me that they were going to provide me with further information based on their own investigations and based on obtaining data from other centres. And I agreed to wait to see what that would show before reporting our own results". Dr.Flory testified directly that St. Jude never asked Mr. Butchart not to report his findings to the MDA, and indeed, there is no evidence that the company did make such a request. In any event, Mr. Butchart did, in fact, report his findings to the MDA, and St. Jude did not object.

190 It is also noteworthy that the CERFS abstract, which was prepared in mid-1999 by Mr. Butchart and his colleagues, stated that "[t]hese findings need to be investigated in other studies". It did not, for example, make any recommendation that surgeons cease implanting the Silzone valve in patients. Further, as recommended, "other studies" were already being conducted by St. Jude, including AVERT.

191 The AVERT DSMB was provided with details of the concerns of Mr. Butchart, and

following an April 1, 1999 meeting unanimously recommended that AVERT proceed as planned, stating that presently they had "no reservations concerning thromboembolic rates" in AVERT. Dr. Schaff also continued to implant the Silzone valve at the Mayo Clinic in the summer of 1999, despite his knowledge of Mr. Butchart's concerns. He testified that "we didn't see increased rates of thromboembolism or reoperation" in AVERT.

192 In July 1999, Dr. Flory gave a presentation to St. Jude's Scientific Advisory Board (SAB), a group of cardiologists and surgeons who provided direction to St. Jude on product development efforts and scientific issues. In the presentation, Dr. Flory presented details of Mr. Butchart's thromboembolic events and Dr. Butany's Toronto cases along with the recommendations from the April meeting of the DSMB that the AVERT trial continue. He also described the company's ongoing investigations. The minutes to the "SAB Meeting Recap", which was an open discussion at the end of the meeting, note that "it was apparent to the SAB members who commented, that the findings did not represent evidence of problems with Silzone. The follow up being conducted by SJM was well-received. SAB members seemed confident in the technology, and in the manner in which issues have been addressed by SJM".

193 St. Jude advised both Health Canada and the FDA of Mr. Butchart's events and kept both regulators updated on their investigations. At no time did either regulator request that St. Jude undertake additional or other investigation activities. Therefore, the feedback that St. Jude was receiving at the time from advisors and experts strongly supported the company's view that Mr. Butchart's cases were not sufficient data on their own from which to draw conclusions. As Mr. Butchart's experience was not being seen elsewhere and investigation revealed no unusual pathology findings, this did not reasonably indicate an additional risk that required an updated warning.

194 Dr. Flory believed that an independent review of Mr. Butchart's data was appropriate and contacted Mr. Jules Dussek, President of the Cardiothoracic Surgeons of Great Britain and Ireland. On September 13, 1999, Mr. Dussek requested an external review of data gathered and reported by Mr. Butchart and colleagues at the University Hospital of Wales in Cardiff. The reviewers released their full report in late November 1999, a week after the MDA Advice Notice was issued. Under "recommendations for further data analysis", they stated that "the ability to draw general conclusions from these results will continue to be limited due to the small number of events observed and the fact that all results are based on data from one hospital". This is consistent with St. Jude's assessment. Notably, the reviewers had released an Executive Summary earlier in the month, on November 8th. It was this one-page Executive Summary that precipitated Ms. Randall's decision to issue the MDA Advice Notice on November 15th. Hazel Randall was Senior Product Specialist - Cardiovascular Implants, Device Technology and Safety at the MDA.

195 Finally, two internal FDA documents are noteworthy. In an internal email dated December 7, 1999, Mathematical Statistician Gary Kamer wrote that the Cardiff data was not sufficient on its own to justify action, that the methodology used "greatly overstated the problem" and that the

AVERT data was "by far" the best source for evaluating the risks of excess thromboembolism. He indicated that the data was a "red flag", in that it demonstrated a need to review more scientifically valid data. Of course, St. Jude was already doing this with its ongoing analysis of AVERT. In a December 10, 1999 internal email, cardiac surgeon Dr. Sapirstein, commenting on a proposed "Dear Doctor" letter that the FDA had requested St. Jude prepare, wrote: "[d]on't want to kill a possibly useful device with the message at this stage."

196 In my view, the defendants thoroughly investigated Mr. Butchart's concerns in spite of their reasonable belief that AVERT provided far more reliable data regarding the safety of the Silzone valve. As Dr. Frater testified, it was "always better to get data from a randomized control study being independently monitored than it is from any single isolated institution. That didn't mean that [Mr.] Butchart was not appropriately commenting on this experience, but in terms of deciding what its importance was in the big picture, the trial was far more important than a single report from a single institution". St. Jude received consistent feedback from other experts at the time that it was reasonable to rely on AVERT as the most reliable indicator of the performance of the valve and adverse events.

Dr. Butany

197 With respect to the concerns raised by Dr. Butany of TGH, the evidence demonstrates that St. Jude investigated these thoroughly as well. In January 1999, Dr. Butany travelled to St. Jude's headquarters at the company's invitation. High-ranking St. Jude scientists and executives were present at the meeting and a "wet lab" review of explanted valves was performed. There is extensive evidence regarding St. Jude's review and follow up with respect to Dr. Butany's concerns, including the efforts that were made to find matched controls in order to conduct a comparative valve review. Also noteworthy is Dr. Butany's own admission that his observations were consistent with those seen in explanted valves of all types: "[a]s I said repeatedly, every one of these modes of failure or every one of these pathology findings can be, were, and are seen with every valve". St. Jude arranged a meeting between Dr. Butany and Dr. Titus to do a pathological review of Dr. Butany's explants on May 19, 1999. Dr. Butany's cases were discussed at the Silzone Summit meeting convened by St. Jude in Toronto on May 20, 1999, which was also attended by several Canadian surgeons. Dr. Butany was also invited to attend a later meeting on Silzone issues in Quebec City in October 1999.

198 Health Canada, the FDA, and St. Jude's SAB were all informed of Dr. Butany's concerns but none recommended that St. Jude alter its course of action in any manner. All of Dr. Butany's evidence was derived from a single centre (TGH), and, as Dr. Schoen testified, was at best a series of anecdotal case reports. Dr. Butany acknowledged that as of the summer of 1999, he had concerns about whether his data could be generalized to all users of the Silzone valve. Dr. Flory testified that there was a bias in the selection of patients implanted with Silzone valves at TGH: "two layers of bias: One, a bias towards using St. Jude valves in double valve and mitral cases; and two, toward using Silzone valves in patients that had a history of endocarditis. The overall concern is it appears

there is selection bias and it is difficult to assess how significant that selection bias is. But it seems to be there". This concern was echoed by Dr. Joan Ivanov, the TGH's statistician in a slide presentation at the Silzone Review Meeting in Quebec City in October 1999.

199 Additionally, with respect to the concerns of both Mr. Butchart and Dr. Butany, none of the clinical data that St. Jude received and reviewed from other clinical studies was consistent with the findings of those doctors. This was the evidence of Dr. Flory, who testified as follows with respect to the concerns of Dr. Butany: "[y]es, the fact that a site was coming to us expressing concern about the valve always causes us concern. However, we weren't seeing the same phenomenon at that point at other centres or in the major clinical work that we had done. So, we wanted to find out more about it. We did take it seriously, but at this point it was a single centre reporting the events".

The DSMB

200 As noted above, the Data Safety Monitoring Board, or DSMB, met on April 1, 1999 and recommended that the AVERT trial continue. As discussed elsewhere, the DSMB members comprised a panel of experts who were not AVERT investigators, had no direct affiliation with St. Jude, and whose role it was (as the name suggests) to monitor the safety of patients enrolled in AVERT. The DSMB met again on November 1, 1999, and made the same recommendation, largely on the basis of there being no statistically significant evidence from AVERT of a difference in performance between the two valves at that time. Following the meeting, St. Jude received a letter from Dr. Holubkov, who at that time was AVERT's Principal Investigator at the Data Co-ordinating Centre at the University of Pittsburgh, stating that "the DSMB unanimously recommended that AVERT continue enrollment as planned. While the DSMB requested that all event rates in AVERT be kept confidential, they noted that AVERT is 'safe to continue' and that there are at present 'no differences' in event rates between the two AVERT treatment arms".

The MDA Advice Notice

201 As noted above, the reviewers for the Society of Cardiothoracic Surgeons of Great Britain and Ireland had released an Executive Summary on November 8, 1999, which was followed later in the month with their full report. It was this one page Executive Summary that precipitated Ms. Randall's decision to issue the MDA Advice Notice on November 15th.

202 The Executive Summary stated that a preliminary statistical analysis showed a statistically significant difference in thromboembolism rates between Silzone and conventional valves in the CERFS study. However, the reviewers also noted that "in view of small numbers and incomplete follow up in the two groups, the p-value and confidence intervals should be interpreted with caution".

203 Before releasing the Advice Notice on November 15th, Ms. Randall sent a copy to St. Jude on November 11th and gave the company one day to comment. Dr. Flory and Dr. Frater both responded that they "continued to believe that the Advice Notice is inappropriate and unwarranted".

The Advice Notice did not have any regulatory implications in the United Kingdom or anywhere else. St. Jude advised the FDA and Health Canada about the Advice Notice the day it was issued.

204 Dr. Flory testified that St. Jude did not consider stopping the sale of the Silzone valve after the Advice Notice was issued because:

> Again, at this time we had just had the Data and Safety Monitoring Board review meeting, which saw no safety issues with the valve. We continued to collect clinical data and review it with the other regulatory agencies, who accepted that. And we continued to believe that the product was safe for sale. Safe for use.

205 Following the Advice Notice, St. Jude sent a "Dear Doctor letter" to Canadian surgeons on November 26, 1999. The letter included a letter from Dr. Frater, the MDA Advice Notice, a summary of the clinical data that St. Jude had regarding the performance of the Silzone valve, a copy of the letter from the University of Pittsburgh of the recommendations of the November 1 DSMB meeting, and copies of Mr. Butchart's abstracts. Dr. Frater's letter stated that "[t]he data from this single centre [Cardiff] is in direct contrast to the data we have received from multiple other studies on the valve with Silzone coating involving a much larger patient population. The intent of this letter is to update you as to the clinical experience with the St. Jude Medical Mechanical heart valve with Silzone coating". The covering letter, signed by Dave Stronach, a Canadian sales representative, advised doctors that "based on the sum of the evidence collected to-date, St. Jude Medical Canada, Inc. continues to be confident in the Silzone technology". Dr. Flory testified that he agreed with this statement:

> [b]ecause at this point, again, as we've discussed before, the Company had done a number of reviews of the data, with independent agencies and government agencies, like the Data and Safety Monitoring Board, and we continued to feel that the valve was safe.

206 The FDA's response to the MDA Advice Notice demonstrates the FDA's belief that there was little reason for concern. St. Jude met with FDA officials on December 2, 1999 regarding the issuance of a "Dear Doctor" letter to surgeons in the United States. The FDA was concerned that the MDA Notice did not contain balanced information as it was based on "limited observational information". After a telephone conversation with Dr. Flory on December 10, 1999, discussing the Dear Doctor letter, an internal FDA memorandum notes that the letter should contain "[t]he message that there is limited observational information of a possible incidence of early thromboembolic (TE) events - and that this is being studied further". Internal FDA documentation reveals that the FDA disagreed with the MDA's decision to issue the Advice Notice and still saw potential in the Silzone valve. St. Jude provided a draft of the "Dear Doctor" letter to the FDA on December 17, 1999, but did not hear back until January. Among the FDA's comments was a suggestion that the letter not even refer to the MDA Advice Notice. An earlier internal draft of the FDA's comments sheds light on the reason for this suggestion. It states:

> Consider whether the specific reference to the MDA's Advice Notice is necessary. US physicians are not likely to be aware that the MDA seems to send out notifications more frequently, and with less supporting data, than we do. Also, our experts have stated that the results of the Cardiff study, the major basis for the MDA notification, need to be interpreted with caution. In lieu of direct reference to the MDA's advisory the letter's discussion of the clinical information provides the reader with the information available for making an informed decision.

Australia/New Zealand Regulatory Action

207 Shortly after the MDA Advice Notice, on November 26, 1999, the Australian health products regulator, the Therapeutic Goods Administration (TGA), cancelled the registration of Silzone products in that country due to concerns about thromboembolic events. The evidence is that the TGA action was based largely on the MDA Advice Notice. Following that Notice, the TGA requested more information from St. Jude. St. Jude sent the TGA a package including information that there had been 244 Silzone valves implanted in Australia and no reported adverse events. St. Jude also provided some details of AVERT and invited the TGA to speak directly with Dr. Holubkov to discuss the study further. New Zealand elected to remove Silzone products at the same time as Australia did and the evidence shows the regulators worked together and New Zealand did not undertake a separate review and decision-making process.

208 The TGA did not take St. Jude up on its offer to speak with Dr. Holubkov and made its decision to cancel the registration of the Silzone valve without reviewing the AVERT data. The TGA stated that its decision was made by a panel of experts who were given the materials forwarded by St. Jude, the Cardiff data, and the TGH survey. However, Dr. Flory testified that he never came to know the names of the individuals on the panel or their backgrounds or expertise. It is of interest that the TGA consulted with Health Canada and the FDA before making its decision. On December 7, 1999, Health Canada held an internal meeting to discuss the TGA action and determined that "there is no indication that the valve is not safe or ineffective at this point".

209 I am satisfied by the evidence that the defendants took seriously all reports of adverse events prior to their recall of the Silzone valve. They reasonably considered AVERT to be the most reliable evidence of the risks associated with the Silzone valve, reinforced through the feedback they received from Dr. Schaff and Dr. Frater as well as the regulators. However, they did not, for this reason, ignore evidence from other sources. When Mr. Butchart and Dr. Butany came to the company with their reports, this was carefully investigated in order to assess whether their reports were isolated to Mr. Butchart and Dr. Butany's respective centres or whether they indicated an additional risk associated with the valve more generally. The results of those investigations reasonably indicated to St. Jude's employees that these events were isolated as they did not show any unusual pathology and were inconsistent with the clinical data that the company had collected from various Silzone surveys and studies, including and in particular from AVERT.

210 Further, throughout 1999, St. Jude was in frequent contact with regulators from several jurisdictions, including Health Canada, the FDA, and the MDA in the UK. Despite conducting AVERT on an ongoing basis, St. Jude nonetheless collected and reviewed clinical data from a number of other sources, including the Japanese Cohort Survey, the London Survey, the Vancouver Survey, LIMRA, and Top Accounts. Each of these studies was of lesser epidemiological value than AVERT, but provided sources of information that showed nothing unusual. There is no evidence that St. Jude attempted to "cover-up" any reports of adverse events. Contrary to the plaintiffs' assertion, the fact that St. Jude did not inform Dr. Butany and Mr. Butchart of one another's concerns does not demonstrate impropriety on the part of the defendants. Dr. Butany's concerns related to explants, pannus overgrowth, valve dehiscence, paravalvular leak and suspected cases of endocarditis. Mr. Butchart's concerns related to thrombus and thromboembolism. As such, I agree with the defendants that the concerns of these physicians were reasonably treated as distinct and unrelated.

211 The MDA Advice Notice and the Australia/New Zealand regulatory action are not separate evidence of a risk as they were driven by Mr. Butchart's concerns. St. Jude reasonably concluded based on a thorough investigation and reliable expert advice that the increased TE events at Cardiff Hospital did not indicate an additional risk that required a warning. Assuming the MDA Advice Notice and Australian/New Zealand regulatory action should be viewed as evidence that St. Jude ought to have issued a warning or recalled the Silzone valve in November 1999, this is countered by the actions and statements of the FDA, Health Canada, the DSMB and the SAB who were all aware of these reports, but did not express any concerns or recommend any action be taken other than the preparation of a "Dear Doctor" letter requested by the FDA on December 10, 1999.

The Recall

212 On January 5, 2000, St. Jude received a report from the University of Pittsburgh that indicated a higher number of explants in the Silzone arm of the study. Peter Perduzzi, a statistician from Yale and member of the DSMB, performed a statistical analysis of the data and Dr. Chesebro, DSMB chair, determined that a DSMB meeting should be held. It was scheduled for January 21, 2000. Dr. Flory recognized that one of the possible outcomes of that meeting was that after reviewing the data, the DSMB would recommend that enrolment in AVERT be terminated. As a result, St. Jude began to plan for this scenario. Before this, the information available to St. Jude did not indicate an additional risk that would have reasonably required an updated warning or some other action.

213 On January 21, 2000, the DSMB unanimously recommended that AVERT patient enrolment be immediately suspended when the AVERT data showed a statistically significant increase in the rate of explants due to paravalvular leak in the Silzone arm of that study. At that time, the company acted swiftly to voluntarily recall all Silzone products worldwide. In Canada, all Silzone valves, Regent valves (which were all Silzone-coated at that point in time) and Sequin Annuloplasty Rings with Silzone were recalled.

Conclusion on Common Issue 1b

214 The evidence shows that St. Jude effectively monitored the clinical performance of the Silzone valve, thoroughly investigated the concerns that were reported to them, and appropriately assessed the information gained through those investigations. Until the decision was made to recall the valves, the information that St. Jude had and the advice it received supported a reasonably held belief that there were no additional risks that had not already been communicated or required an additional warning or other action. The plaintiffs have not established that St. Jude fell below the standard of care with respect to its post-market surveillance and duty to warn of a reasonable and prudent heart valve manufacturer in similar circumstances. Accordingly, this portion of Common Issue 1 is answered in the negative.

COMMON ISSUE 2

What effect, if any, does such Silzone coating have on tissue healing?

215 Common Issue 2 is a question of general causation. This common issue requires the court to determine whether there is evidence of a difference in healing response between Silzone and non-Silzone valves, whether there is a plausible scientific explanation for the difference, if any, and whether the difference, if it exists, is adverse, in that it makes Silzone more likely to cause or contribute to a medical complication than uncoated Dacron. The plaintiffs contend that Silzone is toxic and that it not only impairs or delays tissue healing, but that it also damages existing annular tissue in the heart, which is a very strong biological response. The evidence that bears on this issue arises in three principal areas: (i) the scientific literature on silver; (ii) healing in the sheep studies; and, (iii) clinical evidence of toxicity derived from Dr. Wilson's clinico-pathological correlation of 18 Silzone valves in 14 patients.

216 The plaintiffs adduced evidence from Dr. Healy as well as from Drs. McLean and Cherian who are both experienced and qualified toxicologists. Dr. Cherian is a Professor Emeritus at the University of Western Ontario, a metals toxicologist and an expert on metallothionein. Professor McLean is a Professor Emeritus at University College, London. Dr. Healy is a Professor of Bioengineering and Materials Science at the University of California at Berkeley. They testified about the toxicity of silver on cells involved in the healing process. Neither Dr. McLean nor Dr. Cherian expressed a clear opinion that Silzone was toxic, but Dr. Healy concluded that the release of silver ions from the Silzone coating places patients at risk and that silver's cytotoxic properties impairs pannus formation.

217 The defendants' experts were Dr. Williams and Dr. Rodricks. Dr. Williams is a Professor Emeritus at the University of Liverpool. He is one of the world's leading biomaterial experts with over 40 years of experience in conducting research in the field, including extensive work in the use of silver as a biomaterial. Dr. Rodricks has more than 45 years of experience in evaluating the toxicological safety of products, including almost 20 years with the FDA where he directed the FDA task force responsible for assessing the toxicological risks from metals in medical devices and

developed the FDA Guidelines for the preclinical toxicity testing of medical devices.

218 Dr. Wilson and Dr. Factor are cardiac pathologists. Their evidence addressed healing in the sheep studies. As well, Dr. Wilson reviewed the findings from his 14 patient study. Dr. Schoen was the defendants' expert. I will describe their qualifications later. Mr. Butchart, for the plaintiffs and Drs. Hirsh, Mizgala, Snyder, Sexton and Factor, for the defendants, also provided opinions on selected patients in the 14 patient study.

Tissue Healing Process

219 The tissue healing process of a prosthetic heart valve implant is complex at both the cellular and molecular level, but it is similar to the manner in which the body's reparative processes heal any injury, modified by the presence of a foreign body. Inflammation takes place, blood clots, tissue forms and the wound closes, sealing the injured site.

220 The first stage of healing commences immediately on the implant of a prosthetic valve. The Dacron of the sewing cuff is filled with biological material from the bloodstream. Due to the presence of a foreign material, an inflammatory response occurs. At a cellular level, tissue proteins from the blood are deposited or adsorbed to the surface of the fibres of the sewing cuff, both within the cuff's material and on its surface. As the proteins are adsorbed to the surface of the cuff's fibres, they activate platelets in the blood that adhere to the proteins' surface and, in turn, attract more platelets from the passing blood. As the platelets aggregate to the protein covered surface of the cuff fibres, they release their contents and thrombin is generated, which together with fibrin, creates thrombus.

221 The second stage of the healing process involves a series of cellular events, during which polymorphonuclear (PMN) cells, lymphocytes and monocytes enter the wound site. As the monocyte cells leave the bloodstream and enter the connective tissue of the thrombus they are converted into macrophage cells to remove foreign debris, kill invading bacteria and counteract viruses. Macrophages can join together to create foreign multi-nucleated giant cells and perform a similar function. The presence of a large number of foreign body giant cells may indicate an attempt to deal with particulate debris or be a response to the presence of Dacron.

222 The final stage of healing involves remodelling or the formation of pannus. As the macrophages engulf dead tissue or bacteria, substances are emitted and fibroblast cells form and stimulate the production of collagen, which is composed of approximately 20 different proteins. At the same time, leukocytes from the passing blood are deposited and lyse the thrombus that was originally deposited on the fibres of the sewing cuff. Eventually, as the macrophages clear the lysed thrombus and the body walls off the biomaterial, the collagen replaces the thrombus with pannus, which is composed of strong fibroconnective tissue. Ideally, the blood contacting surface of the pannus is covered with a layer of endothelial cells that work to inhibit the growth of further thrombus, creating a non-thrombogenic surface.

The Mechanism of Action of Silver

223 Toxicity means an adverse effect on some part or system in the body. The experts are in general agreement concerning the factors which establish the potential of silver to be toxic to human tissue. Any potential toxic effect related to silver will arise from silver ions (Ag+) as metallic silver is inert. Because the silver ion is the potential toxic agent, the amount and rate of release of such ions determine whether there can be any toxic reaction to tissue in a given circumstance. Toxicity is, in turn, influenced by other factors including the form of silver, adsorption, excretion and cell type. When the silver ion (Ag+) is bound up with another entity, it is biologically inactive. Thus, the potential for toxicity is related to bioavailability, or the amount of material that is available to interact with cells as well as the body's protective mechanisms that reduce potential toxic effects. Silver salts such as silver nitrate release more silver ions more quickly than silver metal and as such, salts have a greater potential to affect cell toxicity than silver metal.

224 Protein adsorption is an important factor in the bioavailability of all biomaterials. Silver ions will bind to a number of things in the human body including chloride ions, sulfur compounds, and proteins like albumin, metallothionein, and glutathione. Dr. Cherian testified that there are lower levels of metallothionein and antioxidants in heart tissue, but he did not provide a clear opinion that the diminished protective effect of these substances can cause toxicity to annular tissue. Albumin is the most abundant of the plasma proteins and Dr. Cherian agreed with Dr. Williams that silver ions have an affinity for albumin. Although albumin may increase the rate of silver ions released initially, the ions remain tightly bound to the molecules of albumin, limiting the number of available free silver ions. Silver ions may be released from the compounds that bind them, but released silver ions may again be bound by new proteins and rendered inert. The experts agree that silver ions will be excreted by normal processes in urine and feces.

225 While silver ions do not discriminate between mammalian and bacterial cells, mammalian cells are more protected from silver ions than bacterial cells. While Dr. Healy and Dr. Cherian testified that silver ions will affect mammalian and bacterial cells in a similar manner, neither produced any convincing evidence to support this and both acknowledged that they had limited personal experience studying bacterial cells. Dr. Hancock, an expert in microbiology, and Dr. Williams were the most qualified on this issue. They explained why silver is selectively more active against bacteria than human cells arising from differences in the structure and function of mammalian and bacterial cell types. As a result of these differences, silver ions can demonstrate effective killing of bacterial cells without being toxic to host cells. If differences of this nature did not exist, there would be no antibiotic medication of any kind since bacteria must always be killed in the presence of other cells. Moreover, a reason that silver has been used for centuries in medical applications is because it offers high differential toxicity between bacterial and human cells.[47]

The Scientific Literature on Toxicity of Silver

226 Dr. Williams indicated that you need to look at the whole of the literature on silver

biocompatibility and toxicity in order to get an idea of toxic potential. Silver ions can be toxic at some dose. The question with silver and other metals is at what level you might see toxicity from the metal in the context of the normal exposure of individuals for the use in question. He testified that while all data should be looked at, the animal studies are far more predictive of what might happen in humans than *in vitro* studies. Dr. Rodricks cautioned that all studies are not equal. The more helpful studies involve similar chemical entities to the one being investigated - in this case, metallic silver.

227 Dr. Healy testified that he reviewed more than 500 studies concerning silver or silver compounds, including studies that were positive about the use of silver in medical devices, but in providing his opinions to the court, he selected only 12 papers to include in his report, all describing the toxic effects of silver. The focus of his testimony was on these studies, although he acknowledged there were other studies that showed no or minimal toxicity to silver. He also relied on silver concentration measurements taken by Matthew Ogle, a company scientist, using samples from the 10 week sheep study. I will later explain why his reliance on this data is misplaced.

228 Dr. Healy concluded that there was no well established toxicity level for silver and that toxicity was dose and time dependent. In forming his opinions, he largely relied on *in vitro* studies that demonstrate that at relatively low concentrations, silver ions can and do injure mammalian cells. There are studies that show that silver causes disordered collagen biosynthesis and interferes with the assembly of connective tissue components; that silver ions affect cell DNA synthesis leading to the inability of cells to advance through division and replication; that silver ions can penetrate the mitochondria where the cell's energy is produced and thereby affect the cell's ability to reproduce and carry out its functions; that the heart has very low levels of antioxidants compared to the liver to counteract the toxic effects of free radicals that damage tissue; and that at relatively low concentrations, silver ions will impair and kill cells involved in the healing process including fibroblasts, monocytes, leukocytes and lymphocytes.

229 Drs. Rodricks and Williams discussed the limitations and proper uses of the studies that Dr. Healy and the plaintiffs' witnesses have emphasized in their testimony, including papers by McCauley, Hemmerlein, Hollinger, Wataha, Steffensen, Garcés-Ortiz, Ellender and Ham, Hidalgo and Dominguez, and Sudmann.[48] They identified two major problems. First, the results of *in vitro* laboratory studies, while useful, cannot be extrapolated to predict how a material will react with tissue *in vivo* in the body. Second, most of the studies relied upon by the plaintiffs are not terribly relevant as they investigate forms of silver (i.e. silver salts) in which the bioavailability of silver ions is much greater and is released more quickly than the slower release of the metallic silver on the Silzone fabric. As well, some studies are merely individual case reports, the lowest level of epidemiological evidence.[49]

230 Drs. Rodricks and Williams also discussed other studies that are more relevant to an evaluation of silver toxicity and its application to Silzone. Dr. Hancock testified that based on his review of the literature, the vast majority of studies indicated that silver was effective against

bacteria, confirming Dr. Rodricks's testimony that silver's low toxicity is one of the reasons it has a long and successful history in medicine. The defendants' experts supported their opinions with sounder analysis based upon a more comprehensive and balanced view of the scientific literature. I therefore have greater confidence in relying on their opinions.

In Vitro Studies

231 Despite their use of the *in vitro* data related to silver to support an argument that Silzone is toxic, the plaintiffs' experts also seemed to agree that such extrapolation is problematic. For example, Dr. Cherian testified that *in vitro* tests can give various types of useful information: "[b]ut I agree that you cannot extrapolate *in vitro* studies into *in vivo*." Dr. McLean viewed *in vitro* testing as part of a "step-wise" process which, along with animal testing, can be used to assess materials. In going up the ladder of evidence, Dr. McLean said that *in vitro* tests can shed light on possible mechanisms of action and provide warnings of possible safety concerns, but then "[t]here's a limit to what you can do with *in vitro* tests", and you need to go to animal tests. Dr. Healy agreed that it is difficult to extrapolate because of the challenge in making the *in vitro* test mimic the particular environment in which you are going to implant the device. Thus, the plaintiffs' experts agreed with Drs. Rodricks and Williams that *in vitro* testing has limitations that must be considered in drawing conclusions about the toxicity of a material in the body.

232 Dr. Healy relied on the Steffensen and Wataha papers in forming his opinions and suggested that the levels of silver exhibiting cytotoxicity in these *in vitro* studies might also cause problems in tissue *in vivo*. These studies used silver nitrate and silver sulfate solutions which were applied to human cell cultures. Thus, unlike in the body where the silver ions are bound up with other compounds, all of the silver ions would have been available to contact the cells surrounded by the solutions of silver salts. Moreover, metals such as the Silzone coating release small amounts of silver slowly over time as opposed to a silver salt which has greater solubility and releases quickly.

233 The *in vitro* studies conducted in the laboratories of Dr. McCauley dealt with potential cytotoxic effects of silver sulfadiazine, which is used in the treatment of burn patients. Dr. Healy used the McCauley studies to compare silver levels in those *in vitro* studies to the levels in the Silzone valve. Dr. Williams explained why such a comparison was inappropriate and not relevant to heart valves. Subsequent studies on silver sulfadiazine, for example by Lansdown,[50] have confirmed that silver sulfadiazine does not impair healing in the burn wound environment with grams of silver sulfadiazine much greater than the amount of metallic silver released from Silzone in the sewing cuff.

234 Dr. Williams disputed Dr. Healy's opinion that a silver ion in contact with a cell will cause damage over time. Dr. Williams testified that he had performed many studies on the time-dependence of metal levels in tissue, and although they varied, there is no evidence to support Dr. Healy's opinion. As the *in vivo* environment is dynamic rather than static, silver ions that are released from the Silzone coating will be distributed; they will be removed by macrophages and

largely excreted. Ninety per cent of absorbed silver is excreted, typically in feces. Moreover, Dr. Healy agreed that the tissue healing process is dynamic, that cells have a natural life expectancy and that the same cells will not be exposed to silver ions in the annulus of the heart for the duration of the implant.

235 In discussing the Hemmerlein study, Dr. Williams explained that it is not possible to extrapolate from an *in vitro* study using fast release silver salts to the effects of Silzone. Moreover, Dr. Bambauer's studies directly contradict the speculation of the authors in Hemmerlein. The question of whether silver on catheter cuffs could lead to tissue problems and loosening was examined in the Dr. Bambauer investigations. In those studies, which impregnated the substrate using the Spi-Argent process, the catheters were effective and not loose. This is a more relevant comparator than an *in vitro* study with a salt that ionizes quickly. Thus the Bambauer Studies, which more directly addressed the question, contradict the suggestion that loosening of the cuffs would occur if a slowly releasing silver compound was applied.[51]

The Kraft Studies[52]

236 Dr. Healy and Dr. Wilson both relied on a study by Kraft et al. to suggest that silver would have an effect on the microvasculature of a wound and inhibit healing. This was an *in vivo* study where the investigators made a chamber on the back of a hamster and enclosed it in a titanium frame. They saw that silver had an effect on the microvasculature of the tissue within the chamber. Dr. Schoen criticized the study because it did not evaluate healing beyond three days and the inflammatory reaction observed may have related to the surgery. Dr. Williams thought that there was a problem with the experimental approach. He testified that he searched the literature for other papers using the same experimental technique and found only one, raising questions about the reliability of this technique. Moreover, the Kraft group performed a second study using a similar technique in which they found that stainless steel also affected the microvasculature of the wound. However, stainless steel is used commonly as a biomaterial without any obvious clinical problems. Dr. Williams concluded that the test technique in both studies showed results contrary to clinical performance.

237 The suggestion that silver or Silzone could impact healing through an adverse effect on the microvasculature is also contradicted by the work of the plaintiffs' own expert witness, Dr. Olson, in a co-authored study that examined the effects of metallic nanoparticles of silver on wounds.[53] Although Dr. Olson testified that there are a number of distinct differences between the wound dressing tested in that study and the Silzone valve, the study evaluated the potential for healing facilitated by silver ions released by metallic silver compounds in a wound dressing and concluded that the silver-coated dressings promoted rapid wound healing and enhanced the formation of vascular tissue.

238 Dr. Rodricks reviewed the study that was co-authored by Dr. Olson. He testified that it exhibited even better healing than was seen in a study by Lansdown et al.[54] In that study, two silver

salts that release silver ions were introduced into deep wounds in rats. The silver compounds were introduced in concentrations much greater than in Silzone (500 mg in the study as compared to between 17 to 50 mg on the cuff). This did not cause a toxic effect and it appeared to improve healing. The study also showed that silver has the capacity to induce the production of metallothionein.

The Goodman Studies[55]

239 The plaintiffs rely on studies by Dr. Steven Goodman who examined and compared platelet adhesion and aggregation on exposure to the Silzone-coated fabric and non-coated fabric. Dr. Goodman observed greater platelet disruption and reduced platelet aggregation on the Silzone-coated fabric and suggested that this could explain the thinner pannus observed in the sheep studies. The plaintiffs argue, relying on the evidence of Mr. Butchart, that Dr. Goodman's studies support a finding that the Silzone coating had a biological effect on healing into the sewing cuff by adversely affecting the organization of thrombus into stable pannus.

240 Dr. Tweden, Dr. Williams and Dr. Hirsh each discussed the Goodman studies in their testimony.

241 Dr. Tweden described studies she had conducted with Dr. Goodman before her work on the Silzone project. One of these studies examined the behaviour of platelets to pyrolitic carbon, a material that is considered to be blood-compatible with a low potential for thrombogenecity. In that study, they observed extensive platelet spreading and disruption, a response similar to that observed with the Silzone fabric.

242 Dr. Williams was familiar with Dr. Goodman's work and regards him as a "good scientist", but characterized Dr. Goodman's studies as relatively simple *in vitro* studies that are difficult to extrapolate to *in vivo* performance regarding wound healing or thrombogenicity. Dr. Hirsh did not think that Dr. Goodman's findings provided a reliable foundation for Mr. Butchart's opinion that Silzone affects platelets and red blood cells to increase the risk of thromboembolism.[56] He testified that the role of platelets in wound healing was controversial and abnormal wound healing had not been described in chronic conditions that result in a very low platelet count. Like Dr. Williams, he also pointed out that Dr. Goodman performed his experiments in a static system in which platelets were suspended in a buffer and that this is very different from *in vivo* where there is a constant flow of platelets that are suspended in plasma which contains modulating proteins.

243 The plaintiffs also overlook Dr. Goodman's suggestion in the 1998 paper (and referred to again in his later paper) that the rapid disruption and coverage of the silver coated fabric by the platelets may more rapidly initiate later stages of healing:

> The observation of greater surface coverage increased platelet spreading and extensive disruption of platelets on the silver treated fabric may provide an explanation for the reduced pannus formation observed *in vivo*. Since platelet

> spreading and disruption are a normal part of wound healing processes it is possible that the rapid disruption and coverage of the silver coated fabric by the platelets may more rapidly initiate later stages of healing. That is the flat spread platelet cytoskeletons may provide a matrix for the adhesion and ingrowth of cells necessary for healing. *Hence silver coating may not only reduce bacterial infection by virtue of its bacterial toxicity but may also reduce infection by initiating a more rapid healing of the sewing ring. This would then reduce the fabric surface area available for bacterial adhesion and colonization. Of course more rapid healing may also have benefits with respect to device thrombogenicity.* (Emphasis added)

244 For these reasons, I do not think that the Goodman studies are terribly helpful to the plaintiffs' toxicity theory. If anything, the study appears to show a potentially beneficial effect from Silzone on healing.

245 Finally, in a study by Trerotola and others,[57] the authors reported that two patients experienced rash and discolouration, but no tissue damage. This study also used a catheter that had been subsequently removed from the market. Trerotola can be contrasted with a study by Kathuria et al.,[58] which also involved an IBAD coated catheter. Dr. Rodricks described the results as showing a "very compatible response" in rats, with no loosening of the coated catheter cuff and good tissue morphology.

246 In their written submissions, the plaintiffs did not reference studies by Sudmann or Garcés-Ortiz,[59] although both were relied on by Dr. Healy in his testimony. The Sudmann study involved the Christiansen hip prosthesis, a replacement device that had massive failures. The Garcés-Ortiz study involved Ketac silver dental cement, which also contained lead and aluminum fluoride, later determined to cause the cytotoxic effects of the cement.

247 In summary, the plaintiffs have focused on *in vitro* studies, investigations involving silver salts which release ions very quickly, and/or case reports that involve unusual sets of facts or unreliable experimental techniques that are of limited value in assessing the *in vivo* toxicity of Silzone.

Other Scientific Literature on Silver

248 The collection of scientific articles considered by the defendants' experts to form their opinions was far more comprehensive and far more relevant than the largely *in vitro* studies referred to by the plaintiffs. It constitutes a more reliable body of scientific opinion.

249 For example, Dr. Rodricks evaluated 200 to 250 studies, including the literature cited by Drs. Cherian, McLean, Healy and Mr. Butchart. As well, he conducted an independent exploration of the pertinent silver literature from 1950 to 2010. He provided an analysis of a subset of 114 *in vivo* studies that addressed the effects of silver and silver compounds in implantable medical devices

including vascular grafts, orthopaedic prostheses, grafts and pins, surgical meshes and rings, catheters, and urological stents. Among the studies were a significant number of RCTs as well as non-randomized clinical trials and cohort studies. Dr. Rodricks found that there was no data in these studies indicating that silver or silver compounds used in the implantable devices were toxic.

250 Dr. Rodricks selected a number of these *in vivo* studies to discuss in more detail in his testimony.[60] In their Reply submissions, the plaintiffs point out limitations in some of the studies referred to by Dr. Rodricks, for example, the studies by Collinge et al. on fixation pins; Lansdown et al., on the use of silver sulfadiazine and silver nitrate in rats; and Batt et al., on silver-coated polyester grafts. However, they do not reference any testimony about these studies.Similarly, the plaintiffs reference one paragraph from a review article by Dr. Lansdown. In cross-examination, Dr. Rodricks accepted that the article was authoritative because of Dr. Lansdown's research in this area, although he did not think the article was published in a peer-reviewed journal.[61] However, Dr. Rodricks was never referred to this paragraph in the article and asked to comment on it. As the plaintiffs failed to adduce any testimony on the alleged limitations in the studies, these submissions lack an evidentiary foundation.

251 Although I have carefully reviewed each of the studies discussed by Dr. Rodricks, I will only provide a few examples that I consider particularly relevant.

The Bambauer Studies

252 These studies were conducted by Dr. Rolf Bambauer, of the University of Saarland, Homburg/Saar, Germany. It will be recalled that Dr. Tweden spoke with him about his work early in the development of the Silzone project. The devices under study were hemolysis catheters that were treated with silver using either ion implantation (Spi-Argent II) or the IBAD process (Spi-Argent I). Hemolysis catheters are susceptible to infection because they need to pass through the skin and into veins. For these reasons, the Bambauer Studies have direct relevance to the Silzone product. Patients were studied up to 300 days. Drs. Rodricks and Williams evaluated different studies, but both concluded that they supported the safe use of silver, reduced infection and demonstrated no adverse effects in patients. Silver levels in the blood were found to be very small and the IBAD coating did not cause thrombogenicity.

253 The plaintiffs point out that the Bambauer Studies showed that the Spi-Argent coating inhibited attachment of proteins and cells compared to an uncoated surface. They submit that the lack of fibrin, blood cells and thrombogenicity seen on the IBAD coated surfaces in the Bambauer Studies as compared to an uncoated surface was an indication that a silver coated surface will reduce tissue formation (contrary to Mr. Butchart's hypothesis that the Silzone coating increases thrombogenicity because unhealed clotting material forms on the sewing cuff).They assert that the defendants try to dismiss the inhibitory effects of the coating by suggesting that a similar result will not play out in the interstices of a sewing cuff because it is not in a blood flowing environment and that this ignores the fundamental reality of Dr. Bambauer's observation that the presence of

Spi-Argent caused delayed and diminished protein attachment as compared to controls.

254 Dr. Williams was cross-examined about these observations in the Bambauer studies and satisfactorily explained why it is inappropriate on this issue to draw analogies between the surface of catheters, which are designed to have a surface free of blood and other debris, and the interstices of Dacron cuffs. It is the physical differences in the design of the devices that control whether there will be formation of a clot and subsequent tissue formation. Dr. Williams also pointed out that tissue did actually grow into the outside portion of the cuff that was on some of the catheters used in the studies, and which was coated with Spi-Argent I or II. It is true that Dr. Bambauer did not attempt to evaluate or study comparative ingrowth between the coated and uncoated catheters, but his paper records and Dr. Williams noted that the tissue infiltration into the Spi-Argent cuff was "intensive without any inflammatory signs" and needed to be removed with a knife. This is some evidence that, notwithstanding the lack of protein attachment, tissue ingrowth did occur on the coated cuffs. Thus, the Bambauer Studies also show that a Silzone- coated device can be thromboresistant in free flowing blood, but permit tissue ingrowth.

Vascular Graft Studies

255 Vascular grafts are often used to replace portions of femoral (leg) arteries in patients 50 to 60 years old, and are expected to last for their lifetimes, or 20 to 25 years. They are typically made of Dacron or Gortex, so the fabrics are similar to the sewing cuff in the heart valve. The grafts are attached to the remaining artery by an anastomosis, and blood will flow into the interstices in this area and clot in the same manner as blood clotting in the interstices of the heart valve sewing cuff. The clot is then reorganized with new tissue. Some parts of the vascular graft, such as the lumen through which blood flows, are different than a heart valve, but other parts, such as the anastomosis, are similar to the sewing cuff. Dr. Williams testified that the clotting and tissue reorganization in the anastomosis of the vascular graft "is a very, very similar mechanism" to the tissue growth that occurs in the sewing cuff. Dr. Schoen also said that healing into a prosthetic valve sewing cuff is well represented by healing of a vascular graft.

256 The B. Braun Vascular Systems Silver Graft is coated with silver by the same IBAD process used to coat the Dacron fabric of the Silzone valve. While the vascular graft is coated with silver from the outside of the fabric, and may have a thin coating, experts agreed they would still expect to see some effect in the anastomosis if silver was toxic, such as (i) leakage at the anastomosis where the graft attaches to the artery, (ii) an adverse effect on endotheliazation of the vessel causing it to block very quickly, and (iii) inflammation of the tissue surrounding the graft.

257 In a study of the graft's performance, the B. Braun Vascular Graft was implanted into the aorta of pigs and compared to uncoated grafts.[62] Gelatin was added to the grafts, but as Dr. Williams explained, this has no effect on the contact between silver and tissue. Microscopic evaluation after explant revealed similar healing between the silver-coated grafts and control grafts. There was no significant difference in either neo-intimal thickness or in the immunohistochemical

investigations between the coated and uncoated groups. Consistent with the authors' conclusions, Dr. Williams found that there was no disadvantage of the silver coating in terms of healing, and that the aortas remained patent or open. None of the signs of a toxic reaction were present.

258 The plaintiffs rely on this study and the evidence of Dr. Rodricks in cross-examination, but their submissions do not fairly describe his evidence. Dr. Rodricks testified correctly that Dr. Ueberrueck's study concluded that the measurement of neo-intimal thickness after *six* months (as opposed to three months) revealed no significant differences between coated and uncoated grafts.[63] Vascular grafts coated with silver were also implanted into rabbits by Dr. Ueberrueck's group. The study was published in the prominent *Journal of Biomedical Materials Research.*[64] The animals were challenged with bacterial infections, and after 52 weeks the devices were explanted. Dr. Williams explained that this study confirmed the antibacterial effect of silver in these silver-coated devices with no adverse effects on healing. Blood silver levels were taken and confirmed what was seen in the animal studies and in the LIMRA. After the initial release, silver levels decreased to a constant low level.

259 Finally, the B. Braun Vascular Graft was studied over 18 months in 50 patients supervised by the Committee on Infections in Vascular Surgery of the German Society of Vascular Surgery.[65] While this was a non-randomized cohort study, the investigators found that the study supported the safe use of the coated devices. The results show no adverse effect on the healing process, including no reports of bleeding in the anastomosis. Dr. Williams concluded that there was good healing in the grafts and this would be comparable to healing associated with the Silzone valve.

Silver-coated Prostheses

260 The investigators in a study by Hardes et al. studied 20 patients who received very large silver-coated megaprostheses that replaced parts of the bones in their arms or legs.[66] The megaprostheses were coated with silver metal, but by a different process than IBAD, and are marketed in Europe. The amounts of silver used in the prostheses were many times greater than that used in the Silzone valve. The amount of silver ranged from 0.33 grams (330 mgs) to 2.89 grams (2890 mgs). In comparison, the amounts of silver used in the Silzone valve varied depending on size. The largest possible amount of silver in a Silzone valve was 0.050 grams (50 mgs), with the average being around 0.017 grams (17 mgs). The amount of silver in the larger prostheses of 2.89 grams was therefore 170 times the amount in the average Silzone valve, but as Dr. Rodricks explained, the investigators found no evidence of toxicity even with this relatively large amount of silver.

Dr. Williams' Research

261 By the 1980s, there was widespread recognition of the antimicrobial properties of silver compounds and an increasing interest in incorporating the materials into medical devices. In 1989, Dr. Williams, along with colleagues at the University of Liverpool and the Biomedical Department of the Johnson Matthey Technology Centre, undertook a comprehensive review of the safety and

efficacy of silver and silver compounds in medicine. He and colleagues published a review article that focused on the physiological events at the interface of the materials and tissue, corrosion and degradation effects, the development of local tissue responses, systemic effects following implantation of silver devices, and included an assessment of the antimicrobial effects of silver.[67]

262 In this paper, the authors evaluated the potential toxicity of silver compounds to cells and discussed both their own findings and the literature in the section entitled "Cytotoxicity". When Dr. Williams' laboratory used an *in vitro* method to evaluate various silver alloys and silver samples, they found that the extent of the toxic response was determined by the form of silver. Metallic silver sheet (the form of silver used in Silzone) produced a very tiny response as measured by an observable cytotoxic zone around the sample while other mixtures of silver such as "sintered" silver produced a larger cytotoxic zone. In providing his opinion that Silzone lysed fibroblast cells, Dr. McLean mistakenly believed that Silzone used sintered rather than metallic silver.

263 The paper also described studies in the literature reflecting the effects of silver on mouse peritoneal macrophages. The investigators in those studies found that high levels of silver may have an effect on cell functions but there was no impairment of phagocytic, migratory or interferon-producing capabilities in the cells unless there was also an acute (i.e. immediate) cytotoxic effect. Phagocytosis is the process of ingestion and digestion by cells of solid substances such as other cells, bacteria, bits of dead tissue and foreign particles. This is important because macrophages play an important role in tissue healing and the observations in these studies showed that in the presence of low levels of silver, macrophages could digest or absorb silver particles and still function.

264 This was also demonstrated by research Dr. Williams conducted in his own laboratories to assess the local host tissue response to silver by using an intramuscular implantation method in rats. Some particles from the silver were seen and were demonstrated in fibroblasts and macrophages. However, these materials did not have an adverse impact on the cells, indicating that the material was not toxic to the tissue. The study continued for ten months and Dr. Williams concluded, consistent with other studies referred to in the paper, that silver produced a very mild tissue response. The deposition of silver particles, mainly in macrophages, was also described in a catheter study using silver-coated Dacron without any adverse cellular response.[68]

265 The plaintiffs do not appear to take issue with the conclusions reached by Dr. Williams in the review paper, except to point out that "science is ever-evolving and that peer-reviewed articles published after 1989 and before July 23, 1997 demonstrate the ongoing study and evaluation of the toxicity of silver". I am satisfied that the conclusions reached by Dr. Williams and colleagues in this paper fairly represented the state of knowledge on silver in 1997 and indicated that silver could be safely used in a permanently implantable device.

Regulatory Filings

266 Dr. Rodricks undertook a review of the regulatory filings in the United States and Canada

from February 1992 to January 2010. He compiled a list of the "FDA Approvals for Silver-Containing Medical Devices: Feb. '92 to Jan. '10".[69] Since 1992, over 100 silver-containing medical devices have been approved for use in patients in the United States. A similar compilation was created for approvals by Health Canada, at "Health Canada Approvals for Silver-Containing Medical Devices: Feb. '92 to Jan. '10".[70] From February 1992 to January 2010 Health Canada also approved over 100 medical devices which contained silver for use in patients in Canada. The types of medical devices included wound dressings, catheters, tracheotomy tubes, surgical patches, laryngectomy tubes, and endotracheal tubes.

267 The plaintiffs point out and the defendants do not dispute that the vast majority of approved medical devices containing silver post-date the Silzone valve. This evidence cannot be used to evaluate the defendants' decision to market the Silzone valve and to continue to market it up to the recall in January 2000, but it can be used to evaluate whether or not silver is a safe biomaterial. Regulatory agencies, such as the FDA and Health Canada, have the responsibility to ensure that the benefits or potential benefits of the devices they approve outweigh any potential risks. The risk benefit analysis that Health Canada is required to undertake was discussed in *Glaxo Canada Inc. v. Canada*, in the context of a competitor's challenge to the Minister of Health's decision to grant a Notice of Compliance for a new drug:

> ... In exercising his discretion, the Minister weighs the benefit of the drug against the foreseeable risk of adverse reaction to it. ... [it] is a decision made on the basis of public health considerations. The Minister in exercising his discretion weighs the predicted benefit of the drug in relation to the foreseeable risk of adverse reaction to it. The Minister's determination is one made in contemplation of public health and represents the implementation of social and economic policy.[71]

268 Health Canada's subsequent approval of numerous implantable medical devices containing silver is corroborating evidence of the opinions of the defendants' experts that silver is a safe biomaterial to use in an implantable device.

Conclusion on Scientific Literature

269 The scientific literature overwhelmingly supports the conclusions of Drs. Williams and Rodricks that silver exerts little to no toxic effect in animals and humans, that it can be tolerated by cells involved in the healing process, and that it can be used safely in medical devices. While there is evidence that silver salts can exert a cytotoxic effect on cells *in vitro*, metallic silver, like the outer layer of Silzone, has only mild toxicity to cells *in vitro* and these effects are not generally seen *in vivo* through an adverse host response even where very large amounts are used and continuously released into tissue. The small amounts of silver used on the sewing cuff, and its metallic character, make it highly unlikely it causes a toxic effect. The current use of hundreds of silver coated products, including studies on implantable products coated with silver by the same IBAD process

used in the Silzone cuff, is compelling evidence that Silzone is not toxic when used on the sewing cuff of a heart valve.

Sheep Studies

270 *In vivo* studies provide the best evidence to evaluate biocompatibility. The sheep studies are therefore quite significant in understanding if Silzone is toxic. The competing expert evidence on these studies comes from Dr. Factor, a New York based cardiac pathologist certified in anatomic and clinical pathology, and from Dr. Wilson, a staff pathologist in the Department of Laboratory Medicine at the Hospital for Sick Children. Dr. Wilson is certified in anatomic pathology and has a sub-specialty in cardiovascular pathology. In the 1970s and 1980s, he trained and worked with Dr. Malcolm Silver, an extremely distinguished cardiovascular pathologist. However, over the last two decades, his work and experience has been in a pediatric setting where he sees very few cases of PVL, dehiscence and thrombosis in valves explanted from children. In fact, since his work with Dr. Silver through the time he was retained in this litigation, he has not evaluated any mechanical heart valve explanted from an adult. Since completing his residency, he has done histopathological sections on fewer than five valves involving endocarditis and he acknowledged that endocarditis was not one of his research interests. This is pertinent not only to the sheep studies, but also to the 14 patient study that I will discuss later.

271 While Dr. Wilson is an eminently qualified pathologist with an impressive array of publications in peer-reviewed journals, Dr. Factor has considerably more experience in the areas that are relevant to evaluating the healing in the sheep studies. Like Dr. Wilson, he has taught medical students, conducted research and published, but unlike Dr. Wilson, Dr. Factor's pathology experience has included assessments of many more explanted prosthetic heart valves, almost exclusively from adults. He has far greater experience with infective endocarditis in humans and animals. He has conducted animal research involving prosthetic heart valves in both small and large animals, including sheep, and he has evaluated healing in tissue and mechanical heart valve sewing cuffs implanted in sheep. Apart from this litigation, Dr. Wilson has never been involved in an animal study in which heart valves were implanted in sheep, nor has he evaluated the healing of a sewing cuff in sheep. As both experts base their opinions on observations from photographs and micrographs of the explanted sheep valves, their relative knowledge and experience becomes a much more important consideration than it might otherwise be. Where their evidence conflicts, Dr. Factor's opinion carries more weight.

272 Dr. Wilson's opinion that Silzone is toxic and impairs tissue healing is based on his gross observations of healing differences in the 4 to 5 week and 10 week studies as he saw tissue ingrowth between both Silzone-coated and non-Silzone coated fibres in the histopathological analysis of the valves explanted from the sheep that survived to planned sacrifice. He admitted there was no evidence of toxicity in the microscopic histopathology of the sheep that survived to planned sacrifice, making it implausible that Silzone damages annular tissues. Dr. Wilson was critical of the histology analysis in these studies (as well as in other studies) because the tissue samples did not

focus on "areas of concern in terms of healing, particularly areas where the pannus was too thin or did not exist." I accept Dr. Factor's opinion that Dr. Cameron's sectioning of tissue samples was neither inappropriate nor incomplete.

273 Dr. Factor concluded that there was comparable healing between the Silzone and non-Silzone portions of the sewing cuffs in the Short Term study. Dr. Olson agreed that from his review of the pathology reports, the valves in the Short Term study, including from KTMV-2, all showed comparable healing into the Silzone and uncoated sides of the cuff and there was no information to suggest that the healing was different between the two sides.

274 Although Dr. Wilson testified at trial that the most likely cause of death of KTMV-2 was a PVL or dehiscence due to silver toxicity, in the reports he prepared for litigation he acknowledged that surgical technique or infection could not be excluded. In sheep implants of prosthetic heart valves, it is generally known that early death that is not device-related may occur and surgical technique or infection can be factors. There is evidence that KTMV-2 had fewer stitches than KTMV-1 or KTMV-3 and it is possible that surgical technique contributed to the dehiscence as Dr. Tweden and Mr. Holmberg believed.[72]

275 It is not necessary for me to delve into the detail of the Clostridium organism that Dr. Factor explained and Dr. Wilson disputed was the source of the infection that Dr. Factor said led to the dehiscence and PVL. The important issue is whether the evidence persuades me that silver toxicity is the likely explanation for the death of KTMV-2. In my view, it is called into question by the striking fact that no other animal in either study demonstrated a toxic response to Silzone. All of the other animals in both studies survived to their planned sacrifice dates. Dr. Williams and Dr. Rodricks both found it very hard to understand how this could occur in one animal with no evidence of this in the others. As Dr. Rodricks testified:

> ... as a toxicologist looking at all the data from both studies, in fact, the 5 week study and the 10 week study, given the performance in all of the other animals, it's impossible to imagine that that's -- that that early death is related to a toxic event. In other words, toxicity doesn't work that way. It wouldn't be just having a very, very serious effect on one animal and having no effect on the others. That's not a toxic phenomenon. So whatever happened there, I don't know the answer to, but it isn't silver toxicity, I'm quite confident.

276 I find that Silzone toxicity is an unlikely explanation for the dehiscence and PVL in KTMV-2.

277 Dr. Factor also concluded that in the 10 week study the tissue response to the Silzone- coated cuff was equivalent to the controls. He disagreed with Dr. Wilson that there was marked variability in healing with the Silzone valve and found Dr. Wilson's areas of concern of pannus growth (sometimes too thick; other times, too thin) to be arbitrary. The tissue reaction to Silzone in the microscopic pathology was no different than uncoated Dacron, notwithstanding the presence of

silver particulate. Dr. Factor's overall view with respect to the tissue reaction to Silzone as compared to uncoated Dacron was that there was no difference and that there was no adverse response to silver whether it was attached to fibres of the cuff material or was free in tissue. The inflammatory multinucleated giant cell response was comparable.

278 In the 10 week study, there was one animal, SJII-8, that developed excess pannus. Although the animal survived to planned sacrifice at 10 weeks, the pannus was restricting the movement of one of the valve's leaflets. On receipt of this sheep's explanted valve and surgical records, Dr. Tweden concluded the pannus formation was unusual and as I have said, she contacted Dr. Schoen and asked him to examine SJII-8 and SJII-9's valves. Dr. Schoen found two prominent green suture knots on SJII-8's valve and while he concluded that the relationship between the sutures and the pannus was uncertain, he could find no other apparent cause for the excess pannus. Dr. Cameron conducted a gross and microscopic pathological examination of SJII-8 that revealed nothing unusual.

279 It was Dr. Wilson's opinion that silver toxicity caused the excess pannus. Matthew Ogle, a company scientist, measured the silver concentrations in the annular tissue of the sheep in this study and found that SJII-8 had silver levels that were higher than the other sheep in the study. However, as discussed below, these values are unreliable. Dr. Wilson suggested that the higher silver levels might account for the excess pannus, but this is inconsistent with his Silzone toxicity theory as it assumes an increase in cell activity to cause excess tissue growth at the same time as silver is interfering with cellular functions to impair or delay tissue healing. Dr. Schoen testified that this is biologically implausible.

280 Dr. Schoen and Dr. Errett testified that they had seen numerous cases in non-Silzone valves where excess suture material contributed to excess pannus. It seems to me that excess suture material is a more likely explanation for the excess pannus in this animal than silver toxicity, although, like thrombus, the cause of excess pannus in animals or humans is not always known.

281 I accept the evidence of Dr. Factor and conclude that these sheep studies do not show healing differences at all, and certainly none that can be attributed to Silzone.

Sheep Silver Concentrations and Silver Loss

282 Dr. Tweden's literature review included references to studies that reported on the measurement of silver toxicity in burn patients treated with silver sulfadiazine cream.[73] From her review of these studies, she concluded, as her April 1, 1997 memorandum states: "The most conservative level reported for silver toxicity is 300 ppb". Both Dr. Williams and Dr. Rodricks said that 300 ppb was a reasonable interpretation of the data reported in the studies. Dr. Williams acknowledged that some studies reported higher values and other studies reported lower values, but that 300 ppb was not an unreasonable figure to use as a reference for blood serum concentrations in the animal studies and in the LIMRA in order to assess the risk of systemic toxicity. Although the plaintiffs argue that Dr. Tweden thought 300 ppb was a measurement of silver toxicity at a cellular

level, I am satisfied that Dr. Tweden understood that 300 ppb was a blood serum level. She did not rely on 300 ppb as the concentration level at which silver starts interfering with cells involved in tissue healing.

283 Blood serum concentrations, while of interest, are not directly relevant to an assessment of the toxic effects of silver on tissue. In the study of megaprostheses by Hardes et al. that I referred to earlier, the investigators used 300 ppb of silver as one of the guidelines for assessing toxicity. However, they recognized the limitations of this measurement for reasons I have discussed:

> However, the therapeutic and toxic effects can be only exhibited by the free silver ions (Ag+). If the silver ion is bound it has no function any more. Therefore, the reported threshold values since when [sic] silver can exhibit toxic side-effect can be interpreted with caution only, because the measured silver concentration includes bounded and not bounded silver. Therefore there can be no correlation between the silver concentration and toxic side-effects.

284 The original protocol for the 10 week study as sent to the FDA for comment on August 30, 1996, did not propose to measure silver concentrations in the tissues. However, in the FDA's September 26, 1996 reply, they commented that "It may be useful to consider preserving ... an aliquot of the sewing ring, ingrowth tissue and valve annulus for *in vitro* quantification of silver content" suggesting that "Tissue quantification of silver concentration may prove to be a more sensitive measure, compared to serum levels, of the presence of silver-ion protein complexes in the near vicinity of the sewing ring." Mr. Ogle developed a method for measurement of the silver concentrations using samples from KTMV-2 in October 1996, and after the FDA's request, he proceeded to do an analysis in March 1997 of samples from the 10 week study. Tissue surrounding the valve was examined and tested for silver concentrations. The results were reported, but no conclusions were drawn from them.

285 As the plaintiffs place so much reliance on Mr. Ogle's data, I think it is important to reproduce the following transcript excerpt from Dr. Williams' direct examination. The assumptions he was asked to make accurately describe Mr. Ogle's evidence about the difficulties he encountered in sectioning the tissues for analysis:

> Q. And what I would like to do is ask you to make some assumptions with respect to this work and then I will ask you a couple of questions at the end. What I would like you to assume, first of all, is that in order to make these calculations, Mr. Ogle was provided with a block -- let's deal with the annular tissue concentrations in particular. That Mr. Ogle was provided with a block of annular tissue and sewing cuff from the sheep in question, and in these cases it is each of the sheep in the long-term study. Secondly, I would like you to assume that the sewing cuff had tissue ingrowth into the interstices of the fabric of the cuff. Third, I would like you to assume that Mr. Ogle separated the annular tissue from

the sewing cuff in order to make his measurements using a scalpel blade. And finally, I would like you to assume for the moment that Mr. Ogle probably caught a bit of the silver-coated cuff material in the annular tissue section. Given those assumptions, what conclusions would you draw from Mr. Ogle's measurements of the silver concentration in the annular tissue that we have just looked at?

A. Thank you, I understand those assumptions. In my opinion, it was always going to be very difficult to be able to analyze the silver levels in tissue adjacent in contact with the cuff without the possibility of including some of the fibers. I see technically that as being very, very difficult. With that possibility, in my opinion, just a small amount of the coated fiber being included in the tissue for analysis makes interpretation of that silver level very, very difficult. Could I just add to that that the technology for measuring silver is very similar to that which we used in my paper which we discussed yesterday. It involves digestion of the sample, typically in nitric acid, and then analyzing total silver content; that is the way in which it is done. That gives a total silver content, irrespective of whether that is silver ions in tissue or silver particles. So if you have one bit of fiber with a bit of silver attached to that which is now digested in the sample, clearly, that is going to distort and in my opinion distort in a very significant way the total silver level there. I should also add that even without that assumption, since we know we have seen from pathology slides that there is the occasional particle of silver in tissue anyway, that will also get taken up in that digestion process. So in no way, in no way at all does this figure for silver content reflect total available silver. If it was one small fragment of silver which we have seen has no effect on the inflammatory response, one small fragment of silver would totally distort these figures, and they haven't any implication whatsoever on the relevance to safety.

Q. And so is your opinion then with respect to these measurements the same whether or not Mr. Ogle caught some of the fabric in the diesection (sic) process?

A. I think it is most likely he did, but even if he did not, I do believe that it is very difficult to have any confidence in these figures to give us the level of available silver. In my opinion, both those factors could contribute.

286 In cross-examination, Dr. Healy was asked to make the same assumptions, but refused to do this because Mr. Ogle did not record in his notebook the problems that he described in his evidence and Dr. Healy did not think this was "scientifically valid". As a result, I do not have Dr. Healy's evidence on a point that the plaintiffs emphasize in their submissions. Assuming Dr. Healy is correct and I should have no regard to Mr. Ogle's evidence, I am left to resolve conflicting evidence from Dr. Healy and Dr. Williams about what the data showed.

287 Dr. Healy testified that the silver concentration levels are higher than those that would be toxic to cells involved in the wound healing process, but his opinions are based on toxicity levels seen *in vitro* or on blood serum levels, which have no direct application to the evaluation of toxicity

in tissue. It is not possible to extrapolate from a concentration of silver that is toxic *in vitro* to the *in vivo* situation as the study by Hardes et al. explains. Dr. Rodricks and Dr. McLean agreed that there are no *in vivo* studies describing a threshold value for silver concentration leading to damage to fibroblasts. Dr. Williams' evidence confirms that Mr. Ogle's data tells us very little about toxicity because it does not measure available silver ions in the tissues. Dr. McLean agreed that measuring quantities of silver in tissue does not tell you the dose of free silver ions, which is the only reliable measure of the potential for toxicity.

288 It is also telling that notwithstanding the importance the plaintiffs place on the sheep silver concentration data, Dr. Wilson has had in his possession for more than a decade between five and ten human hearts with Silzone valves in them, but he has never attempted to measure the silver concentration levels in tissue adjacent to the sewing cuff. I think it is fair to infer that if Dr. Wilson believed such measurements to be of scientific value in his analysis of the effect of Silzone on tissue healing, he would have done this. This lends further support to the defendants' position that such measurements are not meaningful even if they could have been reliably obtained.

289 It is also of interest that the sheep silver concentration data from the 10 week study was reported to both regulators. The plaintiffs submit that the data would have been difficult to interpret without a description of the methods Mr. Ogle used to derive the values that are depicted on the chart that was included in the regulatory submissions. Dr. Healy testified that the relevant and important value is that which is provided for silver concentration in the column labelled "Wet (g/g)". However, Mr. Ogle's memorandum, which was included in the submissions to Health Canada and the FDA, does provide a description of how the tissue was prepared for analysis, how the ppb of silver was determined, how the ppb value was converted to weight of silver, how it was compared to the dry and wet weight of tissue, and how a value for weight of silver per weight of tissue was reported. Dr. Wilson acknowledged that Dr. Hilbert is an experienced pathologist. As it was the FDA that requested that silver concentration be measured in the area adjacent to the cuff, I would expect it to pay attention to the results, and it is apparent from Dr. Hilbert's memorandum that he reviewed the results obtained. There is no indication that he had any difficulty interpreting the data or, more importantly, that he had any concerns about it.

290 It is also of significance that the gross photographs and representative microphotographs, as well as the animal care records, pathology reports of Dr. Cameron, and silver concentration results obtained by Mr. Ogle for the 10 week study were all reviewed by Dr. Hilbert who concluded:

> The data provided are satisfactory and adequately demonstrate the short-term safety of the silver coated sewing cuff, based on explant pathology findings and the establishment of blood and selected organ silver levels.
>
> ...

> The sponsor has adequately demonstrated the short-term preclinical safety of the silver coated sewing cuff based on handling and implantation characteristics tissue response and silver levels in blood and selected organs (kidney, liver, heart valve annulus). The individual surgical notes/progress and pathology reports, gross photographs and representative micrographs included in this submission provide satisfactory documentation of the study findings.

291 The plaintiffs are critical of St. Jude's failure to investigate the toxicity level for silver for cells exposed to the silver ions immediately adjacent to the cuff. The evidence shows and I find that no investigations were possible that would have yielded meaningful information. I also find that even if Mr. Ogle's measurements can be considered reliable, the concentrations of silver in the annular tissue of the sheep in the 10 week study are not significant. This is confirmed by Dr. Williams' evidence. He repeatedly disagreed with counsel's attempts to characterize the concentrations of silver in the annular tissue of 6300 ppb, 8330 ppb and 17330 ppb as significant and instead was of the opinion that the amounts were not only extremely small, but represented the total level of silver "wherever it came from" and not available silver ions. Finally, regardless of what the silver concentrations in the annular tissue were, there were no adverse effects seen on the tissue in the pathological analysis.

292 The FDA had also suggested that St. Jude measure the amount of silver in samples of the cuffs themselves and compare these to the amount of silver before implantation in order to assess the release of silver from the cuff. St. Jude attempted to do this. The evidence of Mr. Ogle, Mr. Holmberg and Dr. Williams explains why the evaluation was difficult and no conclusions could be drawn from it. St. Jude provided this information to Health Canada and the FDA, but neither sought further information or expressed any concerns.

Regent Study

293 Unlike the 4 to 5 week and 10 week studies, the Regent study focused on an evaluation of the valve's function and safety rather than the effect of the Silzone coating on tissue healing. The study was conducted at the University of Minnesota under the direction of Mr. Bianco. The study pathologist was Dr. Kirchhof. The study evaluated nine sheep implanted with Regent valves and four controls implanted with non-Silzone valves. The animals were sacrificed at time periods between 20 and 22 weeks, with one early death, SHP-8, at 21 days.

294 The study protocol required St. Jude to arrange for histopathological examination of suspected thrombus formation in the hinge area and samples for two valves, SHP-8 and SHP-15, were sent for evaluation.

295 With respect to the early death of SHP-8 at 21 days, Dr. Factor testified that the gross photograph depicted an infected vegetation that was similar to those he had seen numerous times in infected valves explanted from both animals and humans. He attributed its early death to endocarditis caused by a thrombus infected with Pasteurella. Relying on Dr. Kirchhof's pathology

report which found no infection in the section of thrombus analyzed, and on his own observations of the gross photographs and review of the pathology reports, Dr. Wilson attributed this death to a PVL and thrombus caused by Silzone.

296 As with the early death of KTMV-2, it does not make sense that only one animal in the study would experience a toxic injury. Thrombus is a well-known complication in all animal studies as well as in humans with mechanical valves and there may be multiple possible causes that cannot always be explained. The pathology report attributed the animal's death to Pasteurella sepsis. Dr. Wilson disputed that there was evidence that the Pasturella infection in the blood had affected the thrombus due to the absence of organisms. While there were no organisms found in the section sampled, that does not lead to the conclusion that there were no organisms. Dr. Wilson has seen very few cases of endocarditis and none in sheep. Dr. Factor is clearly more experienced on this issue and I accept his opinion that this was an infected thrombus.

297 With respect to the other study animals, Dr. Factor reviewed all photographs and records from the Regent study and concluded that there was no evidence that Silzone had any toxic effect on heart tissue or impaired healing. Dr. Factor noted excess pannus on some Silzone valves, but this was also present on some control valves. He found comparable variable healing between Silzone sheep and controls, whereas Dr. Wilson found abnormalities in all nine valves, including a number of sheep with PVLs and thrombus.

298 The study concluded that the valve demonstrated preclinical safety. This conclusion was reached notwithstanding the early death of SHP-8, and in reliance on the necropsy reports of Dr. Kirchhof, whose work Dr. Wilson admired. Although the focus of the study was on valve performance rather than tissue healing, Mr. Bianco was a co-author of the ASAIO article reporting on the results of the 4 to 5 week study, and very much aware of the Silzone project. It is therefore reasonable to think that if the Silzone sewing cuff was implicated in the leaks that were identified or that Silzone played a role in the formation of thrombus, this would have been raised.

299 The final report from the Regent sheep study, including all of the necropsy reports that Dr. Wilson relied on for his opinions, was included in the submission filed with Health Canada prior to its approval. The plaintiffs place some reliance on the fact the report was unaudited. Mr. Bianco noted this in his letter submitting the report, but also noted that the GLP audit "rarely if ever" results in altering conclusions or recommendations on preclinical safety of the device under investigation. That this was an unaudited report is of no significance.

Epic Study

300 The Epic sheep study with six Silzone valves and six controls and explants at 20 weeks was conducted at BioSurg, Inc. a facility in Winters, California. Dr. Cameron served as study pathologist. Four more Silzone sheep and four controls were explanted at 52 weeks. The plaintiffs point out that this was the largest and longest sheep study conducted by St. Jude on a Silzone valve. However, the Epic valve was a new tissue valve, used a different fabric on the sewing cuff and

differed from both Regent and Silzone valves in several other respects. In view of this, the study results are not directly applicable to conclusions about the Silzone valve. Nonetheless, the results from the Epic study were positive and did not raise concerns about the Silzone coating. The Study Director, Ross Lirtzman, DVM, concluded in his report of the 20 week study that: "The Epic valves showed no interference with the local inflammatory tissue response: in fact fibrous reaction to the coated cuff is well organized and *pannus formation on the valve surface is thin and smooth*" [Emphasis added]. Dr. Lirtzman's description of well organized (i.e. healed) pannus is some corroborative evidence of Dr. Tweden's view that thinner pannus is more ideal pannus.

301 In contrast, Dr. Wilson found focally poor healing in the Silzone valves in this study overall. He identified leaks in four of the animals. While Dr. Factor agreed with Dr. Wilson that two of the animals demonstrated PVLs, his opinion was that in one animal it was caused by infection and in the other the leaks were similar to leaks frequently seen in valves without Silzone. He found comparable healing variability between the Silzone sheep and controls. Based on his review of the records, explanted valves and histology slides, he found no evidence in any of the sheep in the study that Silzone had any adverse effect on the heart tissues, or that it was toxic or impaired healing.

302 The plaintiffs suggest that the amount of silver remaining on the Silzone-coated valve in the Epic sheep study (81.9% at 52 weeks) as reported in Mr. Ogle's poster be compared with the amount of silver remaining on the B. Braun Vascular Graft (97.8% at 52 weeks) in Dr. Ueberrueck's study.[74] They argue that these results indicate that the silver coating leached off more rapidly from the Silzone cuff than from the vascular graft. This comparison cannot be made as the B. Braun results are derived from an *in vitro* washout study whereas the Epic results are derived from an *in vivo* analysis of silver concentration in tissue. Dr. McLean testified that silver released in an *in vitro* study cannot be used to draw conclusions about the quantity of silver that will be released in a blood environment. Also, Mr. Ogle's evidence was that his sectioning techniques were not uniform ("I guarantee that I clipped some silver fabric. So from that standpoint, I believe it was the worst case amount of loss of silver seen"). The B. Braun results, if they are at all relevant, tend to demonstrate that only small amounts of silver are released from an IBAD coated surface after an extended time.

Tailor Ring and TSPV Studies

303 For completeness, I will briefly mention the Tailor Annuloplasty Ring and the Toronto Stentless Porcine Valve Series (TSPV) sheep studies. Dr. Wilson examined explanted rings from the Tailor study and took some histological sections from them, but did not discuss his findings in his reports or testimony. I infer that he accepted Dr. Factor's conclusions that there were no healing differences between coated and uncoated rings in the study, which used the same fabric as the Silzone valve. Dr. Wilson had the opportunity to review the explanted valves from the TSPV study, but expressed no opinion about the study. The TSPV reports are business records and reach positive conclusions about the healing response of the Silzone-coated valves.

Conclusion on Sheep Studies

304 The sheep studies showed comparable healing into Silzone-coated sewing cuffs and no evidence of toxicity in the gross and microscopic evaluations. These studies are not perfect predictors of what will happen in humans, but as they show the response of a whole organism to a potentially toxic agent with all of the protective mechanisms intact, they are better indicators of biocompatibility than *in vitro* studies. Silzone did not inhibit tissue growth or cause an abnormal inflammatory response that was unusual for an implanted device. The early death of KTMV-2 in the 4 to 5 week study and the pannus overgrowth of the valve leaflet in SJII-8 in the 10 week study was not caused by Silzone toxicity.

Spoliation

305 Common Issue 6 asks: Is the burden of proof of causation or negligence affected by spoliation of evidence by the defendants? It is convenient to address this here as there is no dispute that the organs, explanted heart valves, and histology blocks from the 4 to 5 week and the 10 week studies (the "Masters series sheep study materials") and explanted heart valves from the Regent sheep study (collectively, the "missing materials") were either inadvertently destroyed prior to the litigation or could not be located during the course of the litigation. Although the plaintiffs originally submitted that findings be made in their favour in respect of each of the common issues, they revised their position in their Reply with respect to this common issue. They now submit:

> The answer to Common Issue 6 is:
>
> The burden of proof in causation or negligence is not affected by the spoliation of evidence by the defendants. However, the defendants' spoliation of evidence leads this Court to presume that explanted Silzone valves and tissue samples from the Sheep Studies would have been unhelpful to the defendants' case and helpful to the plaintiffs.

<u>The Legal Test for Spoliation</u>

306 In *McDougall v. Black & Decker Canada Inc.*, the Court referred to *St. Louis v. R.*, for the following statement on the law of spoliation: "[spoliation] occurs where a party has intentionally destroyed evidence relevant to ongoing or contemplated litigation in circumstances where a reasonable inference can be drawn that the evidence was destroyed to affect the litigation".[75] Spoliation can thus be divided into four elements:

1. the missing evidence must be relevant,
2. the missing evidence must have been destroyed intentionally,
3. litigation must have been ongoing or contemplated at the time the evidence was destroyed, and
4. it must be reasonable to infer that the evidence was destroyed in order to affect the outcome of the litigation.

307 This interpretation of the law regarding spoliation has been followed by courts in Ontario.[76]

308 The plaintiffs have not referred to any evidence regarding the relevance of the missing materials. Rather, they invite the court to infer that those materials would have been relevant, apparently based on the circumstances in which the materials went missing. However, they have not referred to any evidence about those circumstances. The plaintiffs also have not referred to any evidence regarding the question of whether the missing materials were destroyed intentionally. Rather, they invite the court to infer such an intention since they assert that the destruction of the materials would have been contrary to federal regulations and St. Jude's internal policies. However, the plaintiffs have not referred to any regulations or evidence of St. Jude's internal policies.

309 The only evidence regarding the circumstances in which the Masters series sheep study materials went missing came from the defendants' answers to undertakings that were read in by the plaintiffs at trial. The evidence of Mr. Holmberg was that the materials were discarded in a lab cleanup despite his instructions to save them. Mr. Holmberg recalled speaking to someone who said that "she did not think the specimens needed to be saved since all the approvals had been received and that slides for all the specimens were available".

310 At the time the materials were destroyed, litigation had not commenced. The plaintiffs have not referred to any evidence as a basis for finding that the materials were destroyed in contemplation of litigation. While they assert that the materials were lost "shortly after St. Jude officials met with the MDA for the second time," the defendants dispute this claim, and the plaintiffs have not referred to any evidence to support it. The defendants also point out that Mr. Holmberg was the source of information regarding the destruction of the Masters series sheep study materials. At trial, the plaintiffs had the opportunity to cross-examine Mr. Holmberg regarding the time during 1999 that the materials were destroyed and whether this was before or after discussions with the MDA in June 1999. The plaintiffs did not do this, nor did they attempt to elicit any further evidence at trial on how the Masters series sheep studies materials were destroyed from any of the other company witnesses who testified at trial.

311 Given that the evidence of Mr. Holmberg is the only evidence regarding the circumstances under which the Masters series sheep study materials went missing, it would not be reasonable to infer that the evidence was destroyed in order to affect the outcome of pending litigation. Indeed, the only available evidence indicates that whoever discarded the material did so because they were under the impression that it was no longer needed for any purpose.

312 In the case of the missing materials from the Regent sheep study (originally in the possession of the University of Minnesota), the defendants' answers to undertakings read in by the plaintiffs at trial detail that St. Jude initially had "some second hand information" that the explanted valves and organs were "inadvertently destroyed in 2000" but then subsequently, the organs were located. There is a document showing their delivery to St. Jude but it was "unable to confirm with any degree of confidence that the explanted valves were ever in St. Jude's possession, or when or how

they went missing". The read-in evidence shows that it is uncertain that St. Jude ever received the explanted valves from the University of Minnesota.

313 In substance, the plaintiffs are asking the court to infer all of the elements of spoliation, dressed up as a presumption from the mere fact that the Masters series and Regent sheep study materials are missing. In failing to refer to any evidence in their submissions on spoliation, the plaintiffs have failed to establish any of the four elements listed above. Thus, the plaintiffs have failed to establish spoliation on a balance of probabilities. It is therefore not necessary to consider whether the defendants have rebutted any adverse inference that would arise from a finding of spoliation, nor is it necessary to consider whether a presumption should be made.

Clinical Evidence of Silzone Toxicity

314 A very large part of the plaintiffs' causation case is based on Dr. Wilson's clinico-pathological correlation of 18 Silzone valves from 14 patients. A clinico-pathological analysis involves reviewing the medical records and analyzing the gross and microscopic pathology for a patient and then correlating the findings. While Dr. Wilson's study is only one part of the plaintiffs' causation picture, it is a very important part. It is the causal lynchpin that attempts to connect the plaintiffs' theory of Silzone toxicity with clinical evidence of abnormal healing and resulting medical complications in patients. Although a number of expert witnesses provided testimony about this, the primary opinions come from Mr. Butchart, Dr. Wilson and Dr. Schoen.

Independence of Dr. Schoen and Neutrality of Dr. Wilson

315 The plaintiffs made a considerable effort to exclude or neutralize the evidence of Dr. Schoen on the basis that he lacks independence. Their attack is focused on Dr. Schoen's consulting work with the medical device industry in general, and with St. Jude, in particular, although less than 1% of his time has been spent consulting for St. Jude and Dr. Schoen consults to several of St. Jude's competitors as well as the FDA. I did not agree to exclude his evidence as inadmissible when this was raised during the trial and my ruling explains why.[77] The plaintiffs reprised this at some length in their written submissions and also during oral argument. Having heard Dr. Schoen's evidence, I have not changed my mind.

316 The plaintiffs do not dispute that Dr. Schoen is a highly qualified cardiac pathologist, but they resist a finding that his evidence is to be preferred solely on the basis of his qualifications. I accept that a trial judge must tread the path of relative experience cautiously as even highly qualified experts can be wrong. Nonetheless, as I said when I was discussing the sheep studies, relative expertise takes on greater significance when the expert opinions are based on the observations that each made from the appearance of the valves. Knowledge about how valves heal comes from experience.

317 While it is true that in their respective roles as litigation experts Dr. Wilson and Dr. Schoen have equivalent experience with Silzone valves, it is not credible for the plaintiffs to argue that Dr.

Wilson's experience matches the depth of experience of Dr. Schoen who, like Dr. Butany, is acknowledged to be among a very small group of six or eight internationally recognized specialists in the pathology of prosthetic heart valves. Dr. Schoen is a professor of pathology at the Harvard Medical School and Director of the Cardiac Pathology Department at one of the four principal teaching hospitals of the Harvard Medical School.

318 Dr. Schoen also holds a Ph.D. degree in materials science and, as well as teaching medical students at Harvard, he also teaches students at MIT working toward PhDs in biomedical engineering. Dr. Schoen's practice has focused on the pathology of prosthetic heart valves and he has examined at least a thousand prosthetic heart valves over the course of a thirty year career. Apart from his early work with Dr. Silver, Dr. Wilson's professional career has taken him in other directions. It is undeniable that Dr. Schoen has far more experience with prosthetic heart valves than Dr. Wilson and that he is far more qualified to discuss the range of healing that can be seen in them. While the concerns that the plaintiffs raise could in some circumstances affect the independence of an expert, I found Dr. Schoen's evidence to be fair and impartial. In my view, he fulfilled the duties of an expert witness who is providing opinion evidence to the court.

319 In contrast, it was Dr. Wilson who lacked neutrality and testified as an advocate in support of the theory of Silzone toxicity. He was selective in his choice of the valves from the sheep studies, choosing not to discuss the explanted Tailor annuloplasty rings or review the TSPV sheep studies and he was also selective in his choice of patients for his clinical study. He testified that he needed "complete medical records" in order to do a clinico-pathological correlation, but, he included three long-term patients despite very incomplete records. There were other long-term patients, the so called "lettered patients", that he did not include, although there is evidence that at least some of them died of non-valve related causes and showed good healing of their Silzone valves. Dr. Wilson confirmed this to be the case with Patient "S", who died with an apparently well healed valve that had been functioning for at least nine years. He gave no adequate explanation for this and I was left with the impression that the patients in his study were not chosen in an unbiased, scientific manner.

320 Dr. Wilson made clinical diagnoses on individual patients that went well beyond his own experience as a pathologist. He had a tendency to be dismissive of the opinions of treating physicians and other experts where their conclusions undermined his theory, although he clearly lacked their expertise. As well, his evidence was not presented in a neutral manner. He was often argumentative, repetitive and unresponsive to questions posed in cross-examination. While the record will speak for itself, I try not to interrupt the testimony of a witness except to seek clarification. There were a number of occasions when I found it necessary to do this and direct him to answer the questions. I do not accept the plaintiffs' suggestion that this is explained by Dr. Wilson's inexperience as an expert witness. Dr. Wilson has previously given expert testimony and he testified in this trial over the course of ten days. Regrettably, Dr. Wilson's commitment to his own theory of causation impaired his objectivity and reliability as an expert witness. I find he lacked neutrality. Given this concern and his limited experience with prosthetic heart valves, I attach little weight to his opinions where they differ from those of Dr. Schoen and the defendants'

clinical experts.

Mr. Butchart

321 Mr. Butchart is an eminently qualified cardiac surgeon, with particular expertise in valve related thromboembolism. Although he is in quite a different category than Dr. Wilson, they have in common that each formed their opinion early on, with little scientific analysis, that Silzone was the culprit. Neither has wavered from that opinion. Understandably, Mr. Butchart was offended and upset by St. Jude's actions when, without informing him (as Dr. Flory now acknowledges he should have), the company contacted Mr. Jules Dussek, the President of the Society of Cardiothoracic Surgeons of Great Britain and Ireland to request a review of his CERFS data. After this, the relationship between Mr. Butchart and St. Jude quickly deteriorated. Mr. Butchart's response to St. Jude's actions was a normal human response, but hispredetermined opinion that patients had suffered because of the Silzone valve and his negative views about St. Jude affected his ability to look at the evidence dispassionately in providing his opinions to the court.

The Timing and Manner of Tissue Healing in Prosthetic Heart Valves

322 Mr. Butchart and Dr. Schoen described different biological processes that result in the formation of pannus, but they agree that an implanted heart valve sewing cuff is capable of healing and, if fully healed, that it will become encapsulated in connective tissue or pannus. Obviously, valves that have been safely implanted in human patients and that continue to function well cannot be removed for study. Dr. Schoen testified that valves that have been explanted for medical complications after different lengths of time demonstrate variable healing characteristics from patient to patient, from mitral to aortic, from inflow to outflow surface on the same valve and around the circumference, largely due to anatomic factors. Dr. Schoen disagreed with Mr. Butchart and Dr. Wilson that tissue formation and ingrowth normally occurs by three months and is necessary for the clinical performance of a valve.

323 Dr. Wilson testified that he observed a grossly abnormal healing process in the heart valves in the 14 patients in the study, involving too little pannus, too much pannus or a combination of both, and sometimes, thrombus with pannus. He attributed these abnormalities and the resulting medical complications in each of the patients to Silzone toxicity. His conclusions are, to a significant extent, based on the assumption that a sewing cuff on a mechanical heart valve will normally be healed by three months and that thrombus will not form on a well healed valve. Mr. Butchart also testified that the literature confirms that healing is complete within the first two to three months, but he did not testify about what he has seen in his own clinical practice.

324 Dr. Schoen demonstrated from comparative gross photographs of selected valves that there is tissue lost in the surgical removal a valve or its removal at autopsy. He explained that assessment by a pathologist of the reasons for poor healing can be constrained by the inability to understand the anatomic context into which the valve was implanted. Understandably, the surgeon's primary concern is addressing the problem at hand and typically, the surgeon is not paying attention to

preserving tissue or endothelium on the valve and the endothelial layer abrades easily. As a result, the specimen the pathologist receives may be and is often different with less tissue on the valve than was there at the time of removal. Dr. Butany's evidence confirms this.

325 This was also demonstrated in a 1981 paper by Marbarger and Clark, where the authors studied the degree of tissue overgrowth and the strength of tissue adhesion in 118 explanted bioprosetheses. Sufficient tissue for evaluation was present in only 66 of the 118 valves.[78] This suggested to Dr. Schoen either that the tissue was not there at the time of explant or had been removed inadvertently in handling the valves. The authors in this study also reported, although on limited data, that many months may be required before tissue ingrowth is complete. As Dr. Wilson's 14 patient study had no valve handling protocol, he cannot account for changes in appearance and quantity of tissue that occurred after the valve was removed from the patient or at autopsy.

The Three Month Guideline

326 All patients with mechanical valves require anticoagulation therapy to reduce the risk of clotting on the valve and are usually prescribed Coumadin (*Warfarin*) with the goal of maintaining the patient's anticoagulation within a target range, measured using the International Normalized Ratio (INR). The therapeutic INR range for a patient is usually set by his or her treating physician, but with reference to general recommendations set out in generally accepted guideline documents such as in the Canadian Cardiovascular Society's Guidelines for the Surgical Management of Valvular Heart Disease. These guidelines recommend, and it is the practice of many physicians, to anticoagulate bioprosthetic or tissue valve recipients for only the first three months following implant. Dr. Wilson's theories that a sewing cuff should be normally healed by three months so as to protect against the formation of thrombus is based largely on his extrapolation from the guidelines and his understanding of this practice of physicians.

327 While there is consensus in the medical community that the anticoagulation guideline is a sound treatment guideline based on clinical studies of the effectiveness of anticoagulation, there is no clinical or animal data to establish that a sewing cuff will be endothelialized within three months. As well, there is no evidence of any practice that the target INR for mechanical valve recipients is lowered after three months, although one would expect this could happen if the sewing cuff on all mechanical valves is completely healed by three months.

328 Dr. Wilson's reliance on animal studies to support his opinion that normal healing in valve patients occurs at three months fails to account for differences in the rate of healing between humans and animals. The Bull and Braunwald studies, on which he and Mr. Butchart relied, demonstrated these differences as the authors found that the rate of tissue organization in human prosthetic valves is "markedly slower" than that seen in experimental animals.[79] There are very few clinical studies that document the time course of healing in mechanical valves. The studies are small, making it difficult to understand what should be expected in the majority of patients over time. The studies that have been done support Dr. Schoen's evidence that the timing and manner of

healing in mechanical valve patients is extremely variable and it is not possible to say with any confidence that healing is complete by three months in the vast majority of patients.[80]

329 This was graphically demonstrated by photographs of the Starr Edwards valve that Dr. Schaff explanted for PVL after 15 years with intact sutures and absolutely no endotheliazation or tissue ingrowth on the sewing cuff. Dr. Schaff has explanted more than 300 valves over a 30 year career. He testified that this valve was at one extreme, but that he had seen many other valves, from different manufacturers, with a wide range of healing characteristics, most explanted after five years.

330 The evidence of Dr. Errett is consistent with this. He testified:

> I think the natural history of healing following valve--mechanical valve or any valve implantation in humans is not entirely understood, and I think that's understandable because valves we place in patients that function normally and last the patient's life are never really studied along the line. So we don't know in thousands of patients what is happening at certain times during the course of that valve's life...we make conjectures on how well they're healed and when they're healed but that is conjecture.

331 Like Dr. Schaff, Dr. Errett had observed non-Silzone valves with the same patterns of healing that Dr. Wilson described, including little to no healing of valves explanted months or sometimes years after implantation, intact pledgetted sutures pulling through the tissue around valves, excess pannus on valves, and valves explanted with little or no endotheliazation. Dr. Butany testified that the pathological findings and modes of failure he observed in his study of 19 Silzone valves are seen in every kind of valve.[81] To the extent that Dr. Wilson's opinions are based on the assumption that a valve will be fully healed and endothelialized by three months, the assumption is unproven.

The Scientific Value of a Clinico-Pathological Correlation

332 The very nature of a class action requires the bifurcation of the causation analysis between general causation and specific causation. The question at this stage is not whether Silzone *did* cause impaired healing in any class member, but rather, whether it *can* cause this adverse effect. The plaintiffs submit that the evaluation of Dr. Wilson's evidence is a question of sufficiency and weight, which combined with other evidence regarding Silzone's effect on tissue and cells, will allow me to determine whether the plaintiffs have discharged their onus with respect to Common Issue 2. The issue that I find difficult is how to assess the sufficiency and weight of a study of 14 patients in answering a question on general causation in a class action. How should the evidence on individual patients be approached and how does it assist the court in reaching conclusions about the effects of Silzone in the broader group of class members who have Silzone valves? During oral submissions, I repeatedly pressed counsel for assistance with this.

333 Counsel for the plaintiffs proposed that I should, in effect, go through each of the patients in the study in order to determine whether or not, on balance, this supports Dr. Wilson's opinions about the effects of Silzone on tissue healing. In other words, are Dr. Wilson's opinions with respect to each patient mostly correct? I do not see how a scorecard on 14 individual patients will assist me in answering a general causation question and the plaintiffs provided no meaningful guidance on this. Assuming that the court agreed with Dr. Wilson that Silzone is the likely explanation for a particular medical complication in eight of the 14 patients, but not in the other six patients, what conclusion could I draw other than this outcome occurred more frequently in patients with Silzone valves? This cannot establish on its own that the Silzone valve is causal of the complication since there is no control group or corresponding group of patients who suffered the complication and is exactly the same except for the Silzone valve.

334 The plaintiffs' approach would be useful if the question to be answered was whether Dr. Wilson correctly concluded that Silzone toxicity is the more probable explanation than other probable explanations for the medical complication in each of the 14 patients. But, this is a question that will only arise in individual hearings. The question at this stage is one of general causation - does Silzone have a different and adverse effect on healing than uncoated Dacron? In other words, is there a causal relationship between Silzone and the harm the plaintiffs allege?

335 The approach I propose to follow is to determine in what circumstances a clinico-pathological correlation of 14 patients can provide evidence of causation. I will then explain why I reject Dr. Wilson's analysis. My conclusion is that this kind of evidence cannot establish a causal link between Silzone and the medical complications that occurred in these patients.

336 As I touched on in the Introduction to these reasons and as I discuss further under Common Issue 3, there is a generally accepted hierarchy within the scientific community as to the kinds of studies that may be helpful in investigating cause and effect relationships. It is generally accepted in the scientific community that a case series such as Dr. Wilson's 14 patient study, provides, at best, weak evidence of whether a treatment, in this case a Silzone valve, causes a condition, for example, PVL. A case series can address the question: what is the frequency of the occurrence of an outcome in patients with a particular characteristic? It can suggest that there might be a problem that should be studied, but a case series cannot answer the question: was the occurrence of PVL more likely in patients with a Silzone valve than in patients without it?

337 Dr. Schoen acknowledged that proper analysis would be difficult as it would require a study with autopsies of patients whose valves functioned without complication. Dr. Wilson cannot be criticized on this account, but there is inherent bias in a study that only includes patients that have experienced medical complications and excludes other patients whose valves appear to have functioned well. As Dr. Schoen explained, "it is very difficult to take 14 patients or even a larger group of patients who have had their valves removed for some problem and draw conclusion [sic] about the patients who are out there doing fine." The absence of a control group or a standard of

comparison limits the use that can be made of the data from a study of this kind. There is simply no information on the patients that are not part of the series and, therefore, one cannot determine if it was the Silzone valve or some other known or unknown factor that caused the condition in issue. This makes it virtually impossible to draw conclusions as to probable causation.

338 Although a clinico-pathological correlation is a methodology that scientists use, I find that absent an extreme or unique situation, scientists would only rely on a case series without controls to establish a hypothesis and would not rely on this kind of evidence to draw conclusions about cause and effect. In *Rothwell*, Osler J. reached the same conclusion after reviewing very similar evidence on the scientific value of different kinds of epidemiological studies.[82]

An Extreme or Unique Situation

339 Dr. Sackett, the plaintiffs' epidemiology expert, illustrated an extreme or unique situation where it may be acceptable to draw conclusions about causation by giving the example of a small case series of 12 patients with a relatively mild disease who all died after receiving the same treatment. In this case, the "treatment" is a Silzone valve, common to all patients in the study, but the "disease" is a variety of medical complications, including PVL, thrombosis, endocarditis or stroke. These are risk factors for all mechanical valve recipients.

340 In analyzing the 14 patients in his study, Dr. Wilson said that he proceeded empirically by a process of exclusion and would only attribute the event to Silzone toxicity where he could exclude other possible causes of the adverse event or the adverse appearance of the valve. The plaintiffs dispute that as a matter of law Dr. Wilson was required to eliminate all other possible causes for medical complications in order to have the court accept his evidence as proof of causation. Causation in law is on a balance of probabilities, but Dr. Wilson approached his task as a scientist. Scientific proof of causation is described in *Rothwell* as follows:

> Proof of causation
>
> Causation in scientific and medical matters may be easy to assign or may be extremely difficult. Causation may be taken as proved, for all practical purposes, in many diseases when a specific organism is invariably found in association with a specific physical condition of disease and other possible causal agents can be eliminated. Causation can be assigned when it has been shown that a specific group of symptoms, characteristic only of a specific agent or disease, is present. Causation can be assigned when a specific pathological condition, characteristic only of a specific causal agent, is shown to exist in a patient, in life or at post-mortem examination.[83] [Emphasis added]

341 Dr. Wilson accepted that this was the degree of proof that was necessary in order for him to draw a causal connection between Silzone and the medical complications experienced by the

patients in this study. His evidence was that every single valve he examined had shown abnormal healing to some degree and the consistent themes of too little pannus, too much pannus, thrombus and paravalvular leak were "so clear, striking and really significant" that he was able to conclude that "the Silzone coating consistently causes disordered healing and can and does cause a variety of life-threatening complications". While the plaintiffs do not require proof of impaired healing in all class members to establish that Silzone can cause impaired tissue healing, a study of this kind cannot support the conclusion that Silzone is the causal agent, unless other possible causal agents for the complications in issue have been excluded.

The 14 Patient Study

342 The crux of Dr. Wilson's opinion was that Silzone was the cause of the complications experienced by eleven of the 14 patients in the study. For the remaining three patients, his opinion was that Silzone was the most likely cause. Mr. Butchart provided opinions on eight of the 14 patients in Dr. Wilson's study.[84] I have reviewed the detailed evidence on each of the 14 patients, but I do not find it necessary to discuss this except by way of example to illustrate the weakness of this evidence in establishing that Silzone is the causal agent for the complications.

343 In virtually all of the cases, Dr. Schoen identified clinical details that indicate alternative causes for the valve problems. The defendants' clinical experts in cardiology, hematology, infectious disease and neurology provided strong evidence of alternate causes or the possibility of alternate causes for the complications in issue.[85] I would expect that the opinions of a patient's treating physician would be significant in a clinico-pathological context and Dr. Wilson agreed that it is the clinician rather than the pathologist who makes the diagnosis. In most cases, Dr. Wilson's opinions are contradicted by evidence from the medical records and the diagnoses of the treating physicians that are found in the records. The evidence of the defendants' clinical experts confirmed those opinions and diagnoses. Several examples will illustrate that there are other medically plausible causes for the complications experienced by these patients that Dr. Wilson and Mr. Butchart have not excluded.

344 There was considerable evidence at trial of the ability of surgeons to diagnose endocarditis based on the gross appearance of a prosthetic heart valve at surgery. The consistent evidence from the defendants' experts is that a surgeon's diagnosis of endocarditis based on observation at surgery is highly reliable. Patient 1 - Erik Andersen, and Patient 2 - Sharon Frost are examples. Dr. David and Dr. Cusimano of TGH were involved with Mr. Andersen's second surgery that replaced his first Silzone mitral valve with a second Silzone mitral valve and replaced his native aortic valve with a Silzone aortic valve. Dr. Latter performed Ms. Frost's explant surgery at St. Michael's Hospital. These physicians are regarded as highly experienced and capable surgeons who, in the late 1990s, would have been familiar with the appearance of endocarditis. Despite the inability to identify bacteria, Mr. Andersen's surgeons believed that infection caused poor healing in his first Silzone mitral valve (Dr. Cusimano described the valve as "obviously infected and dehisced") and the treating physicians thought there was sufficient clinical evidence to support a diagnosis of

endocarditis.

345 In Sharon Frost's case, the evidence for endocarditis is stronger. She had a history of culture-negative endocarditis in her native mitral valve and it was explanted and replaced with a Silzone valve. That valve was explanted and replaced with a second Silzone valve that continues to function. The consistent diagnosis from her treating physicians was that her embolic events following implant of her first Silzone valve were caused by embolic material from an infected vegetation on the valve demonstrated by echocardiography. Dr. Latter recorded a diagnosis of definite endocarditis in his operative note and this remained the discharge diagnosis.

346 All the pathologists agreed that pathology can rule in endocarditis under the Duke Criteria, but cannot rule it out.[86] The pathological criteria, if positive, are sufficient but not necessary to diagnose endocarditis. The Duke Criteria provide clinical factors that allow for a definite diagnosis even where the pathology is negative. While Ms. Frost did not have positive blood cultures, there was pathological evidence of inflammatory process, a diagnostic criterion under the Duke Criteria that is indicative of endocarditis. Neither Mr. Butchart nor Dr. Wilson convincingly excluded this as the explanation for her embolic events.

347 Both Mr. Butchart and Dr. Wilson suggested that as surgeons and other treating physicians in the late 1990s were not yet aware of the issue of Silzone toxicity, they were mistaking Silzone toxicity for endocarditis in their observations of necrotic tissue. While Dr. Schoen conceded that it was theoretically plausible for silver toxicity to cause a similar presentation to infective endocarditis, he disputed that there was any evidence to support the hypothesis. Dr. Sexton has worked on the study of infective endocarditis for twenty years at Duke University Medical Center, has participated in an international study collecting data on over 5,000 patients with infective endocarditis and is a co-author of the paper by Li et al. proposing modifications to the Duke Criteria. He testified that he was not aware of any published scientific literature that Silzone toxicity mimics infective endocarditis at surgery, on echocardiogram, on pathology, or even symptomatically. Drs. David, Cusimano and Latter work at downtown Toronto hospitals and are physicians of class members. If the plaintiffs wanted to establish that in the late 1990s surgeons were mistaking Silzone toxicity for endocarditis, it would have been a relatively simple matter to adduce this evidence. I attach little weight to Mr. Butchart's evidence that he mistook annular necrosis caused by Silzone as infection.

348 It is known that all mechanical-valve recipients are at risk of medical complications and there is an accepted background rate for each complication. For example, the Heart Valve Guidance sets out a background rate of 1.2% per valve-year for the incidence of clinically diagnosed PVL in mechanical heart valve recipients and this is based on studies of patients who have had valves for thousands of patient years. It seems reasonable to think that at least some Silzone patients must have had complications regardless of Silzone, but Dr. Wilson's conclusions ignore or dismiss the background rate. He blamed all of the outcomes in the 14 patients on Silzone, even Patient 7 where he agreed with the treating physicians and experts that the patient had prosthetic valve endocarditis,

but said that Silzone was the underlying cause of the poor healing. He did not exclude the possibility that the endocarditis developed through an infection contracted during dental work several months before the final hospital admission or that the poor healing would have occurred regardless of Silzone.

349 Similarly, for Patient 9, Dr. Wilson's opinion was that Silzone toxicity caused substantially more paravalvular leakage and necessitated the replacement of both Silzone valves, even though this patient had several well-known risk factors for PVL, including multiple valve surgeries, a history of rheumatic valve disease, the explant of a previous non-Silzone valve due to PVL, and a technically complicated surgery in which her Silzone valve was implanted. Patient 11's Silzone valve was explanted after more than 6 years due to PVL. Like Patient 9, he had many of the same risk factors as she did, but none of these were properly excluded, notably a previous PVL.

350 The same is true of Patient 13. Dr. Christakis performed the explant surgery at Sunnybrook Hospital in Toronto. He described the unusual appearance of pannus on the valve, but gave no evidence that Silzone caused the PVL. He also did not comment on the opinions of this patient's treating physicians that annular damage from disease and previous surgeries were the most likely cause of the PVL. These opinions were supported by the defendants' clinical experts.

351 Dr. Christakis also performed the explant surgery for Patient 12. This patient had two Silzone valves implanted in 1997. Nearly eight years later, only the aortic valve was explanted due to a build-up of pannus. Dr. Christakis was not asked any questions about this surgery. He gave no evidence that the appearance of the aortic valve in this patient was unusual or that he observed any abnormalities in the healing of the patient's mitral valve. It can reasonably be inferred there were none. Importantly, Dr. Wilson's theory does not explain how Silzone toxicity would cause an exuberant build-up of pannus in Patient 12 on only the aortic valve while not affecting the mitral valve in the same patient.

352 Similarly, his theory does not explain the lack of a uniform or universal response to Silzone from patient to patient, from place to place on a given sewing cuff, and from valve to valve in the same patient. If there was a problem with Silzone, one would expect there to be a problem whenever Silzone comes in contact with tissue. That this did not occur is most strikingly demonstrated by Mr. Andersen whose two replacement Silzone valves functioned for more than six years, despite Dr. Wilson's opinion that the PVL in Mr. Andersen's first Silzone mitral valve was caused by Silzone toxicity. The fact that there was no Silzone response to the second two valves suggests that the problem Mr. Andersen had with his first valve was not a response to Silzone. There is no credible explanation regarding why the alleged toxic destruction of annular tissue would occur only once in the same patient, although on the plaintiffs' theory, Mr. Andersen received a double dose of Silzone between the two valves over a period of six years.

353 All experts agreed that a toxic material will demonstrate a profound effect on cells, characterized by infiltration of other cells, a sustained inflammatory response and potentially

cellular necrosis or cell death. Neither Dr. Schoen nor Dr. Wilson saw evidence of this in the microscopic pathology in any of the patients. Dr. Wilson testified that the passage of time prevented a diagnosis of cell death, but he found material consistent with previous cell death where silver particulate was present.

354 Dr. Williams' research and the Oloffs study that I referred to earlier, demonstrate that silver particulate can be tolerated at a cellular level. There are a number of implantable devices that release particulate matter, for example hip replacement devices which contain metals and polymers and release millions of particles into the tissue on a daily basis, usually without any adverse effect. Dr. Williams testified that if particulate in tissue is not having an adverse effect on macrophages, it is extremely likely that it is not having any toxic effect on that tissue. Dr. Schoen saw "very little inflammatory reaction to the black particles and characteristically, as is observed in many other studies, a substantial inflammatory reaction to Dacron".

355 The plaintiffs rely on case reports by Dr. Butany and Dr. Tozzi to conclude that Silzone is a causal factor in abnormal healing. These reports raise no more than hypotheses and speculation that the tissue appearance observed by these investigators was caused by some toxic injury.[87] Dr. Butany confirmed in his testimony that this was "purely speculative" and that he had "absolutely no proof" that the elemental silver leached from the sewing cuff and killed myocytes that led to tissue necrosis. Similarly, Dr. Schaff testified that the statement in the 2002 AVERT Annals Paper that "it appears that the Silzone coating inhibits normal fibroblast response and incorporation of the fabric of the sewing ring into host tissue in some patients", was "a poor hypothesis to explain the increased frequency of the finding of poor tissue ingrowth in paravalvular leaks".[88]

356 Finally, Dr. Wilson's theory does not explain how an allegedly toxic agent can cause both too much healing and too little healing in the same patient. As Dr. Schoen said, it is a contradictory hypothesis and biologically implausible. While the plaintiffs claim that silver may interfere with DNA and collagen synthesis, they also claim that excess tissue growth results from silver exposure. However, they provide no scientific evidence for their theory that damaging cell mechanisms will actually cause more cells to grow. The plaintiffs suggested some possibilities to account for the variability in pannus development seen in the 14 patients and during oral submissions provided me with references to the evidence they rely on. I have carefully considered this evidence, but I do not find it persuasive. I conclude that the most likely explanation for variable pannus formation is the healing variability that can occur in any mechanical heart valve patient, as Dr. Schoen testified.

Conclusion on 14 patient study

357 The evidence shows that there are other medically plausible, and in some cases, more likely, explanations for the complications the patients experienced that Dr. Wilson did not exclude. The gross and microscopic appearances of poor pannus development and "abnormal" healing that Mr. Butchart and Dr. Wilson described occur with all types of prosthetic heart valves. At best, this study provides anecdotal evidence of less than ideal healing in 14 patients who all had medical

complications. This evidence needs to be balanced against other anecdotal evidence from a number of surgeons who testified at trial that the majority of Silzone valves, implanted between 1997 and 2000, are still in place and have performed well over many years.

358 Dr. Wilson's theories, like those of Drs. Butany and Tozzi, are no more than hypotheses. His methods would not generally be accepted in the scientific community to prove a causal relationship between Silzone and impaired tissue healing, but even if acceptable, his opinions are convincingly contradicted by Dr. Schoen who saw no different or unique healing reaction with Silzone valves in the patients he reviewed than he has seen in many other valves over a long career. Dr. Wilson's study does not provide reliable evidence that Silzone causes disordered healing and adverse events. It does not establish on a balance of probabilities that Silzone has any different or adverse effect on tissue healing than uncoated Dacron.

Conclusion on Common Issue 2

359 There is no reliable evidence to support the plaintiffs' theory that silver is toxic and is the mechanism by which the Silzone coating interferes with the proper development of pannus to impair or delay tissue healing or damage existing annular tissue in the heart. St. Jude's *in vitro* testing included standardized toxicity and mouse and human fibroblast tests and confirmed that Silzone exerted little potential to be toxic. The sheep studies established that good tissue ingrowth and comparable healing occurred in the sewing cuff and no toxicity was seen in the LIMRA study.

360 While any material can be toxic at some dosage, the scientific literature establishes that silver has a low potential for toxicity. The studies on which the plaintiffs rely primarily involve large doses of fast dissolving silver salts rather than a tiny amount of metallic silver slowly releasing ions largely bound to albumin or other proteins/substances and not bioavailable to affect tissue. Neither of the plaintiffs' toxicologists gave a clear opinion that Silzone is toxic and the evidence of the defendants' experts, supported by a wealth of scientific literature, persuades me that it is not.

361 I have not overlooked the plaintiffs' submissions that additional evidence of the effect of Silzone on tissue healing can be derived from Dr. Wilson's microscopic evaluation of an unimplanted Silzone valve; the AVERT data, (showing a statistical and causal association between Silzone and PVL during the first two years post implant); the FERs; and the Top Accounts survey. None of this evidence persuades me that a Silzone coating on a heart valve has any different or adverse effect on tissue healing than a valve without Silzone.

362 A Silzone coating on a heart valve sewing cuff has no adverse or different effect on tissue healing than uncoated Dacron.

COMMON ISSUE 3

Does a Silzone coating on heart valves, or annuloplasty rings, materially increase the risk of various medical complications including, but not limited to, paravalvular leakage, thrombosis,

thromboembolism, stroke, heart attacks, endocarditis or death?

363 Common Issue 3 is also a question of general causation. It directs the court to determine whether Silzone materially increases the risk of various medical complications. As there is a risk of medical complications with all mechanical heart valves, Common Issue 3 asks whether these risks are greater for patients with Silzone valves than they are for those with the conventional St. Jude valve. The parties agree that the answer to Common Issue 3 can be found in the epidemiological evidence. They disagree on (1) which epidemiological evidence is the most reliable in respect of each complication, (2) how that evidence should be analyzed, and (3) the standard the court should apply to that evidence in determining whether or not Silzone *materially increases* the risk of a particular complication - in other words, how the word "materially" should be interpreted and applied.

364 The plaintiffs adduced evidence from Dr. Madigan, a professor and chair of the Department of Statistics at Columbia University, and Dr. Sackett, a Professor Emeritus in clinical epidemiology and biostatistics at McMaster University. They also rely on the evidence of Mr. Butchart, Senior Cardiovascular Surgeon at University Hospital of Wales, and the data derived from two studies he conducted known as the Cardiff Embolic Risk Factor Study (CERFS) and the Cardiff Late Review (CLR). The defendants' main expert witness under this common issue was Dr. Wells, a biostatistician and epidemiologist, and Director of the Cardiovascular Research Methods Centre at the University of Ottawa Heart Institute. The defendants also adduced evidence from Dr. Hirsh, a Professor Emeritus in the Department of Medicine at McMaster University. All of the experts are highly qualified in their respective areas, but in many cases they took different approaches to analyzing the epidemiological evidence.

Overview of Epidemiological Evidence

365 For the definition of epidemiology, I adopt the language of Justice Osler in *Rothwell*, at para. 51:

> Epidemiology may be described as the study, control and prevention of disease with respect to the population as a whole, or to defined groups thereof, as distinguished from disease in individuals. Clinical epidemiological studies can be carried out for the purpose of investigating the relationship between a particular condition existing in the environment, or population, and a particular disease or condition of health.

366 As I discussed earlier in these reasons, there is a recognized hierarchy of epidemiological studies in the scientific literature.[89] At the top of this hierarchy is the randomized control trial or RCT. RCTs derive their substantial evidentiary value from the process of randomization whereby patients are randomly assigned to either receive or not receive a given treatment. In AVERT, for example, patients were randomly allocated to receive either a Silzone valve or a conventional valve.

367 Randomization provides the best means of balancing for known and unknown background factors in each of the groups being compared that may otherwise confound the outcome of a study. Randomization acts to equalize the prevalence of potential causal factors between groups. As such, when patients are randomized, observed differences between the two groups can more reasonably be attributed to the difference in treatment, since that is the only remaining difference, other than in outcomes, between the groups. All experts agreed that RCTs are considered to be the gold standard in comparing one treatment with another treatment in order to draw inferences about causation.

368 Below the RCT on the hierarchy of epidemiological studies is the cohort study. A cohort study is an observational study in which patients have not been randomized. Results from a cohort study are generally not accepted as evidence of causation because they do not have the benefit of randomization and, as a result, known and unknown potential causes of observed differences between groups cannot be ruled out.

369 Below the cohort study is the case series. A case series is a collection of anecdotal accounts of a particular outcome of interest in a group of patients with a given characteristic (e.g. a Silzone heart valve). A case series can address the question of what the frequency of occurrence of that outcome is in the patients in that group but it cannot on its own provide reliable evidence that the characteristic is causal of the outcome since there is no control group. Unlike a RCT, there is no corresponding group of patients that is exactly the same as the group studied except for the given characteristic.

370 The court was presented with evidence from each type of epidemiological study. AVERT is a RCT. CERFS was a cohort study. Top Accounts and CLR were case series. I will discuss the AVERT study in detail below. Because CERFS, CLR and Top Accounts only studied thromboembolism, I will discuss them in more detail when I consider that complication later in these reasons.

AVERT

371 AVERT was designed as an efficacy study to assess whether Silzone was clinically effective at reducing the incidence of prosthetic valve endocarditis, but the AVERT Protocol also made provision for collecting data on adverse events. St. Jude was the sponsor of the study. Key participants in the design of AVERT were Drs. Schaff and Carrel, the study's principal investigators; Dr. Grunkemeier, a consulting statistician; and Dr. Steckelberg, an infectious disease specialist. Drs. Schaff and Carrel were instrumental in proposing and designing AVERT as a randomized, multicentre, international study and participated in drafting the Protocol, aided by input from Drs. Grunkemeier and Steckelberg. In order for AVERT to have sufficient power to detect a 50% reduction in endocarditis in the Silzone arm of the study, Dr. Grunkemeier recommended a randomized sample size of 4400 patients.

372 Given the sheer size of the study, and as discussed in the Introduction, St. Jude determined that it would require a data coordinating center to receive reports from the various clinical centers

and maintain a database for the study. Based on recommendations from Drs. Schaff and Carrel, the University of Pittsburgh Epidemiology Data Coordinating Center (DCC) was selected for this task. The AVERT Protocol was finalized on July 17, 1998. The AVERT study was to have 17 sites - 10 in North America and 7 in Europe. Dr. Schaff was to serve as Principal Investigator in North America and Dr. Carrel was to serve as Principal Investigator in Europe. The DCC was to perform the monitoring and audit functions in North America, while Medpass International was to fulfill these functions in Europe.

373 A Data Safety Monitoring Board (DSMB) was established at the start of AVERT. The role of the DSMB was to review the AVERT data and make recommendations as to the conduct of the study having regard to the safety of enrolled patients. It was to operate independently from St. Jude and the DCC. Members of the DSMB were selected by the DCC and they included leading experts in relevant fields.

374 On January 21, 2000, the DSMB convened by conference call. Given strong evidence of a higher rate of explant in Silzone valve patients than in conventional valve patients, the DSMB recommended that enrolment in AVERT cease immediately. By that time, 807 patients were enrolled in AVERT; 403 with Silzone valves, and 404 with conventional valves. It is these patients who have been followed from the start of AVERT until present. At various points of time, a "data freeze" was conducted whereby the data up to a certain date were compiled for analysis. For example, the October 6, 1999 data freeze simply includes all data from AVERT up until that date.

375 The plaintiffs acknowledge that AVERT is a well designed efficacy study benefitting from being large, multicentered and randomized. However, they point to limitations in AVERT that, according to the plaintiffs, undermine its reliability, namely, they argue that (i) its design as an efficacy study focusing on the endpoint of endocarditis resulted in the underreporting of adverse events; (ii) inadequate data collection on TE events resulted in the underreporting of TE events; (iii) "improper" adjudication of TE events also resulted in their underreporting; and (iv) "improper" adjudication of the AVERT data on PVLs resulted in the underreporting of PVLs.

376 With respect to (ii) and (iii), above, the plaintiffs adduce these arguments to support their submission that I should consider data from CERFS and CLR in assessing the risk of thromboembolism (which I will also refer to as TE events) posed by the Silzone valve. I will deal with these arguments when I discuss thromboembolism later in these reasons. Likewise, I will deal with point (iv), above, when I discuss PVL.

377 With respect to point (i), the plaintiffs note that because AVERT is an efficacy study focused on the endpoint of endocarditis, patients whose valves are explanted are withdrawn from the study and no further events are recorded in respect of those patients. The plaintiffs argue that this is problematic because it fails to account for adverse events that occur post-explant the etiology of which may be associated either with Silzone or the risk created by explant surgeries that would not have been required but for the presence of Silzone.

378 The plaintiffs did not direct me to any expert evidence indicating that this is a legitimate concern. In fact, as I will discuss below, despite this argument of the plaintiffs, experts for both parties relied almost exclusively on the AVERT data in assessing the risks posed by Silzone, demonstrating that they view it as the most reliable data. Without support from expert testimony I cannot conclude that the plaintiffs' argument in this regard has merit.

The Experts Relied on AVERT

379 While I will consider the plaintiffs' criticisms of AVERT in more detail when I discuss specific complications later in these reasons, I note that the plaintiffs cite limitations in AVERT to direct me to use other epidemiological evidence (CERFS and CLR) in my assessment of the risk of medical complications posed by the Silzone valve. The key inquiry, then, is whether the limitations they cite sufficiently undermine the reliability of the AVERT data that other epidemiological evidence is more reliable in respect of certain complications.

380 In that vein, the best evidence before me for comparing the value of the epidemiological studies is the opinions of the expert witnesses in epidemiology and statistics. The fact that those experts, for both the defendants and the plaintiffs, relied on AVERT in assessing the risks posed by the Silzone valve demonstrates their opinion that AVERT is the most reliable data. When Dr. Sackett, the plaintiffs' expert in epidemiology, was asked if he believed AVERT was the best scientific evidence available to assess the risks and benefits of Silzone, he responded unequivocally: "absolutely". The plaintiffs' expert in statistics, Dr. Madigan, also relied only on the AVERT data.

381 Only Mr. Butchart supported the use of other epidemiological evidence - namely, CERFS and CLR - and only in assessing the risk of thromboembolism. I will discuss his evidence in more detail when I discuss thromboembolism later in these reasons.

382 Faced with the clear opinion of the expert witnesses for both parties that AVERT constitutes the most reliable data for assessing the risk of medical complications associated with the Silzone valve, I have difficulty understanding how I could come to any other conclusion.

The Nature of Epidemiological Evidence

383 As I noted above, citing Justice Osler in *Rothwell*, clinical epidemiological studies can be carried out for the purpose of investigating the relationship between a particular condition existing in the environment, or population, and a particular disease or condition of health.[90] Earlier in his reasons, at para. 49, Justice Osler noted that "[t]he design, organization and interpretation of such studies are the province of epidemiology and they involve, to some degree, the discipline or science of statistics".

384 In the present case, statistical epidemiological evidence has been presented to aid me in determining whether or not Silzone valve patients experience a higher risk of medical complications than conventional valve patients. In other words, the purpose of this evidence is to determine the

risk of medical complications posed by the Silzone valve *relative to* the risk posed by the conventional valve. This introduces the concept of *relative risk*. A relative risk (or "risk ratio" or "hazard ratio") is a numerical expression of the risk of medical complications for one class of patients relative to another. In *Rothwell*, at para. 82, Justice Osler used the following example to illustrate the concept of relative risk:

> Suppose 5% of babies born to mothers who do not smoke weigh less than the normal weights for their gestation at the time of birth, but 15% of the babies of mothers who do smoke are underweight. The relative risk of being light weight at birth for the infants of smoking mothers is 15% over 5% or 3. In other words, an infant whose mother smokes has three times the absolute risk of being underweight when born than the infant whose mother does not smoke.

385 In the present case, the simplest manner of calculating the relative risk for each complication is to divide the number of instances of that complication in the Silzone arm of AVERT by the number in the conventional arm. For example, if there were 150 instances of a complication in the Silzone arm and 100 in the conventional arm, this would yield a risk ratio of 150/100 = 1.5. A risk ratio of 1.0 for a given complication indicates that the risk of that complication is the same for both Silzone and conventional valve patients. A risk ratio of 2.0 indicates that the risk of that complication in Silzone patients is double the risk in conventional patients.

386 Performing the calculation described above will only yield an *estimate* of the relative risk for that complication. This is referred to as the *point estimate* of the relative risk for that complication. The point estimate is essentially the "best guess" of the true risk ratio. Where, as in the example above, the point estimate is 1.5, this means that the data demonstrate that there is a 50% chance that the true risk ratio is above 1.5, and a 50% chance that it is below 1.5. In other words, the point estimate is the average of the possible values of the true risk ratio.

387 While the point estimate can be useful in assessing the degree of risk facing Silzone versus conventional valve patients, more information is required to assess the reliability of the point estimate. The mere fact that a relative risk is above 1.0, indicating a higher risk facing Silzone valve patients, is insufficient to determine that Silzone valves actually do present a higher risk than conventional valves. This is because chance can never be ruled out as the causal factor driving a statistical result. In assessing the reliability of statistical results, the most important factor to consider is the likelihood that the result is the product of chance. As Justice Osler noted in *Rothwell*, at para. 66:

> The possibility that two events may coincide by pure chance and without the intervention of any necessarily causal effect can never be entirely eliminated. The effort of those who design statistical and epidemiological studies is always directed to minimizing the probability of chance and the effect that it will have upon the results of the study.

388 As Dr. Wells testified, in order to determine the likelihood that a statistical result is not simply the product of chance, scientists perform a statistical test on the study results. The test reveals the probability that the observed result is the product of chance. Dr. Wells emphasized the central importance of *statistical significance* as the threshold for determining whether a statistical result is the product of chance. If the probability that a statistical result is the product of chance is less than 5% the result is considered statistically significant, meaning chance is considered to be an unlikely explanation for the result. The importance of statistical significance was never questioned by any of the experts for either party.

389 Statistical significance can be expressed in terms of both a *confidence interval* and a *p-valu* e. The p-value represents the probability that the data are sufficient to reject a given hypothesis. For example, in AVERT, given the hypothesis that the Silzone valve and the conventional valve present the same degree of risk for a certain complication, the p-value represents the probability that this is true. In other words, it represents the probability that there is no difference in the risk faced by Silzone versus conventional valve patients. In order for a p-value to be statistically significant, it must be less than 0.05, meaning there is less than a 5% chance that the hypothesis is correct - that the Silzone and conventional valve present the same degree of risk. In other words, where the p-value is 0.05, we are 95% certain that the Silzone valve presents a greater degree of risk than the conventional valve. In terms of risk ratios, this would mean that we are 95% certain that the true risk ratio is greater than 1.0.

390 The confidence interval represents the range of values for the risk ratio within which, based on the data, a statistician can be 95% confident the true value for the risk ratio lies. For example, where the point estimate for a risk ratio is 1.5, the range for the confidence interval may span from 0.7 to 2.3. This would mean that, based on the data, one can be 95% certain that the true risk ratio lies somewhere between 0.7 and 2.3. In the present example, the lower end of the confidence interval is 0.7 and the upper end is 2.3. For the data to demonstrate a statistically significant increased risk in Silzone valve patients, the lower end of the confidence interval must be above 1.0. Thus, a statistically significant result is observed where the p-value is less than 0.05 and the lower end of the confidence interval for the risk ratio is at least 1.0.

391 As I indicated above, the importance of statistical significance in assessing the reliability of statistical results was never seriously questioned by experts for either party. Dr. Wells testified that in determining whether there is evidence of a difference (for example, between the Silzone valve and the conventional valve), "the role of statistical significance is central in this whole process". Likewise, Drs. Madigan and Sackett agreed that where the difference disclosed in a study is not statistically significant, the convention amongst scientists is to treat this as an absence of evidence of a real difference. This is consistent with Justice Osler's observation in *Rothwell* at para. 69 that, "[i]t must suffice to say, and I do not believe this assumption was challenged by any witness or by counsel, that medical and biological science has adopted what is called the 5% level of statistical significance as the criterion by which to judge the possible effects of chance".

392 Likewise, I note that the experts and counsel for both parties in this case frequently referred to statistical significance in discussing statistical results, demonstrating its central importance in assessing the reliability of those results. As I indicated in the Introduction to these reasons, I think the message of *R. v. J.-L.J.*, in which the relevance of the *Daubert* criteria was recognized by the Supreme Court, is that the court ought to assess the weight to be given to individual pieces of scientific evidence using the same methods and principles generally accepted and applied in the relevant scientific communities. It is uncontroversial to note that scientists employ statistical significance in assessing the reliability of epidemiological evidence. As such, I must do so as well.

The Limits of Epidemiological Evidence

393 Given the importance of epidemiological evidence in this case, I think it is necessary for me to articulate its limitations in determining causation. Epidemiology is the study, control and prevention of disease and other health-related outcomes in *populations*, rather than in *individuals*.

394 The Ontario Workplace Safety and Insurance Tribunal (WSIAT) has considered epidemiological evidence on many occasions, and I believe its words of caution are apposite here. In *Decision No. 1685/04*,[91] the WSIAT stated some relevant principles with respect to epidemiological evidence (the decision was related to workers who developed cancer after exposure to asbestos):

a) "Epidemiology cannot determine which particular factor caused a particular person's disease but only what factors are statistically associated with the occurrence of disease in groups of people".[92]

b) "Since epidemiology studies populations, not individuals, it cannot prove that a particular worker's cancer was caused by the studied exposure".[93]

c) The converse is also true: epidemiology cannot establish that the adverse event was *not* caused in a particular worker. "Epidemiology's usefulness in a claim relates more to issues of risk and the studies cannot prove or disprove causation in an individual case".[94]

395 As such, epidemiological evidence ought not to be considered determinative in respect of causation in individuals. For example, in the present case, where the epidemiological evidence demonstrates a statistically significant increase in the risk of a complication in Silzone valve patients, this does not mean that all Silzone valve patients who suffer the complication would not have suffered it but for Silzone. Likewise, where the epidemiological evidence does not demonstrate an increased risk of a complication in Silzone valve patients, this does not demonstrate determinatively that Silzone did not cause that complication in any individual patients. In short, epidemiological evidence is not determinative of individual causation.

The Bradford Hill Criteria

396 The defendants argue that I must determine if there is an *association* between Silzone and a given medical complication before I can determine if that association represents a *causal link*. They argue that epidemiological data, on its own, can only provide evidence of an association between a medical complication and the Silzone valve, and that the Bradford Hill criteria must be considered before a causal link can be inferred. In their submissions in respect of each complication the defendants applied the Bradford Hill criteria and, with the exception of major PVL in the first two years post implant, they argue that the criteria demonstrate that none of the statistical associations between the Silzone valve and medical complications are indicative of causal connections.

397 The Bradford Hill criteria are a series of indicia that scientists use to help determine if an association is causal. They help guide scientists in determining whether or not it makes sense to infer causality from an observed association. Dr. Wells testified that epidemiological studies can generally only demonstrate an association between an intervention and a complication, rather than a causal connection. He described the Bradford Hill criteria as a "framework in which to consider causation" that "brings up certain ideas that you should think about if you want to move from the word 'association' to the word 'causation'".

398 In my view, the defendants' submission that I *must* consider the Bradford Hill criteria before making findings of causation is not supported by the evidence. Nor, for that matter, are their submissions regarding the application of the criteria to specific medical complications.

399 The architect of the criteria, Sir Austin Bradford Hill, noted that his criteria are not "hard and fast rules of evidence that must be obeyed before we accept cause and effect",[95] and I note that the criteria have not been elevated to the status of a legal test before legal causation can be determined. In a draft policy paper from March 2005, which was referred to by the WSIAT,[96] the Workplace Safety and Insurance Board (WSIB) discussed the Bradford Hill criteria and noted that the absence of any of the criteria does not necessarily rule out a causal relationship.[97]

400 Similarly, Dr. Wells was far from adamant that I must consider the Bradford Hill criteria in order to make determinations of causation. Rather, he testified that he uses the criteria "just as things to think about". He also said that "[the Bradford Hill criteria] are often used, but as I have indicated, I like to use it more as a framework providing general guidance than as a specific course of action that you must follow".

401 In the context of interpreting the results of a RCT, Dr. Sackett also did not agree with the defendants' position that it is necessary to consider the Bradford Hill criteria. During an exchange regarding the contents of a text on evidence-based medicine authored by him, Dr. Sackett was asked about whether a section concerning the application of the Bradford Hill criteria indicates that they ought to be applied to RCTs:

> Q: And there's a section on page 155 that starts out: "Are the results of this

harm/tiology study valid?[sic]" do you see that?

A: Right.

Q: And this would apply to a variety of types of clinical studies, correct?

A: Again these would almost always be observational studies. That is, they would be the case control or cohort studies, they wouldn't be randomized trials that we'd be talking about here.

Q: Do you agree with me that you don't say, and you can take the time to read it, that you don't say in this section under "Are the results of this... study valid" anywhere that it doesn't apply to a randomized control trial?

A: It's not that it doesn't apply, it's that you wouldn't begin to apply it.

Q: But what it says -

A: I'll take your word that I didn't say it. *But what I'm saying is, if there was a randomized control trial, you wouldn't be concerned about these sorts of issues.*

...

Q: You agree that you need to look at those factors even in assessing the validity of a randomized control trial?

A: *No.* [emphasis added]

402 What I take from Dr. Sackett's testimony is that he does not agree that the Bradford Hill criteria need to be considered when interpreting a RCT. Rather, in his opinion, the Bradford Hill criteria are useful when interpreting the results of studies that are lower in the hierarchy of epidemiological evidence. I also note that counsel for the defendants' emphasized Dr. Sackett's expertise in the area of epidemiology, stating that he is "probably the most expert on the issue of epidemiological evidence" on the plaintiffs' side. Thus, in my view, the expert evidence does not

support the defendants' argument that I must consider the Bradford Hill criteria in assessing the AVERT data.

403 Further, even if I were to accept that I must apply the Bradford Hill criteria, in my view, I could not do so without the aid of expert testimony. That is, which criteria ought to be considered in interpreting the data for any given complication, as well as the weight that should be given to those criteria, are questions that can only be properly answered by a scientist with the appropriate expertise.

404 However, no expert testified as to whether and how any of the criteria ought to be applied in respect of any of the complications in question under this common issue. All I have in this regard are the defendants' bald assertions that, having regard to the criteria, none of the statistical associations in AVERT are indicative of a causal connection, except for major PVL in the first two years post implant.

405 In my view, neither I, nor counsel for the defendants, are properly qualified to assess whether and how the criteria ought to be applied in respect of any particular complication. In fact, even Dr. Wells did not consider himself properly qualified to assess whether and how to consider the criteria. Regarding the data from AVERT for death, Dr. Wells felt he was not qualified to properly consider one of the Bradford Hill criteria: biological plausibility. He stated: "I think it is not in my expertise, but it would be in someone else's expertise to say what is the biological rationale or plausibility [that Silzone causes deaths]". Given Dr. Wells' attestation that he is not qualified to apply this criterion, I do not believe I or counsel for the defendants are so qualified. Thus, in my view, the defendants' assertions for each complication regarding how I ought to apply the Bradford Hill criteria amount to nothing more than argument dressed up as evidence.

406 For these reasons, I do not believe I am bound to consider the Bradford Hill criteria. Further, even if I were so bound, there is no reliable evidence before me that could support my applying and weighing the criteria in any particular manner.

How the Epidemiological Evidence should be Analyzed

407 Having determined that AVERT, as a RCT, provides the best available evidence for assessing the relationship between the Silzone valve and medical complications, the next step is to consider the proper method of analyzing that data. While Dr. Madigan and Dr. Sackett for the plaintiffs and Dr. Wells for the defendants have all analyzed the same AVERT data, they applied different statistical methods and arrived at different findings and conclusions in providing their opinions about whether the AVERT data shows that Silzone increases the risks of particular medical complications and, if so, when those risks are present.

408 Dr. Wells performed a Kaplan-Meier/life table analysis with a log rank test of significance, using the pre-determined test of statistical significance under the AVERT Protocol, namely a p-value of 0.05 or less. Dr. Madigan used a Cox Proportional Hazards Model, a cohort analysis and

a linearized rate analysis in analyzing the AVERT data. Dr. Sackett proposed a two-part test for harm that he applied to the results of Dr. Madigan's cohort analysis ("Dr. Sackett's two-part test"). Each of these methodologies is described below.

Time-to-Event Analysis: Kaplan Meier Curves and the Cox Proportional Hazards Model

409 Time-to-event analysis refers to a method of analysis in which only the first occurrence of a particular medical complication in a patient is counted - subsequent events in the same patient are not. Once a patient experiences a complication, he or she is "censored", meaning that for the purposes of future calculations relating to that complication, he or she is excluded from the study. Patients are also censored for various other reasons such as death, loss to follow up, or explant of the valve. Two time-to-event curves (one for each treatment arm in a study), referred to as Kaplan-Meier ("KM") curves, are compared to each other in order to determine whether or not a difference exists between two study groups. KM curves, together with life tables (discussed below), are widely used in statistics and show how events/complications are occurring over time.

410 In a KM analysis, the hazard ratio provides an estimate of the comparison of how the two groups perform with respect to the outcome of interest for the full time period under analysis. Dr. Wells testified that it "expresses the relative probability that an event will occur when the two groups are compared". As an estimate only, the hazard ratio has to be considered in relation to the 95% confidence interval to determine the precision of that estimate. A numerical comparison of two KM curves is performed through a log-rank test by putting the information into a formula to generate a p-value. This is then used to determine if there is a "real", or statistically significant difference between the groups.

411 The Cox Proportional Hazards Model ("Cox model") is also a very widely used method in biostatistics that considers time-to-event rates, hazard ratios and p-values, similar to the KM approach. The Cox model, however, adjusts for influential variables in the analysis. Dr. Madigan testified that where there is evidence that variables influence the overall analysis, the Cox model is preferable to a KM analysis because it stratifies or adjusts for these variables. The variables said to be in issue in AVERT are study site and valve position - aortic or mitral. In RCTs, randomization is key since it should produce two groups that are comparable - all factors should be well-balanced in the two groups. For this reason, Dr. Wells disputed that a more complex Cox model was appropriate as any differences in patients at different sites would be accounted for by randomization. The AVERT Protocol did not contemplate using the Cox model to stratify by study site suggesting that the study organizers, who are all extremely experienced research scientists, were relying on randomization to perform this function.

412 Dr. Wells and Dr. Hirsh took issue with Dr. Madigan's analysis of events by valve position as this is a sub-group analysis that may introduce confounders and compromise the integrity of randomization. A more reliable analysis of aortic and mitral valve patients would require that these groups be randomized separately, but in AVERT patients were not randomized by valve position.

While some of the differences in the results obtained by Dr. Madigan and Dr. Wells can be explained by their choice of different statistical methods (KM versus Cox), Dr. Wells testified that he also "ran the Cox model" and found no material differences. This would be particularly so where the data did not show significant variation by either study site or valve position. In those cases, the choice of statistical method would make little difference.

413 However, for some complications the choice of statistical method does make a significant difference. In those cases, there are two main reasons for preferring Dr. Wells' choice of a KM analysis. First, the Cox model was not the *a priori* method of analysis under the AVERT protocol. As such, its use gives rise to concerns about *post hoc* significance bias, that is, bias that arises when methodology is determined after data has been generated. The KM analysis employed by Dr. Wells is consistent with the analysis selected by the AVERT investigators before any data was produced and is the only analysis that does not give rise to this concern.

414 A related, but arguably more important reason for preferring the KM method to the Cox model is that the KM analysis is the only analysis that does not forfeit the benefits of randomization. All experts agree that AVERT is the most reliable and scientifically valid data for evaluating the risks of complications associated with Silzone valves. This consensus derives from the fact that AVERT is a RCT. In my view, it follows that the most reliable method of determining whether there is an overall difference in the risk of a medical complication is an analysis of the AVERT data that preserves the initial randomization of the AVERT patients into the Silzone and non-Silzone groups.

Linearized Rates Analysis

415 A linearized rate is an overall measure of the rate of occurrence of an event within a particular group. Unlike a KM analysis or the Cox model, patients are not censored from the study once they experience a complication. It is calculated based on the total number of events occurring in the group divided by the total exposure of the group in terms of person years of follow up multiplied by 100. It is presented in percentage terms per year (i.e. 1%/year). As a result, if there is a high frequency of events in a few patients in a group, this can skew the linearized rate upwards. In other words, patients who have multiple events because of their own particular risk factors may contribute excessively to the calculated event rate. It is therefore necessary to consider the rates to be approximate only and to adjust the rates for valve related events that can occur repeatedly as both the Edmunds and Akins Guidelines recommend. The Edmunds Guidelines are designed "to facilitate the analysis and reporting of results of operations on diseased cardiac valves", while the more recent Akins Guidelines are designed "to facilitate analysis and reporting of clinical results of various therapeutic approaches to diseased heart valves such that meaningful comparisons can be made and inferences drawn from investigations of medical, surgical, and percutaneous interventional treatment of patients with valvular heart disease".[98]

416 One of the main reasons for using linearized rates is to compare results to an external

standard such as Objective Performance Criteria (OPCs).[99] Although a linearized rates analysis of the AVERT data was a method of analysis that was used by Dr. Schaff et al. in the AVERT Annals Paper, Dr. Schaff testified that this was done because those interested in heart valves are familiar with the OPC rates, but he explained that a linearized rates analysis is not necessary with a RCT such as AVERT. This is because there is already a comparator between Silzone and non-Silzone groups. Dr. Wells performed a linearized rates analysis of the AVERT data based on the September 2008 data freeze but only after the defendants were served with a report from Dr. Madigan that included such an analysis. Dr. Wells testified that this was not in his initial analysis plan. Like Dr. Schaff, he thought such an analysis was unnecessary as AVERT permits a direct comparison between the two groups.

417 In his first expert report analyzing the AVERT data, Dr. Madigan did not perform a linearized rates analysis. He acknowledged that he performed this analysis at the request of counsel only after he had produced an analysis of the AVERT data in his first report. This gives rise to concerns about *post hoc* significance bias, because the decision to conduct a linearized rates analysis was only made after the results of the initial analysis were already known. Dr. Madigan's use of a linearized rates analysis is puzzling as he admitted that he did not compare his linearized rates with the OPCs. He testified that any comparison between OPC rates and rates in the AVERT study "runs the risk of being hopelessly confounded". The plaintiffs have not compared Dr. Madigan's linearized rates with OPCs or any other external factors or trials. This raises questions about why this analysis was done and the utility, if any, it has in addressing the questions that are before the court.

418 I also have concerns about Dr. Madigan's methodology. Dr. Madigan admitted that he did not conduct his analysis in accordance with standard guidelines as he used a 90-day cut-off for early events rather than the more standard 30-day post implant cut-off that Dr. Wells used.[100] The 30 day cut-off is used in all the AVERT papers that included a linearized rates analysis as well as in the Heart Valve Guidance. It was also used by Mr. Butchart in his CERFS analysis. Dr. Wells' methodology also controls for the potentially misleading impact of multiple events in a few patients, although he presented his data in both ways. For these reasons, it is my view that Dr. Madigan's linearized rates analysis of the AVERT data is unreliable. I accept the defendants' submission that Dr. Wells' linearized rates analysis can be used as a check on his KM analysis, but a linearized rates analysis is unnecessary where there is data from a RCT and should be given much less weight.

Life Tables vs. Cohort Analysis

419 The cohort analysis as well as the KM and accompanying life tables analysis are both tendered as evidence of *when* risk is present. That is, where there is evidence that the Silzone valve increases the risk of a complication overall over the duration of the AVERT trial, either the KM or the cohort analysis can be used to determine when during the trial the increased risk was present. I will first describe each of these two methods, before discussing which I find more reliable.

420 Life Tables are presented in Dr. Wells' evidence as tabular versions of the information in the KM curves. They break down the distribution of time-to-event data into yearly intervals and are used to understand what is specifically happening within particular segments of the KM curve. While separate life tables are created for each treatment arm, Dr. Wells' evidence was that these tables are not used to compare or combine the results. Life tables are routinely used by demographers and actuaries not only as a means of determining the chances of an individual experiencing an event over a lifetime (e.g. overall number of car accidents experienced by men vs. women), but also when these events are occurring (e.g. at what age). The defendants submit that the life tables are the most reliable method for answering the questions raised in Common Issue 3 since they identify not only whether there is an increased risk in the Silzone valve group, but also when any such risk is present.

421 Dr. Madigan used a cohort analysis to analyze and compare the relative risks of complications in the Silzone and standard-valve patients in successive cohorts. A cohort analysis looks forward in time and determines the overall prospective relative risk for a given complication at the beginning of each year. Patients are censored from the study for a given complication if they experience that complication, death, or explant. The year 1 cohort for a complication consists of all patients randomized into AVERT in either the Silzone or the conventional arm of the study. The year 2 cohort for a complication consists of all study patients who did not experience that complication before the start of year 2, or who were not otherwise censored from the study due to death or explant. The events used to calculate the relative risk for the year 2 cohort are those events that occurred *after* the start of year 2. The members of each successive cohort, and the events considered, from year 3 through year 9, are determined in the same manner.

422 The KM and cohort analyses differ in what they disclose about the timing of risk. The cohort analysis attempts to show whether the relative risk of a particular event increases or abates over time. The KM analysis and accompanying life tables attempt to show when a patient is more at risk of experiencing a particular complication. In both analyses, patients are censored from the study at certain points, such as death or explant. However, as Dr. Wells testified, a KM analysis takes into account all of the AVERT data and analyzes that data as randomized. Where a patient has experienced an event or was censored from the study, data related to that patient continues to be included in the analysis - in other words, the key benefit of a RCT, namely randomization, is preserved. In contrast, with the exception of the Year 1 cohort, Dr. Madigan's analysis forfeits the benefits of randomization because the data for any particular year does not include all the patients in the AVERT trial. Data relating to those patients who had earlier experienced the complication is not included in the analysis of the rate ratios in subsequent years. As a result, data is being analyzed in subsets and there is no assurance that the Silzone and non-Silzone patients included in this subset are randomized. While the life table analysis also presents data from a KM analysis on a yearly basis, Dr. Wells did not calculate hazard ratios for individual years. Thus, unlike Dr. Madigan's cohort analysis, Dr. Wells' analysis preserves randomization, and the life tables provide a means to understand trends in the KM curves by looking at the entire spectrum of randomized data.

423 A further difficulty with the cohort analysis is that events in later years can skew the rate ratio and findings of statistical significance in earlier years. This was explained by Dr. Wells with reference to one of Dr. Madigan's slides:

> And so two things are going to come up. The first will be that if in year nine and the patient is in year nine, we find something that is quite statistically significant, which I have noted by that star, you have to remember that since year nine is also included in all the other cohorts, that the influence of that star could impact on all the other cohorts that he is going to look at. So that star, that yellow star in year nine could affect the year eight cohort; it could affect the year seven cohort, six, five, four, three, two, and even the one cohort. And an example that we have of this is death, okay, that the death reported in October 2009 in slide 78 of Dr. Madigan's, okay, and we saw this in the Kaplan-Meier curve, there was for whatever reason a big change in year nine and that big change in year nine, because the cohort, according to that yellow arrow, that particular cohort is embedded in all the others, it had the triggering effect of making all of those statistically significant. So to your eye, it may seem that something is going on all the time, but in reality, it may only be going on in the later years but impacting on the earlier years.

424 As a result, with the cohort analysis, rate ratios and findings of statistical significance change from one data freeze to another, and not only for years where new data is obtained. This is illustrated by a comparison of the findings of Dr. Madigan's analysis of "all cause mortality" for the data freezes in September 2008 and October 2009.

Freeze	Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Sept. 08	1.2	1.2	1.4	1.4	1.5*	1.6*	1.4	1.3	1.8	
Oct. 09		1.4*	1.6*	1.6*	1.8*	2.0*	1.8*	1.8*	2.6*	3.2*

*indicates a finding of statistical significance

425 As can be seen from the above chart, the relative risk of "all cause mortality" changed between data freezes and now shows a statistically significant difference in this outcome throughout the life of the study. Based on data up until September 2008 (the top row), the increased risk of mortality for Silzone patients was only statistically significant in years 4 and 5. When data from September 2008 to October 2009 is added to the analysis (the bottom row), it has the effect of making the risk ratio statistically significant for every year, despite the fact that the new data is only from year 9. A method of analysis in which data in later years can so drastically influence the calculated risk ratio for earlier years clearly provides an unreliable means for determining *when* a risk is present. In contrast, Dr. Wells' life table[101] shows that in terms of number of deaths, there are actually *more* deaths in the non-Silzone group up to the fourth year; the numbers are virtually

identical at five years; and remain close up to 8 years. Unlike with life tables, it is impossible to know from the data in the cohort analysis what the risk of mortality was in any given year. Given our knowledge that there were actually more deaths in the non-Silzone group up until year 4, the fact that the cohort analysis for the October 2009 data freeze shows a risk ratio of 1.8 with statistical significance in that year graphically illustrates the unreliability of that analysis.

426 The only expert testimony that was at all favourable to the cohort analysis came from Dr. Sackett who testified that it "made sense" to him. Dr. Madigan agreed that a cohort analysis is not recommended by the Edmunds Guidelines or Akins Guidelines or the Heart Valve Guidance. He acknowledged that he himself had not used this kind of analysis in any other study. There is no evidence that it has ever been used in the analysis of data from a prosthetic heart valve trial or in any RCT. Dr. Wells could not think of any example of either a randomized or non-randomized study where a cohort analysis had been used. For all these reasons, where the data shows an overall increased risk over the time period of the study (here, years 1 to 9 of AVERT), I find that the cohort analysis is not a scientifically reliable method of assessing *when* that risk is present within that timeframe. *When* the risk is present will be important in determining liability and damages, if any, at the individual stage of these proceedings. The most reliable evidence to assess this is Dr. Wells' KM analysis and accompanying life tables.

Dr. Sackett's Two-Part Test for Harm

427 Dr. Sackett's two-part test for harm flows out of Dr. Madigan's cohort analysis. Until closing argument, it was unclear whether the plaintiffs were relying on the two-part test as a materiality standard under Common Issue 3, that is, a standard to determine whether the Silzone valve materially increases the risk of a particular medical complication. During oral submissions, the plaintiffs clarified that they were not relying on the two-part test for this purpose, but as a methodology to assess the risk of continuing harm. In fact, plaintiffs' counsel advised the court that "Drs. Madigan and Sackett decided they needed to come up with a method to assess whether the risk that was known to exist at one point in time was continuing".

428 Dr. Sackett is an extremely distinguished epidemiologist, but his testimony was not persuasive. He admitted that the first time he proposed his two-part test for harm was during his direct examination at trial. Not only does his harm test not appear in any of his reports, but he provided no credible explanation for proposing this in his testimony, but not before. Given Dr. Madigan's admission that he had never before used a cohort analysis in any study, it appears that Dr. Sackett's two-part test and the cohort analysis to which it is linked were developed solely for the purposes of litigation and as such, must be looked at with considerable skepticism. As I have found the cohort analysis to be an unreliable methodology for determining when an increased risk is occurring, it follows that Dr. Sackett's application of his two-part test to the results of this analysis is similarly unreliable. Had I reached a different conclusion about the cohort analysis, I would nonetheless reject Dr. Sackett's two-part test for the following reasons.

429 Dr. Sackett proposed applying two criteria to the rate ratios/relative risks derived from Dr. Madigan's analysis of the AVERT data. He testified there is evidence of harm if the point estimate of the relative risk for a particular year is greater than 1.0 and the upper end of the 95% confidence interval for that relative risk is greater than 2.0. Dr. Sackett supported his choice of the two criteria on the basis that while a point estimate greater than 1.0 can indicate there "might be a problem", the choice of a doubling of the risk at the upper end of the confidence level was "a low bar" and far greater than the one-third increase in risk that he said that a clinician or a patient would accept. He testified:

> A. Well, the approach that I used was, again, in terms of confidence would be a fairly low bar, but it would be, for the sake of argument, let's say that we would call it safe if it doesn't double the occurrence of some complication that occurs only once in awhile with our current treatment. In other words, would the confidence interval include a doubling of risk when we compare Silzone patients with standard valve patients as we continue this follow-up. I would have to admit that as a clinician, usually dealing with drug situations, most clinicians wouldn't tolerate a doubling as something that we would be willing to abide, that we would be quite concerned about increases of, you know, frequently increases of say 20 or 30 percent, not a hundred percent, would be a cause for concern among clinicians that I am dealing with. But I chose the doubling as a low bar.

430 During his testimony, Dr. Sackett referred to a peer-reviewed paper co-authored by Dr. Wells as support for his two-part test, but Dr. Wells explained the many differences between the approach set out in that paper and Dr. Sackett's approach.[102] I am satisfied that to the extent Dr. Sackett was relying on the concept of minimally clinically important difference (MCID) as discussed in this paper, his reliance is misplaced. Importantly, the approach proposed in the paper is to compare the relative risk and confidence interval to the *predetermined* MCID for the study and not to the upper end of the confidence interval.

431 An MCID refers to the smallest difference in the risk of an event that would lead a treatment provider to change a patient's management. MCIDs are selected *a priori* before a clinical trial begins as part of a study's design and are specific to certain outcomes. It is clear that Dr. Sackett did not do this, and it is unclear whether Dr. Sackett intended that 1.0 or 2.0 or some other number be considered the MCID for the purposes of his analysis. He offered no direct testimony on this, but the plaintiffs' submissions assume that the MCID in Dr. Sackett's two-part test is 2.0 "based on his clinical knowledge and judgment of patient values" and that this applies equally to all of the medical complications in issue. Dr. Wells testified that he also made the assumption that Dr. Sackett was using a MCID of 2.0 as this was the only way he could make sense of this criterion. The defendants submit that the only other choice for a MCID is 1.0 because Dr. Sackett compares the point estimate relative risk to 1.0 to see if it is higher than 1.0. Dr. Wells testified that he had never seen a study where the MCID was set either *a priori* or *post hoc* at every number greater than 1.0.

432 Dr. Wells' paper describes four different possible findings on clinical importance of study results: Definite, Probable, Possible and Definitely Not. The plaintiffs rely on the apparent choice of 2.0 as the MCID in Dr. Sackett's analysis and submit that his test contemplates that "if the point estimate of the relative risk is greater than one (whether statistically significant or not) and the upper end of the confidence interval includes the MCID, the study results are consistent with Silzone patients facing clinically important risks in later years".[103] The plaintiffs overlook that under the analysis used in the paper, this only shows results indicating *possible* clinical importance. Evidence that shows a possibility of harm is inconsistent with the plaintiffs' burden to prove causation on a balance of probabilities. In Dr. Wells' paper, it is only where both the upper end of the confidence interval and the point estimate of the relative risk are above the MCID that the study results show *probable* clinical importance.

433 Dr. Sackett testified that he was concerned about the cases he described as "definite cases" of clinical significance, but under Dr. Wells' analysis, this requires that the *lower* end of the confidence interval be greater than the MCID. It is apparent that Dr. Sackett and Dr. Wells use very different definitions of "definite" clinical importance. Dr. Sackett's test would be met at its lowest threshold with a point estimate of just above 1.0 and an upper confidence interval just above 2.0, but the lower end of the confidence interval is never considered.

434 To compound the lack of clarity around this evidence, Dr. Sackett, in response to a question from the court, prepared a diagram of his approach that showed the lower end of the confidence intervals in every case to be above 1.0, indicating statistical significance.[104] He testified that even a statistically significant increased risk would not be clinically important unless the upper end of the confidence interval was above 2.0, indicating a doubling of the risk. Dr. Sackett recanted from this position in re-examination and testified that it did not matter to his approach if the lower end of the confidence interval was below 1.0. However, the diagram that he drew shows that for probable harm, the lower end of the confidence interval is above 1.0, indicating statistical significance, and the point estimate for the relative risk is above 2.0, or a doubling of the risk. This is in fact the standard that the defendants propose to determine if there is a material increase in risk.

435 Dr. Hirsh testified that it was "flawed methodology" to ignore the lower end of the confidence interval simply because a treatment has been proven harmful in the past. As he testified: "[w]hy not just look at upper and lower confidence intervals because at a different point in time, it is possible that it moves in another direction. That it's no longer significant". Dr. Sackett was unable to identify any scientific paper that used a relative risk greater than 1.0 and the upper end of the confidence interval above 2.0 to draw conclusions about harm without statistical significance. Statistical significance is the widely accepted method of analyzing study results and was used in this trial by both Dr. Wells and Dr. Madigan. There is no evidence that Dr. Sackett's two criteria have been generally accepted by epidemiologists, statisticians or other research scientists. This leads me to conclude that his two-part test for harm is not reliable, and I reject it.

Does Silzone Materially Increase the Risk of Medical Complications?

436 To determine whether Silzone materially increases the risk of medical complications, I must first identify the appropriate complications to consider. This is an area of considerable disagreement between the parties. For example, as I will discuss in more detail below, the parties disagree on whether or not all-cause mortality is a valid complication for me to consider. In addition, for many of the complications, the parties disagree on what evidence I ought to consider in making my determinations of materiality. In short, there are a number of complication-specific disagreements between the parties. I will now discuss my findings for each complication.

Paravalvular Leak (PVL)

437 The risk of PVL is associated with all prosthetic heart valves. It is not defined in either the Edmunds or Akins Guidelines and is instead listed as a sub-category of non-structural dysfunction (NSD). The Heart Valve Guidance, discussed earlier in these reasons, refers to PVL as "any evidence of leakage of blood around the prosthesis between the sewing ring and the native annulus".

438 The adverse event form in the AVERT Protocol had a box to record NSDs as adverse events, as well as a separate box to record whether the NSD was a PVL. It also included a box to note whether the PVL was "major" or "minor". However, "major" and "minor" PVL were not defined until after the recall of the Silzone valve. The proper category of PVL to analyze, including whether major and minor PVLs should be analyzed separately, is an area of contention between the parties.

439 Based on the DSMB's finding of a significant increase in the rate of PVL leading to explants, the University of Pittsburgh worked with Dr. Schaff and in 2002 adopted a working definition of major PVL as "leaks that were followed either by a repair or an explant or a death". In January 2005, this definition was modified to mean a PVL that "results in reoperation, repair, re-intervention, explant, or death". Dr. Kennard explained the reasons for adopting the new definition as follows:

> After reviewing much of the data, we realized that this [the previous working definition of "major PVL"] really wasn't covering all cases correctly and, after discussions with Dr. Schaff again, we came up with a definition that was more precise and that definition was taken to the investigators for them to vote on whether they agreed with that definition of major paravalvular leak and they did agree.

440 Once this definition was implemented, the DCC looked back at the previous data and adjudicated whether recorded PVLs met this definition. The plaintiffs argue that this process was flawed, and that Dr. Kennard and Sharon Lawlor performed inappropriate adjudications of the AVERT data that resulted in the underreporting of PVLs. I do not think it is necessary for me to go into detail discussing the plaintiffs' submissions in this regard, because, as I will explain below, I am not satisfied that any of the plaintiffs' alternative categories for PVL are reliable.

441 Because of the lack of a pre-specified definition of major PVL in the AVERT Protocol, the

changing definition after recall, and the resulting adjudications, Dr. Madigan was concerned about the validity of analyzing major PVL as an endpoint and did not do so. Rather, he counted all PVL events together, whether designated as major or minor. He analyzed PVLs using four different categories:

* "Non-Structural Dysfunction (NSD)" which included, but was not limited to PVLs
* "PVL (Echo)" which included events reported in the AVERT Echo Substudy which recorded leaks that were detected by echocardiography but not diagnosed clinically
* "PVL (AE)" which combined all PVLs diagnosed in AVERT and reported in accordance with the AVERT Protocol ("AE" stands for "adverse events")
* "PVL (AE+Echo)" which combined the PVL (Echo) and PVL (AE) categories

442 In contrast, Dr. Wells, Dr. Schaff, and the DCC each distinguished between major and minor PVLs in their analyses. The defendants argue that any bias that might arise out of the changing definition of major PVL and the subsequent adjudications is minimal and, in any event, would tend to make the Silzone valve look worse than if the definition from the Heart Valve Guidance were adopted. Dr. Schaff testified that he had no concerns about biasing the AVERT study by changing the definition of major PVL and adjudicating the data based on the new definition, stating that "the purpose was to make [the recording of events as major PVLs] more accurate". I will briefly consider each of the categories that were used to analyze PVL.

Non-Structural Dysfunction

443 In my view, non-structural dysfunction is an inappropriate category to analyze for determining the relative risk for PVL. As the defendants' experts pointed out, NSD includes a range of complications other than PVL, including many which have nothing to do with the sewing cuff and thus could not be attributed to Silzone. As a result, any determinations with respect to NSD would be unhelpful in determining whether Silzone increases the risk of PVL. When asked why AVERT analyzed PVL and not NSD, Dr. Schaff testified that "major paravalvular leak seems to be a more precise definition. If we left it in the category - if I left it in the category of non-structural dysfunction, I suppose one could wonder what is the non-structural dysfunction; it could be any one of several problems. If you leave it under paravalvular leak, you know exactly what the problem is [sic]". No expert testified that NSD is a reliable category for me to analyze.

444 Because NSD includes a range of complications, many of which are unrelated to the sewing cuff, I have determined that it is an inappropriate category to analyze.

PVL (Echo)

445 The data in this category comes from the AVERT Echo Substudy which considered PVLs that were detected only by echocardiography rather than through the recognition of clinical

symptoms. The records of these PVLs were kept in a separate database at the DCC from the PVLs that were clinically diagnosed. According to Dr. Kennard, the Echo Substudy was conducted because the DSMB recommended that an echocardiography substudy be undertaken in order to determine whether any AVERT patients who had not demonstrated clinical symptoms of paravalvular leakage nonetheless had PVLs. Of the patients who were eligible to participate in the Echo Substudy, about 85% did so. Only Dr. Madigan conducted a statistical analysis of the results from the Echo Substudy.

446 Dr. Wells had two reasons for not considering the Echo Substudy. First, as a substudy that did not include all of the AVERT patients as randomized, it does not possess the benefits of randomization. Second, he was concerned that many of the PVLs detected would not be clinically relevant. That is, they would not be PVLs that would result in a clinical diagnosis and be reported on the AVERT Adverse Effects Form. The inclusion of non-clinically diagnosed PVLs could result in the overstatement of the risk of clinical PVLs.

447 To limit the possibility that his analysis of the Echo Substudy would overstate the risk of clinical PVLs, Dr. Madigan included in the analysis only those PVLs which were designated as "moderate" or "severe". According to Mr. Butchart and Dr. Christakis, this would include only cases for which a clinical diagnosis would be likely. However, the plaintiffs adduced no direct evidence from a cardiographer that all, or even most, of the cases of PVL labelled as moderate or severe in the Echo Substudy would result in clinical symptoms. Notably, the majority of PVLs detected by echocardiography did not later progress to clinical PVLs, as evidenced by the AVERT Adverse Effects Forms.

448 In my view, the Echo Substudy is unreliable because it forfeits the benefits of randomization and because it includes PVLs that would not, and did not, result in clinical symptoms. As such, it is not useful to me in determining whether Silzone increases the risk of clinical PVLs.

PVL (AE)

449 PVL (AE) is Dr. Madigan's analysis of all clinically diagnosed PVLs in AVERT, counting major and minor PVLs together. The defendants argue that this is an inappropriate category for analysis because it will not provide meaningful information to the Court in individual trials. In support of this argument, they note that major and minor PVLs have very different consequences. They also argue that because the relative risk obtained from the PVL (AE) analysis is not specific to major or minor PVL, it is not useful in establishing causation for individuals, since individuals suffer either a major or a minor PVL, not a "PVL (AE)". In addition, as the defendants point out, the Heart Valve Guidance directs that paravalvular leaks "must be reported as major or minor". The plaintiffs argued that analyzing major and minor PVLs separately understates the risk ratios for both categories. However, no expert testified directly on this point.

450 In my view, in the absence of any expert testimony to the contrary, the fact that the Heart Valve Guidance clearly directs that major and minor PVLs be reported separately indicates that it is

inappropriate to treat them as a single complication. I am also mindful that the risk ratios derived from the PVL (AE) analysis would not be useful in determining causation in respect of individuals who suffered either a major or a minor PVL. As a result, it would be inappropriate for me to use the results of the PVL (AE) analysis in determining whether Silzone increases the risk of PVL.

PVL (AE+Echo)

451 This category simply combines the PVLs from the "AE" and "Echo" categories. I find the "AE+Echo" category to be unreliable for the same reasons I discussed above in respect of the "AE" and "Echo" categories.

Dr. Wells' Analysis of PVL

452 Dr. Wells analyzed major and minor PVL as separate complications. This approach is consistent with the Heart Valve Guidance, all other AVERT investigators save Dr. Madigan, and that of peer-reviewed publications on the AVERT study.[105] It also does not suffer the failings of the categories analyzed by Dr. Madigan, discussed above.

Major PVL

453 Based on Dr. Wells' analysis of major PVL using the October 2009 data freeze, the defendants concede that on an overall basis the point estimate for the risk ratio for major PVL is 3.03 and that the increase in the risk of major PVL in Silzone valve patients is statistically significant. Dr. Wells' log-rank test of significance found a p-value of 0.01 (where below 0.05 indicates statistical significance).[106] However, with respect to *when* the increased risk is present, the defendants argue that the life table for major PVL makes clear that it is only in the first two years. Therefore, according to the defendants it can only be said that Silzone increases the risk of major PVL for two years post implant. As Dr. Wells explained by reference to the KM curves for major PVL:

> I compared the overall experience of the 400 [patients] in each of the two groups with respect to paravalvular leak, major paravalvular leak, and I'm finding a statistical difference between the two groups.
>
> The next step is to go back and say, well, where [*when*] is that difference occurring? *And as you rightly pointed out with this changing slope in the first year or two years, that is where the major difference is between the Silzone and non-Silzone have occurred* [sic], *and after that the two curves run roughly parallel, indicating they have a very similar experience*. [emphasis added]

454 The life table from AVERT for major PVL is as follows:[107]

Number of Months post implant	Number of Events in Silzone Group	Number of Events in Non-Silzone Group
0-12	10	3
12-24	4	0
24-36	1	1
36-48	0	1
48-60	2	1
60-72	0	0
72-84	0	0
84-96	0	0
96-108	1	0
108+	0	0

455 The life table demonstrates that of the 18 instances of major PVL in the Silzone group, 14 were in the first two years. Out of six events in the non-Silzone group, three were in the first two years. Of patients who reached at least two years post implant, there were four major PVLs in Silzone valve patients and three in conventional valve patients. As Dr. Wells testified, and as is obvious from looking at the life table, the difference in the rate of major PVL in Silzone versus conventional valve patients can be almost entirely attributed to events in the first two years post implant. The defendants also cite two other studies that came to similar conclusions.[108] In my view, the evidence clearly demonstrates that it is more likely than not that Silzone causes an increase in the risk of major PVL for two years post implant, but not thereafter. I will discuss whether or not this increase constitutes a "material" increase later in these reasons.

Minor PVL

456 With respect to minor PVL, as with major PVL, the defendants concede that the AVERT data demonstrates a statistically significant increase in the risk of minor PVL for Silzone valve patients but they argue that this increased risk is only present in the first two years post implant. Using the October 2009 data freeze, on an overall basis, Dr. Wells calculated a point estimate of the risk ratio for minor PVL of 2.29, with a p-value of 0.03. As with major PVL, the life table is instructive with respect to *when* the increased risk is present. Dr. Wells' life table for minor PVL is as follows:[109]

Number of Months post implant	Number of Events in Silzone Group	Number of Events in Non-Silzone Group
0-12	10	4
12-24	4	3
24-36	2	0
36-48	0	0
48-60	1	0
60-72	2	1
72-84	0	0
84-96	0	1
96-108	0	0
108+	1	0

457 The life table demonstrates that the rate of minor PVL doesn't drop off as dramatically after two years as the rate of major PVL in Silzone valve patients. In the first two years post implant, there were 14 minor PVLs in the Silzone group and seven in the conventional group. After two years post implant there were six in the Silzone group and two in the conventional group. However, for years 3 to 6 post implant, there were five minor PVLs in the Silzone group and only one in the conventional group.

458 Unlike for major PVL, Dr. Wells did not testify directly that the increased risk for Silzone patients is only apparent in the first two years post implant. Also in contrast to major PVL, the defendants do not cite any other studies that conclude that the risk of minor PVL is higher in Silzone patients for only two years post implant. As can be seen in the life table above, for years 3 to 6 post implant, there were five minor PVLs in the Silzone group and only one in the conventional group. In my view, given this evidence, and given that on an overall basis Dr. Wells' analysis found a statistically significant increase in the risk of minor PVL, I believe it is more likely than not that Silzone increases the risk of minor PVL for *six* years, rather than only two years, post implant. The evidence does not demonstrate an increased risk for minor PVL in Silzone patients following six years post implant. I will consider whether or not this increased risk is "material" later in these reasons.

Thromboembolism (TE Events)

459 Thromboembolism is defined in the Edmunds Guidelines as "any embolic event that occurs in the absence of infection after the immediate perioperative period (when anaesthesia-induced unconsciousness is completely reversed)". An embolic event occurs when an embolus (a detached intravascular mass) lodges itself somewhere in the body, causing a blockage. This is different than a

thrombus, which is a blockage at the site of origin of the embolus. The Edmunds Guidelines definition was incorporated into the AVERT Protocol's definition of embolism and was further broken down into Neurologic Embolic Events, Peripheral Embolic Events and Myocardial Infarction (heart attack). The AVERT Adverse Effect Form contained these categories and also broke them down by severity and type of event.

460 Neurologic Embolic Events were broken down into the following categories: transient ischemic attack (TIA), which is a fully reversible neurologic event that last less than 24 hours; Reversible ischemic neurologic deficit (RIND), which is a fully reversible neurologic deficit that lasts between 24 hours and 3 weeks; and stroke, which is a neurologic deficit that lasts more than 3 weeks or causes death. Peripheral Embolic Events and myocardial infarction were both broken down by severity on the AVERT Adverse Effect Form as minor, major, or fatal.

461 As I noted earlier in these reasons, the plaintiffs, primarily on the basis of testimony from Mr. Butchart, point to limitations in AVERT that they argue undermine its reliability in assessing the risk of TE events. They argue that inadequate data collection for TE events and the "improper" adjudication of TE events resulted in their under reporting in AVERT. They also argue that because AVERT was originally designed as an efficacy study with a primary endpoint of endocarditis, it was not properly designed to assess the risk of TE events. The plaintiffs adduce these arguments to support their submission that I should also consider data from CERFS, CLR and Top Accounts in assessing the risk of TE events posed by the Silzone valve. I do not agree.

462 As I stated earlier in these reasons, despite the alleged deficiencies in AVERT that the plaintiffs point to, all of the experts in epidemiology and statistics relied only on the AVERT data in assessing the risk of complications, including TE events, associated with the Silzone valve. I find that this fact overwhelmingly demonstrates that AVERT provides the most reliable data.

463 The only expert who testified in favour of my considering CERFS, CLR and Top Accounts was Mr. Butchart, who himself conducted both CERFS and CLR. Given that Mr. Butchart was alone in this regard, and given the clear opinion of all of the other experts that AVERT provides the most reliable epidemiological data, I do not find it necessary to consider his evidence in detail. Nor do I think it is necessary to consider the deficiencies the plaintiffs' perceive in AVERT in any great detail. What follows is a synopsis of the parties' opposing arguments with respect to CERFS, CLR and Top Accounts, as well as my reasons for rejecting this evidence.

Cardiff Embolic Risk Factor Study (CERFS) and Top Accounts

464 CERFS was a study led by Mr. Butchart that commenced in 1995 at the Cardiff Hospital in Wales to investigate thromboembolic events and risk factors associated with mechanical heart valves generally. The protocol called for approximately 200 patients being enrolled over a period of two years and originally included four different valves, including the St. Jude standard bi-leaflet valve, but *not* the Silzone valve. Even though the study was coming to an end, Mr. Butchart agreed to include the Silzone valve in the study after discussions with St. Jude in late 1996. It was

originally intended that 100 Silzone patients would be enrolled in CERFS and that these patients would be included in the study consecutively rather than on a randomized basis. As with AVERT, the withdrawal of the valve from the market terminated enrolment in the study.

465 CERFS was a relatively small study of 167 patients who were implanted with St. Jude mechanical valves; 116 with conventional valves and 51 with Silzone valves. Of these patients, 65 had mitral valve replacement (mitral alone or double valve replacement), with 46 receiving non-Silzone valves and only 19 receiving Silzone valves. The study found an increased risk of major TE in these 19 mitral valve recipients.

466 Mr. Butchart endeavoured to corroborate his findings in CERFS by referring to the Top Accounts Survey, which was a case series. As I explained earlier in these reasons, case series are at the bottom of the hierarchy of epidemiological studies. Dr. Flory, for the defendants, reviewed the Top Accounts Survey to determine whether it supported Mr. Butchart's reports of higher TE events, and determined that it did not. Given the unreliability of case series in determining causation and the fact that no experts other than Mr. Butchart - including Drs. Madigan and Sackett - placed any reliance on it in assessing the Silzone valve, I place no weight on the Top Accounts Survey.

467 The plaintiffs argue that CERFS provides more reliable data than AVERT in assessing the risk of TE events associated with the Silzone valve. They note that unlike AVERT, CERFS was specifically designed to assess the risk of TE events. They also argue that patient follow up in CERFS was more thorough than in AVERT.

468 The defendants argue that the data from CERFS is unreliable for several reasons. They note that CERFS was a non-randomized cohort study with no contemporaneous control group. As such, it sits below AVERT on the hierarchy of epidemiological studies. It also involved only one hospital and a fairly small number of patients.

469 As for the results of CERFS, I note that while Mr. Butchart found a higher incidence of TE events in patients with Silzone valves in the mitral position, this was based on only 19 patients in the study who were implanted with such valves. For all TE events overall, Mr. Butchart actually found the risks between Silzone and conventional valve patients to be almost identical. Mr. Butchart's finding in mitral valve patients is inherently unreliable because it constitutes a sub-group analysis, which, as Dr. Hirsh explained, is likely to be nothing more than a chance finding. The experts in epidemiology and statistics all agreed that sub-group analyses tend to be unreliable.

470 While the plaintiffs note that CERFS, unlike AVERT, was designed to assess the risk of TE events posed by heart valves, the defendants point out that CERFS was not initially designed to consider Silzone valves at all. It was designed to assess the risk of TE events in conventional valves, not Silzone valves, and Silzone valves were only introduced into the study at the tail end of its originally planned duration.

471 The defendants also argue that CERFS is unreliable because its findings have not been

duplicated in other studies, and because Mr. Butchart used inappropriate methods to assess the data. They argue that his use of a linearized rates analysis, his comparison of Silzone complication rates to OPC rates, his use of complication rates reported in the medical literature for comparison purposes, and his failure to follow the Edmunds Guidelines in reporting complication rates from CERFS, all compromise the reliability of the data he derived from the study.

472 It is not necessary for me to delve into the minutiae of either parties' arguments regarding the reliability (or lack thereof) of CERFS. The relatively small size of the study, and the fact that it took place entirely at one hospital counsel against its reliability. In addition, the most critical factor behind my determination that CERFS is less reliable than AVERT is that all of the experts in epidemiology and statistics, for both parties, relied on AVERT in making their determinations regarding causation. No expert other than Mr. Butchart testified that I ought to consider the findings in CERFS. I take this as compelling evidence that AVERT provides more reliable data than CERFS.

Cardiff Late Review (CLR)

473 Sometime after the introduction of the Silzone valve into CERFS, the Cardiff Hospital began implanting Silzone valves in all mechanical heart valve patients. Following the recall of the Silzone valve, all patients who had been implanted with Silzone valves at the Cardiff Hospital were brought back for review by Mr. Butchart. This involved what the plaintiffs describe as a "full examination" by Mr. Butchart and his colleague Dr. Fraser of 55 Silzone patients. The majority of these patients were interviewed and examined in July, 2004. Hospital records and death certificates were also collected and examined for some patients who had died prior to the commencement of the review.

474 In my view, CLR does not provide reliable evidence upon which to base findings of causation. It was a case series, and as such sits well below AVERT in the hierarchy of epidemiological studies. Unlike AVERT, CLR was conducted without the benefit of a control group and was not randomized. The data from CLR may be sufficient to support a hypothesis, but it is not sufficient to support a finding of legal causation. Dr. Hirsh testified that CLR does not provide reliable evidence to support a causal relationship between Silzone and TE events. In addition, and most importantly, Drs. Madigan and Sackett did not rely on CLR in their analysis of the Silzone valve.

475 For all of the above reasons, I will not consider the results of CERFS, CLR or Top Accounts in assessing the risk of TE events associated with the Silzone valve.

What the AVERT Data Demonstrates Regarding the Risk of Thromboembolism

476 Based on the October 2009 data freeze, on an overall basis Dr. Wells found no statistically significant difference in the risk of any TE events in Silzone versus conventional valve patients.[110] Nor, in fact, did Dr. Madigan employing the Cox model. Thus, on an overall basis, employing time-to-first-event analyses, the data from AVERT demonstrate no statistically significant difference in the risk of TE events between Silzone and conventional valve patients.

477 The only analysis to demonstrate any statistically significant difference in the risk of TE events facing Silzone versus conventional valve patients derives from linearized rates analyses. Earlier in these reasons, I determined that Dr. Wells' linearized rates analysis is reliable as a check on the findings of his KM analysis, but that Dr. Madigan's linearized rates analysis is unreliable. Dr. Wells only found a statistically significant difference in the risk of TE events in the Silzone versus the conventional valve for patients with valves in the mitral position, and only when he included outliers - that is, patients who experienced four or more events. When patients in the Silzone group who experienced four or more events are excluded, his finding loses statistical significance.

478 As both Dr. Wells and Dr. Hirsh testified, analyzing data in sub-groups, such as by valve position, is problematic. As Dr. Hirsh testified:

> A. ... Now, there is a statistical axiom that if the overall results were are [sic] not statistically significant, if you find a sub-group that is statistically significant... you've got to look at that with a great deal of circumspect because it means that there is another sub-group where the results goes in another direction [sic].
> Q. Just stopping there for a minute, which is then more important, the overall data or the sub-group data?
>
> A. Well, the overall data is the important data.

479 Thus, Dr. Wells' finding of an increased risk of TE events in patients with mitral valves is unreliable as it is a sub-group analysis. In fact, Dr. Wells himself testified that this analysis is unreliable and explained that he only analyzed the data by valve position in order to respond to Mr. Butchart's analysis, which distinguished between aortic and mitral valve recipients. As indicated above, the overall data, which Dr. Hirsh testified is the most important, demonstrate no statistically significant difference in the risk of TE events facing Silzone versus conventional valve patients.

480 Further, as Dr. Hirsh testified, because there was no randomization by valve position in AVERT, a sub-group analysis of the AVERT data by valve position is less reliable than the analysis of all positions together, because it is subject to confounding in a way that an analysis of the complete set of data - which maintains the benefits of randomization - is not.

481 I find that the most reliable data with respect to TE events is Dr. Wells' KM analysis of the overall data from AVERT. As I stated above, Dr. Wells did not find a statistically significant difference in the risk of TE events facing Silzone versus conventional valve patients. The following table summarizes his overall findings, as of the October 2009 datafreeze, for TE events using the KM analysis:[111]

Complication	Number of Events in Non-Silzone Group	Number of Events in Silzone Group	P-value (<0.05 = statistically significant)	Risk Ratio: point estimate (95% confidence interval)
Thromboembolism	49	51	0.73	1.07 (0.77, 1.49)
Embolic Event - Stroke	14	18	0.41	1.34 (0.67, 2.69)
Embolic Event - RIND	7	11	0.31	1.62 (0.63, 4.18)
Embolic Event – Transient Ischemic Event	24	26	0.74	1.10 (0.63, 1.91)
Embolic Event – Myocardial Infarction	2	6	0.12	3.27 (0.66, 16.25)

482 I find that there is no reliable evidence demonstrating a statistically significant increased risk of TE events in Silzone versus conventional valve patients.

Bleeding

483 Bleeding is defined in both the Akins and Edmunds Guidelines as "any episode of major internal or external bleeding that causes death, hospitalization, or permanent injury (e.g. vision loss) or necessitates transfusion". All mechanical heart valves require anticoagulation drugs to counter the thrombogenic potential of the housing and leaflets on the valve.[112] The thinner a patient's blood, the more likely the patient is to experience a bleeding event.

484 The defendants argue that bleeding is not a meaningful endpoint to analyze because it was tracked without any analysis regarding whether each event was "valve related". They argue that without an analysis of valve relatedness, the category is not useful because it does not support a finding that observed differences between the Silzone and conventional groups are due to the presence of Silzone.

485 In my view, the defendants' argument in this regard is not supported by the evidence. Both the Akins and Edmunds Guidelines require the collection and analysis of data on bleeding events without any mechanism to track whether such events are valve related. In addition, with a RCT like AVERT, there is no need to track events for valve relatedness because the whole objective of randomization is to ensure that observed differences between the two groups can be properly attributed to the fact that one group has Silzone valves while the other has conventional valves. No expert testified in support of the defendants' argument in this regard and I do not accept it.

486 Nonetheless, the more significant fact is the fact that Dr. Wells' KM analysis found no statistically significant difference between the Silzone and conventional groups in terms of bleeding events. Dr. Wells' point estimate for the risk ratio was 1.35, with a p-value of 0.1. As discussed earlier in these reasons, a p-value above 0.05 indicates a lack of statistical significance.

487 The only analysis that found a statistically significant difference in the rate of bleeding events between the two groups was Dr. Madigan's Cox model analysis. However, for the reasons I

discussed, Dr. Madigan's Cox model is less reliable than Dr. Wells' KM analysis. Where their results diverge, I prefer the analysis of Dr. Wells. I also note that Dr. Madigan's finding only barely reaches statistical significance, with a p-value of 0.04 and a confidence interval of 1.02 to 2.14.

488 In the result, I find that there is no reliable evidence indicating a statistically significant difference in the rate of bleeding events between the Silzone and conventional valves.

Valve Thrombosis

489 As I noted at the beginning of my discussion of TE events, above, valve thrombosis differs from TE events in that the former occurs on or near the operated valve whereas the latter occurs elsewhere in the body when a mass breaks away and travels through the bloodstream, eventually causing a blockage.

490 Valve thrombosis is defined under the Edmunds Guidelines as "any thrombus, in the absence of infection, attached to or near an operated valve that occludes part of the blood flow path or that interferes with the function of the valve". This was the definition used in the AVERT Protocol. The plaintiffs argue that the AVERT investigators ought to have used the broader definition of valve thrombosis set out in the Akins Guidelines, and that the choice of the Edmunds Guidelines resulted in the underreporting of valve thrombosis. However, no expert testified that this is the case, and, in any event, I accept the defendants' argument that even if the choice of the Edmunds Guidelines definition resulted in underreporting, this would have affected both arms of the study equally due to the effect of randomization.

491 As of the October 2009 data freeze, Dr. Wells calculated a point estimate for the risk ratio for valve thrombosis at 3.03, with a p-value of 0.31, indicating a lack of statistical significance. Notably, although the point estimate is high, the lack of statistical significance is a result of the fact that only 4 valve thrombosis events were recorded in AVERT; three in Silzone valve patients and one in a conventional valve patient. Both Dr. Madigan and Dr. Wells testified that with so few events any statistical analysis is virtually meaningless. Both also agreed that there was no evidence of a statistically significant difference between the groups in terms of the rate of valve thrombosis.

492 In my view, there is no reliable evidence of a difference in the risk of valve thrombosis in Silzone versus conventional valve patients.

TEB

493 TEB is not a complication unto itself. Rather, it is a composite endpoint consisting of the last three complications considered above: thromboembolism, bleeding, and valve thrombosis. The defendants argue that for this reason TEB is not a meaningful endpoint for analysis. This is because even if I found that Silzone materially increases the risk of TEB, an individual bringing and individual claim would still need to demonstrate that they suffered one of the constituent complications in order to prove causation. For similar reasons, TEB was not an *a priori*

complication for analysis under the AVERT Protocol. Rather, each of these three complications was analyzed separately.

494 While it is not recognized by the Edmunds Guidelines, TEB first appeared in the Akins Guidelines in 2008. The plaintiffs note that Mr. Butchart, among others, has been advocating for the analysis of TEB as an endpoint because "thromboembolism and thrombus are part of the same complex, and the risk of bleeding is increased by the medical treatment of this complex".

495 While the plaintiffs assert that TEB is a meaningful endpoint for analysis, they do not explain why. In their argument, the plaintiffs simply explain what TEB is, why it has developed as a newly recognized endpoint, and what the AVERT data shows. In my view, the reason TEB is suggested as an endpoint in the Akins Guidelines is to look at the combined hazards of thrombogenicity and anticoagulation and how they interact. TEB is not suggested as a useful endpoint for assessing the safety of a prosthetic heart valve. Indeed, other than repeating the general reasons for analyzing TEB as reflected in the Akins Guidelines, Mr. Butchart and Dr. Christakis provided no additional justification for analyzing TEB in the context of AVERT. As Dr. Hirsh testified, analyzing TEB as a category may be useful for comparing the efficacy or safety of anticoagulation drugs, but not for assessing the difference in the risks associated with Silzone versus conventional valves. Indeed, Dr. Hirsh "objected" to the plaintiffs' analysis.

496 In the circumstances of AVERT, Dr. Hirsh's opinion was that there is no good reason to consider TEB as an endpoint. Similarly, Dr. Wells was of the opinion that an analysis of TEB was not useful for comparing the risks between the two valves. Dr. Wells was also concerned that analyzing TEB would introduce the risk of double-counting a finding of significance. For example, the risk ratio for TEB could reach statistical significance even where none of the risk ratios for the three constituent complications is statistically significant. If such were the case, a patient who suffered one of the constituent complications, for which statistical significance was not found, would be deemed to have suffered TEB, for which statistical significance was found. As such, the patient would erroneously be deemed to have suffered a complication for which statistical significance was not found. In the opinions of Dr. Wells and Dr. Hirsh, this demonstrates that TEB is not a useful endpoint for assessing the risk of complications.

497 In my view, TEB is not an appropriate endpoint for me to consider. Dr. Wells and Dr. Hirsh clearly explained that TEB is useful for assessing the efficacy and safety of anticoagulation drugs, and not for assessing the risks associated with a prosthetic heart valve. Meanwhile, neither Mr. Butchart nor any other expert explained why TEB ought to be used as an endpoint. Rather, the only explanations given were the reasons for including TEB in the Akins Guidelines, which, as described above, only relate to assessing the impact of anticoagulation drugs and not to the efficacy of TEB in assessing the risk of a prosthetic heart valve.

498 For all of the above reasons, I find that TEB is an inappropriate complication for me to consider under this common issue.

Death

499 "Total deaths" is defined in the Edmunds Guidelines as "all deaths due to any cause after a valve operation". Those guidelines also define three subcategories: valve related mortality, sudden unexpected unexplained death, and cardiac death. The Akins Guidelines define "all-cause-mortality" as including "all deaths from any cause after a valve intervention". When deaths occurred in AVERT, the AVERT Adverse Effects Form directed that the cause of death be stipulated as "valve related", "other cardiac related", "other cause", or "unknown".

500 The defendants argue that I should consider only the "valve related" category because it is the only category that can tell me whether a death can be properly attributed to the Silzone valve. The plaintiffs argue that I should consider only the broader category of "all-cause-mortality". I agree with the plaintiffs. In my view, the plaintiffs' position better accords with the expert testimony at trial.

501 Both Drs. Madigan and Sackett testified that randomization in AVERT should equalize the influence of confounding variables between the two groups. I agree with this assessment. As I stated earlier in these reasons, a primary purpose of randomization is to ensure that observed differences in outcomes between the two groups (such as a difference in the rate of death) can be properly attributed to the difference in treatment between the two groups (one group has Silzone valves and the other has conventional valves). Dr. Sackett added that, in his opinion, all-cause-mortality is a more reliable category for analysis than the subcategories on the AVERT Adverse Effects Form because problems relating to data collection and reporting led to a disproportionate number of the deaths in AVERT being labelled as cause "unknown". In addition, Dr. Schaff testified that deaths that resulted from coronary embolism, cerebral bleed or stroke should be categorized as valve related under the Edmunds Guidelines. However, the listing of deaths prepared by Dr. Kennard and the DCC lists as non-valve related deaths that resulted from these very conditions. Thus, any analysis of deaths adjudicated as "valve related" is unreliable and likely underestimates the impact of the Silzone valve.

502 The defendants submit that all-cause mortality is not a meaningful category because death can result from many causes that are unrelated to the Silzone valve. The defendants acknowledge that randomization can be expected to equalize the impact of confounding factors, but they argue that it cannot be expected to equalize for the "virtually unlimited" causes of death that may have arisen since the beginning of the AVERT trial. No expert testified in support of the defendants' position in this regard. The defendants also argue that the DSMB's request that the DCC investigate the causes of death after year 8 demonstrates their view that all-cause-mortality provides inadequate information. I do not agree. The reason the DSMB requested more information on the deaths that occurred after year 8 was because there was a substantial increase in the rate of death in the Silzone group after year 8. Their intention to investigate further was quite reasonable in the circumstances, but it does not demonstrate that all-cause-mortality is an unreliable category for analysis. Dr. Wells testified that, like the DSMB, he would like more information about the causes of the deaths after

year 8, but he did not testify that he thought all-cause-mortality was an unreliable category for analysis.

503 In my view, all-cause-mortality is the most reliable category of death to consider. Drs. Madigan and Sackett testified directly on this point, and no expert contradicted their opinion. I am also concerned that, for the reasons detailed above, the "valve related" category of death underreports the true rate of deaths that can be attributed to the Silzone valve.

504 Both Dr. Wells and Dr. Madigan performed statistical calculations to obtain risk ratios for all-cause-mortality on an overall basis using the October 2009 data freeze. Dr. Wells calculated a point estimate for the risk ratio of 1.33, with a p-value of 0.047 and a confidence interval of 1.01 to 1.75, indicating statistical significance. Dr. Madigan calculated a point estimate of 1.36, also with statistical significance.

505 The striking characteristic of the data related to all-cause-mortality, however, is the dramatic increase in events in the two years prior to the October 2009 data freeze (more than 8 years post implant). Following is the life table for all-cause-mortality:

Number of Months post implant	Number of Events in Non-Silzone Group	Number of Events in Silzone Group
0-12	28	22
12-24	5	7
24-36	7	4
36-48	10	10
48-60	6	15
60-72	6	11
72-84	11	7
84-96	7	10
96-108	5	17
108+	4	11

506 For the first eight years post implant, there were eighty events in the non-Silzone group and eighty-six in the Silzone group. In years 9 and 10, there were only nine events in the non-Silzone group versus twenty-eight in the Silzone group. It is clear that both Dr. Madigan's and Dr. Wells' findings of a statistically significant increase in the risk of death in Silzone patients are almost entirely attributable to the data from years 9 and 10.

507 In my view, the data demonstrates that Silzone does not increase the risk of death for the first

eight years post implant.

508 The life table provides powerful evidence that Silzone does, in fact, cause an increase in the risk of death in Silzone patients beyond 8 years post implant. However, both Dr. Wells and Dr. Madigan testified that the statistical analysis of a study becomes less certain and can be less reliable later in the life of a study. This was one of the reasons Dr. Wells would have liked to see more clinical information about the causes of death in Silzone patients who died more than 8 years post implant.

509 Dr. Wells performed "conditional probability" calculations for each year of data for all-cause-mortality. The conditional probability, in the present case, is the likelihood that a patient will die in a given year. For year 9, a non-Silzone patient who began the year had a 2.39% chance of dying that year (with a confidence interval of 0.87 to 5.62), whereas a Silzone patient had an 8.65% chance (with a confidence interval of 5.39 to 13.49). The available data from 9 years post implant and beyond indicates that non-Silzone patients had a 4.3% chance of death (1.34 to 10.89), and Silzone patients had a 13.02% chance (7.26 to 21.99).[113]

510 The above data are indicative of an increased risk of death in Silzone patients in years 9 and beyond, but they do not demonstrate a statistically significant difference between the two groups. This is because the confidence intervals overlap. For year 9, the lower end of the confidence interval for Silzone patients is 5.39, while the upper end for non-Silzone patients is higher, at 5.62. For year 10 and beyond, the overlap is even larger, with an upper end in the non-Silzone group of 10.89 and a lower end in the Silzone group of 7.26. The overlapping confidence intervals demonstrate a lack of statistical significance, meaning there is an absence of evidence of a difference between the Silzone and conventional valves. In addition, as the experts testified, the wide confidence intervals are indicative of a great deal of uncertainty.

511 In year 9 post implant and beyond, given the level of uncertainty and the lack of statistical significance in the data demonstrating an increased risk of death in those years, I am not satisfied that the data, by itself, demonstrates that Silzone increases the risk of death.

Explants

512 Common Issue 3 asks whether Silzone increases the risk of *medical complications*. St. Jude argues that explants are not medical complications, but rather are a symptom that results from medical complications. However, the DCC and the AVERT investigators did use "explants for any reason" as an endpoint for analysis. Dr. Madigan also analyzed "explants for any reason". Dr. Wells, on the other hand analyzed the endpoint "explants except those occurring as a result of PVL". He testified that counting all explants would result in the double-counting of explants that were already counted in the major PVL category, which includes PVLs that result in explants.

513 I note that the reason the Silzone valve was withdrawn from the market was an increased rate of explants *due to PVL* in the Silzone arm of AVERT. This supports the defendants' argument that

explants are not a medical complication, but rather the symptom of a medical complication - in this case a symptom, or consequence, of PVL. It also supports Dr. Wells' position that counting all explants in a separate category will double-count patients whose valves were explanted due to a major PVL.

514 The validity of Dr. Wells' concern, in fact, is graphically illustrated by the life table for "explants for any cause". In the first two years post implant, there were 19 explants in the Silzone arm of AVERT and only 2 in the conventional arm.[114] After two years post implant, as of the October 2009 data freeze, there were 6 explants in the Silzone group and 5 in the conventional group. It is clear that if Silzone does increase the risk of explants, it only does so for two years post implant. However, as Dr. Wells testified, most of the explants in the Silzone group in the first two years were the result of major PVLs.

515 I have already found that Silzone increases the risk of major PVL for two years post implant. And I agree with Dr. Wells' concern that it would not be sensible to conclude from the data that Silzone increases the risk of explants as a distinct complication. Rather, all that can be concluded is that Silzone increases the risk of major PVL, which correspondingly resulted in more explants in the Silzone group.

516 In order to analyze explants as a distinct complication, one would have to consider explants other than those occurring as a result of PVL, as Dr. Wells did. Dr. Wells found that the risk ratio for this category was 1.78, with a p-value of 0.35, indicating a lack of statistical significance and a high degree of uncertainty. In my view, the data does not demonstrate that Silzone increases the risk of explants as a distinct complication. What the data does demonstrate is that Silzone increases the risk of major PVLs in the first two years post implant, many of which lead to explants.

Reoperation

517 As with explants, the defendants argue that reoperation is not a valid endpoint to analyze because it is a symptom of a medical complication, rather than a complication itself. The defendants also point out that the Heart Valve Guidance refers to reoperation as a "*consequence* of a morbid event", rather than a morbid event itself. For this reason, Dr. Wells performed no statistical analyses of reoperation in AVERT.

518 The DCC, using a KM analysis, and Dr. Madigan, using a linearized rates analysis, both analyzed reoperation as an endpoint and found a statistically significant increased risk in Silzone patients. However, in my view, it is abundantly clear from the life table for reoperation, that, as with explants, the difference is almost entirely due to major PVLs which required reoperation (it bears noting that to explant a heart valve requires, by definition, a reoperation). In the first two years post implant, there were 24 reoperations in Silzone patients and 4 in conventional patients. After two years post implant, there were 7 in Silzone patients and 8 in conventional patients. This is precisely the pattern observed in the life tables for major PVL and explants. As I stated above in considering explants, I have already found that Silzone increases the risk of major PVL in the first two years

post implant. In my view, no other distinct conclusions can be drawn from the fact that most of these major PVLs resulted in explants and/or reoperation. Thus, the data do not demonstrate that Silzone increases the risk of reoperation as a distinct event.

Endocarditis

519 None of the statistical evidence indicates an increased risk of endocarditis in Silzone valve patients and the plaintiffs concede that no such increase exists. As such, I find that Silzone does not increase the risk of endocarditis.

The Meaning of "Materially"

520 The legal test that is set out in Justice Cullity's certification decision is whether Silzone "materially" increases the risk of medical complications above the level observed in conventional valves. At paragraph 62 of his decision, Justice Cullity said:

> I believe the revised common issues produced at the hearing of the motion can be reduced slightly in number without affecting their content. I would also make a few changes in the wording. *The most important of these would be to substitute, in what would become issue #3, a reference to a material increase in the risk of complications for the existing words that might be considered to address even the remotest possibility of causation.* [emphasis added]

521 The parties agree that the word "materially" modifies the word "increase" in Justice Cullity's formulation of Common Issue 3 - they agree that an increase is only legally significant under this common issue if it can be deemed "material". However, the parties disagree on how the word "materially" should be interpreted, or, in other words, what constitutes an increase that can be deemed "material". As I will discuss below, the parties' disagreement stems largely from their divergent interpretations of Justice Cullity's intentions in inserting the word "materially" into Common Issue 3.

522 The plaintiffs argue that I ought to deem an increase in the risk for a given complication "material" where the risk for Silzone valve patients is at least one and one third times the risk for conventional valve patients. The defendants argue that an increase should only be deemed material where the risk for Silzone valve patients is double the risk for conventional valve patients. In other words, the plaintiffs argue that for a complication to be material, the point estimate for the risk ratio must be at least 1.33, whereas the defendants argue that it must be at least 2.0.

The Plaintiffs' One and One Third Standard for Materiality

523 The plaintiffs support their proposed standard by arguing that the significance of an increase in the risk of a complication from the perspective of a clinician should bear on my determination in this regard. They cite the concept of the "minimal clinically important difference" (MCID), which I

described earlier when discussing Dr. Sackett's two-part test for harm. An MCID refers to the smallest difference in the risk of an event that would lead a treatment provider to change a patient's management. As the plaintiffs note, it makes sense that clinicians attribute MCIDs to complications in a manner that reflects the nature or seriousness of each complication. That is, the more severe the complication, the lower the risk of that complication needs to be in order for that risk to be deemed "clinically important". For example, the MCID would be lower for heart attacks than for headaches because heart attacks are more severe.

524 The plaintiffs cite case law that uses the concept of MCIDs to aid in determining whether certain risks must be disclosed to a patient. For example, they cite informed consent case law, such as *Hopp v. Lepp*,[115] for the proposition that a risk which is a mere possibility is material if its occurrence carries serious consequences. The plaintiffs note that such risks must be disclosed to the patient.

525 In my view, the plaintiffs' one and one third standard is not supported by the evidence, but rather is based only on one offhand comment by Dr. Sackett that an increase of 1/3 would be of concern to physicians or patients. Neither Dr. Sackett nor any other expert gave evidence that the fact that a given degree of risk may concern physicians means that degree of risk is "material" for the purposes of determining this common issue. There is no evidence from Dr. Sackett that a matter of concern to physicians is equivalent to a material increase in risk. In addition, Dr. Sackett conceded that the degree of risk that would be of concern to physicians would depend on the severity of the complication at issue, yet the plaintiffs led no evidence regarding the relative severity of the complications at issue in this case. Thus, in my view, the concept of MCIDs and the informed consent case law cited by the plaintiffs is not relevant to my determination of general causation.

526 I also note that the plaintiffs did not propose the one and one third standard for materiality until they filed reply submissions, after they saw that the defendants had proposed a standard for materiality - a doubling of the risk standard - in their closing submissions. In my view, if the plaintiffs truly believe that this is the proper standard of materiality, they ought to have presented evidence of this at trial. The circumstances under which the plaintiffs proposed the one and one third standard give rise to serious concerns of reliability. It is apparent that not only was the test adapted by counsel from one comment made by Dr. Sackett, but this was done late, after the evidence was concluded, and only in reply submissions.

527 In attributing significance to MCIDs, the plaintiffs conflate Justice Cullity's use of the word "material" in Common Issue 3 with notions of clinical significance by reference to informed consent case law. In the context of this case, "material increase" does not equal "clinically significant". As the plaintiffs acknowledge, the word "material" in Common Issue 3 modifies the word "increase". Common Issue 3 queries whether the *increase in the risk* of a complication is material, not whether the complication itself is material having regard to its severity. I do not agree with the plaintiffs' submission that the word "materially" in Common Issue 3 ought to be interpreted by reference to

MCIDs, the basis for Dr. Sackett's casual reference to a one and one third increase in risk.

528 The true nature of Justice Cullity's use of the word "material" in Common Issue 3 can be understood by considering his reasons for inserting it. Justice Cullity was concerned that the previous language in Common Issue 3 ("can cause or contribute to") "might [have been] considered to address even the remotest possibility of causation". Justice Cullity did not have in mind the severity of complications when he inserted the word "material". Rather, he intended to ensure that findings with respect to whether Silzone increases the risk of complications would be sufficiently meaningful that they would be indicative of something more than a remote possibility of causation.

529 I find that the plaintiffs' one and one third standard for materiality is not supported by the evidence and derives from considerations that do not bear on questions of causation. I therefore reject it as the standard for materiality under this common issue. The only other standard proposed is the defendants' doubling of the risk standard.

The Defendants' Doubling of the Risk Standard for Materiality

530 The defendants argue that a risk ratio of 2.0 should be adopted as the standard for materiality under this common issue. As I will now explain, the defendants' argument in this regard flows from the nature of the "but for" test, and requires an understanding of some arithmetic (something the reader should find effortless after this painful journey through the statistical evidence).

531 The defendants note that at the individual stage of these proceedings each class member will have the onus of proving on a balance of probabilities that but for the presence of Silzone on his/her heart valve, the complication that was suffered would not have occurred.[116] They further note that there exists a "background rate" for each complication at issue in this trial. That is, all of the complications at issue occur with conventional valves as well as with Silzone valves. The "background rate" for a complication is the risk of that complication associated with the conventional valve. In order for class members to prove individual causation, they must prove that they would not have suffered the complication if they had been implanted with a conventional valve - that their complication was not an occurrence associated with the background rate. This is simply a logical extension of the application of the "but for" test to the Silzone valve.

532 I will briefly explain the arithmetic behind the defendants' argument that I should adopt a risk ratio of 2.0 as the standard of materiality under this common issue. I will start with an example for illustrative purposes. A risk ratio of 1.6, for example, would indicate that the rate of occurrence of a complication for the Silzone valve is 1.6 times the rate for the conventional valve. Given two groups of patients of equal size - one with Silzone valves and one with conventional valves - if 100 patients in the conventional group suffered the complication then 160 in the Silzone group would suffer the complication. In this scenario, using the "but for" test, Silzone could be said to have caused the complication in 60 out of the 160 patients who experienced the complication in the Silzone group. The other 100 patients would have been expected to suffer the complication despite the Silzone valve, because we know that 100 patients in the conventional group suffered the

complication. In other words, the background rate would result in 100 patients suffering the complication, so for 100 of the 160 Silzone patients who suffered the complication, the complication would be attributable to the background rate, and not to Silzone. As such, for those 100 patients in the Silzone group, one could not say that Silzone was a "but for" cause of their complications.

533 This scenario presents a conundrum in determining causation in each individual case in the Silzone group. If Silzone can be said to have caused only 60 of the 160 complications in the Silzone group, then, in the absence of any other evidence, for each of those 160 individuals it can only be said that there is a 37.5% probability that Silzone caused the complication in their particular case (60/160 = 37.5%). Since this is below 50%, it cannot be said that, on a balance of probabilities, Silzone caused the complication in *any* of the 160 instances. So while in this scenario it is apparent that Silzone increases the risk of the complication, it cannot be said on a balance of probabilities that it caused the complication in any given patient.

534 The defendants note that this problem is solved when the risk ratio is greater than 2.0. For example, in the above scenario, if the Silzone group had experienced 201 complications (a risk ratio of 2.01), then 101 out of those 201 patients would not have suffered the complication "but for" the presence of Silzone on their valves. Thus, the likelihood that Silzone caused the complication in any one of those patients would be 101/201 = 50.2%. So on these facts, *all* of the 201 patients would be able to demonstrate that Silzone caused their complication on a balance of probabilities.

535 A peculiar outcome would result from the strict application of the concept described above. If no other evidence was considered other than the risk ratio, then in the former scenario none of the 60 patients who would not have suffered the complication but for the presence of Silzone on their heart valve would be able to demonstrate causation in their particular case. On the other hand, in the latter scenario, *all* of the 201 patients would be able to do so despite the fact that Silzone was a "but for" cause of the complication in only 101 of them. The problematic nature of this outcome is recognized in the U.S. Federal Judicial Center's *Reference Manual on Scientific Evidence*:[117]

> The use of probabilities in excess of .50 [which corresponds to a risk ratio of 2.0] to support a verdict results in an all-or-nothing approach to damages that some commentators have criticized. The criticism reflects the fact that defendants responsible for toxic agents with a relative risk just above 2.0 may be required to pay damages not only for the disease that their agents caused, but also for all instances of the disease. Similarly, those defendants whose agents increase the risk of disease by less than a doubling may not be required to pay damages for any of the disease that their agents caused.

536 Nevertheless, the defendants argue that a risk ratio of 2.0 should be adopted as the standard for materiality under Common Issue 3. The parties agreed that it was necessary to establish a materiality standard for the purposes of causation, but I was presented with only two alternatives. I

have explained why I have rejected the plaintiffs' one and one third standard. A doubling of the risk standard is an approach that is used by the WSIAT and in American courts to demonstrate causation. Also, unlike the plaintiffs' one and one third standard, I believe it accords with Justice Cullity's intention in revising Common Issue 3.

537 As I stated above, by inserting the word "materially" Justice Cullity intended to ensure that findings with respect to whether Silzone increases the risk of complications would be sufficiently meaningful that they would be indicative of something more than a remote possibility of causation. The defendants' standard achieves this objective. As the discussion above demonstrates, whether a risk ratio for a complication is above or below 2.0, in the absence of any other evidence, is determinative of whether it is more likely than not that an occurrence of that complication in an individual can be attributed to the Silzone valve. Thus, the defendants' standard satisfies Justice Cullity's intention that the word "materially" should increase the probability that a finding of an increased risk may actually translate into a finding of causation.

538 I therefore adopt the defendants' doubling of the risk standard as the standard for materiality under this common issue. However, as I will detail below, I disagree with the defendants' position in terms of how this standard ought to be applied.

The Proper Application of the Doubling of the Risk Standard (A Presumptive Threshold, Rather than a Prescriptive one)

539 The defendants argue that patients who suffered complications for which the risk ratio is below 2.0 should not be able to proceed to the individual stage of these proceedings on the basis that the increase in the risk of the complication they suffered is not material. However, for patients who suffered complications for which the risk ratio is above 2.0, the defendants seek to retain the right to rebut the finding of causation that would result from a strict application of the arithmetic detailed above. That is, in the example where 201 patients suffer a complication in the Silzone group, the defendants seek to retain the right to argue that any particular claimant out of the 201 potential claimants would not have suffered the complication but for Silzone; in other words, that the claimant was amongst the 100 patients who would have suffered the complication anyway as part of the background rate. Presumably, the defendants would need to adduce probative evidence other than the epidemiological evidence in order to do this.

540 The defendants' arguments in this regard are contradictory. On the one hand, they seek to retain the right to rebut individual causation where the risk ratio is above 2.0. But on the other hand, they argue that class members who suffered from complications for which the risk ratio is below 2.0 should be barred from proceeding to the individual stage of these proceedings; meaning they would be barred from having the opportunity to adduce evidence to rebut the negative finding of causation that would arise having regard only to the epidemiological evidence.

541 However, in seeking to retain the right to rebut individual causation where the risk ratio is greater than 2.0, the defendants implicitly acknowledge that probative individualized evidence

could be adduced at the individual stage of these proceedings. By "individualized evidence", I mean evidence that pertains only to an individual class member, rather than to the class as a whole. Individualized evidence is evidence of causation that is specific to an individual. This contrasts with evidence of general causation, such as the epidemiological evidence from AVERT.

542 If, at the individual stage of these proceedings, probative individualized evidence could be adduced to rebut the positive finding of causation that would result having regard only to the epidemiological evidence where the risk ratio is greater than 2.0, then in follows that the reverse must also be true: probative individualized evidence could also be adduced to rebut the negative finding of causation that would result where the risk ratio is below 2.0. This being the case, it would be unreasonable to bar class members from proceeding to the individual stage of these proceedings on the basis that the risk ratio for the complication they suffered is below 2.0.

543 To support their argument that class members who suffered from complications for which the risk ratio is below 2.0 ought to be barred from proceeding to the individual stage of these proceedings, the defendants would have to argue that there is no probative individualized evidence that could rebut the negative finding on causation that would result where the risk ratio is below 2.0. The defendants do not make this argument. Rather, as discussed above, they implicitly acknowledge that there *will* be probative individualized evidence at the individual stage of these proceedings.

544 Further, because this is a common issues trial, the plaintiffs made no submissions regarding what individualized evidence they would adduce at the individual stage of these proceedings, nor should they have been expected to. Since the parties made no submissions regarding individualized evidence (other than the 14 patient study), I cannot make a finding that would assume that no probative individualized evidence will be adduced at the individual stage of these proceedings. Thus, I cannot direct that class members who suffered from complications for which the risk ratio is below 2.0 will be barred from proceeding to the individual stage of these proceedings. Whether or not the epidemiological evidence demonstrates that the risk ratio for a complication is greater than 2.0 is only determinative of individual causation where there is no evidence other than the epidemiological evidence.

545 This interpretation is consistent with the case law relied upon by the defendants. In *Daubert v. Merrill Dow Pharmaceuticals, Inc.* (*"Daubert II"*),[118] the U.S. Ninth Circuit Court of Appeals dismissed the plaintiffs' claim on the basis that the epidemiological evidence relied upon by the plaintiffs did not demonstrate that the defendant's drug, Bendectin, doubled the risk of the birth defect suffered by the plaintiff. Two critical facts demonstrate that *Daubert II* does not support the defendants' position:

(1) *Daubert II* was an individual trial, not a common issues trial. As such, the plaintiffs *did* have the opportunity to adduce individualized evidence.
(2) The plaintiffs did not present individualized evidence. As the Court in that case stated, *"[p]laintiffs do not attempt to show causation directly*; instead, they rely

> on experts who present circumstantial proof of causation." [emphasis added]

546 *Daubert II* is simply an example of an individual trial in which the epidemiological evidence was the only evidence of causation relied upon by the plaintiffs. In that case, the epidemiological evidence could not by itself prove causation because it did not demonstrate a risk ratio greater than 2.0. This is not controversial. As I explained above, absent individualized evidence to the contrary, a risk ratio of less than 2.0 cannot support a finding of causation in an individual case. However, *Daubert II* does not support the defendants' contention that class members who suffered a complication for which the risk ratio is below 2.0 should be barred from proceeding to the individual stage of these proceedings.

547 *Young v. Memorial Hermann Hospital System* is another example of an individual trial in which the plaintiff adduced no evidence other than epidemiological evidence which demonstrated a risk ratio below 2.0.[119] Thus, it too does not support the defendants' argument that class members who suffered complications for which the risk ratio is below 2.0 should be barred from making claims at the individual stage of these proceedings.

548 *Hanford Nuclear Reserve Litigation* explicitly cautions against the approach advocated by the defendants.[120] The court stated that the lower court's application of a doubling of the risk standard "forced the plaintiffs to prove that they were exposed to specific levels of radiation, *without regard to individualized factors*".[121] As such, the court determined that the lower court "erred in requiring epidemiological evidence which would... require a plaintiff to prove exposure to a specific threshold level of radiation that created a relative risk of greater than 2.0".[122] The court noted that its decision was consistent with the "Reference Guide on Epidemiology" contained in the U.S. Federal Judicial Center's *Reference Manual on Scientific Evidence*. As the court explained:[123]

> The Manual explains how epidemiological proof can be adapted to meet the "more likely than not" burden of proof by requiring statistics to reflect a relative risk factor of 2.0 before a plaintiff can recover. The discussion there, however, recognized that when available, known individual risk factors are also relevant. The Manual states that it limits its discussion to the role of epidemiology in proving individual causation.

549 Thus, the most that can be said of the case law relied upon by the defendants is that it directs that, *in the absence of any other evidence*, a risk ratio below 2.0 does not support an inference of causation, whereas a risk ratio above 2.0 does.

550 Both parties make reference to the practice of the WSIAT in determining issues of causation. The plaintiffs note that the WSIAT does not bar individuals who suffered a medical complication from recovering on the basis that the risk ratio for the complication they suffered is below 2.0. In fact, the defendants also acknowledge that WSIAT decisions have only required a relative risk of greater than 2.0 to establish causation *absent factors specific to an individual worker's case* that would impact a balance of probabilities analysis.

551 WSIAT *Decision No. 600/97*, which considers how to determine causation in respect of workers who were exposed to asbestos and later contracted cancer, neatly demonstrates the WSIAT approach.[124] Note that instead of risk ratios, the WSIAT employs "standardized incidence ratios", or "SIRs", where an SIR of 200 is the equivalent of a risk ratio of 2.0. In the context of *Decision No. 600/97*, the SIR for the condition for which causation was being considered was 150, which corresponds to a risk ratio of 1.5. Following is a helpful excerpt:[125]

> 116. [E]pidemiological statistical measures look at "group risk" because they study populations rather than the cause of a particular worker's cancer. There is no way of knowing with certainty whether an individual worker would be one of the majority of workers who, in this example, would have developed the cancer even without occupational exposure, or whether he/she would be one of the minority of workers who would not have developed the cancer "but for" the occupational exposure. Nonetheless, the statistical probability of any individual worker being one of the minority of workers who would not have developed cancer "but for" the occupational exposure is 50/150 x 100 = 33%. That does not establish, on a "balance of probabilities" that the individual worker's cancer arose out of, or was due to, his/her employment.
>
> 117. *But it also does not necessarily prevent such a finding on the "balance of probabilities" when epidemiological evidence is considered in light of all other evidence.*
>
> 118. *Adjudicative decisions about causation do not simply convert statistical probabilities into decisions about causation using the legal standard of "balance of probabilities".*
>
> 119. Even in cases such as this where most of the evidence associating a workplace with a cancer is epidemiological evidence, *there may be factors about the individual worker or his/her exposure that increase that individual's risk such that an adjudicator will be persuaded that it is more likely that he/she is one of the workers whose cancer would not have developed "but for" the work exposure* (i.e. that it is more likely that he/she was one of the 50 out of 150 workers whose cancer would not have developed "but for" the work exposure)...
>
> 120. We understand the OWA argument that a substantial number of cases in the relative risk of 1.5 example would meet the "but for" test of causation and be compensated if they could be identified - and that requiring a relative risk of 2 (i.e. an SIR of 200) would mean that this group (1/3 of the miners in the example above) would be unfairly denied compensation.
>
> 121. In our view, this does not mean the legal test of causation for adjudicating claims under the Act changes. But it does illustrate the importance of attempting to identify those who are more likely to be in the "excess risk" group of cases - particularly when the SIR is less than 200.
>
> 122. *To decide a claim from an individual worker in the population used in the OWA example, the Tribunal would consider not only the epidemiological evidence*

> *about the group risk, but also any evidence about the individual worker that might indicate whether his risk was greater than, or less than, the group risk. The Tribunal would, for example, consider specific medical evidence about the worker as well as evidence about whether he was exposed to other risks (such as smoking if that is a risk factor for the disease the worker developed).* The Tribunal would also consider evidence about the particular worker's work exposure to see whether the worker had a different risk associated with his/her work exposure than did other workers in the group for which the relative risk of 1.5 was calculated. [emphasis added]

552 As I will outline in more detail below, I believe the practice of the WSIAT provides a useful framework for the adjudication of individual claims at the individual stage of these proceedings.

553 Since this is a common issues trial, I am to determine general causation, not individual causation. For the reasons described above, had I found the defendants liable under Common Issue 1, I would not have applied the doubling of the risk standard prescriptively such that class members who suffered a complication with a risk ratio below 2.0 would be denied the opportunity to present individualized evidence of causation in their cases. Rather, as I will describe in more detail below, I would have applied the doubling of the risk standard *presumptively*.

554 Below, I will discuss how the doubling of the risk standard ought to be applied if I had found the defendants liable under Common Issue 1.

The Doubling of the Risk Standard is a Presumptive Threshold

555 While the above discussion demonstrates that it would be inappropriate to bar class members from proceeding to the individual stage of these proceedings on the basis that the risk ratio for the complication they suffered is below 2.0, it also demonstrates that whether or not a risk ratio is above 2.0 bears on how questions of individual causation ought to be determined. It is apparent to me, as the plaintiffs point out, that the WSIAT employs a risk ratio of 2.0 as a *presumptive* threshold, as opposed to a prescriptive threshold, for individual claimants.

556 Where the epidemiological evidence demonstrates a risk ratio above 2.0, then individual causation has presumptively been proven on a balance of probabilities, absent evidence presented by the defendant to rebut the presumption. On the other hand, where the risk ratio is below 2.0, individual causation has presumptively been disproven, absent individualized evidence presented by the class member to rebut the presumption. That is, whether or not the risk ratio is above 2.0 determines upon whom the evidentiary responsibility falls in determining individual causation. *Daubert II* and *Hanford Nuclear* also support the use of a risk ratio of 2.0 as a presumptive threshold in the manner practiced by the WSIAT.

557 I also note that the level of a risk ratio relative to 2.0 determines the *extent* of the evidentiary responsibility for the party on whom it lies. In other words, a class member faces a greater

evidentiary hurdle where the risk ratio for the complication he/she suffered is 1.2, than when it is 1.8. Indeed, in the present case, a class member who suffered a complication for which the risk ratio is 1.2 (corresponding to a presumptive percentage chance of causation of 20/120 X 100 = 16.7%) would have a substantial evidentiary hurdle to overcome in order to persuade the trier of fact in his/her individual action that Silzone was more likely than not the causal factor driving his/her complication. Likewise, the defendant faces a greater hurdle where the risk ratio is 4.0, than where it is 2.2. Thus, the risk ratio for any given complication determines both the *direction* and the *extent* of the evidentiary responsibility when individual claims are brought forward.

558 This approach is entirely consistent with the case law. The defendants did not present any case law that supported their contention that I should use a risk ratio of 2.0 as a *prescriptive* standard without regard to the potential for individualized factors relevant to particular class members. In fact, as detailed above, *Hanford Nuclear*, *Daubert II*, the U.S. *Reference Manual on Scientific Evidence*, and the procedure employed by the WSIAT all support the use of a risk ratio of 2.0 as a presumptive, rather than prescriptive, standard for individual causation.

559 As such, this is the approach that I believe is appropriate. If I had found the defendants liable under Common Issue 1, I would have applied the doubling of the risk standard for materiality presumptively, as described above. Patients who suffered complications for which the increase in the risk is not "material" (i.e. below 2.0), or even not statistically significant, would still be able to recover at the individual stage of these proceedings provided they presented sufficient individualized evidence to rebut the presumption of a lack of causation that flows from a risk ratio below 2.0 and persuade their trier of fact that Silzone was the "but for" cause of their complications.

560 I believe this approach is consistent with Justice Cullity's formulation of this common issue. A presumptive doubling of the risk standard for materiality does more than "address the remotest possibility of causation".[126] Indeed, it defines materiality as the point at which the evidence of general causation is sufficient to permit a presumption of individual causation in an individual case. But at the same time it does not shut the door on individual class members solely on the basis of evidence regarding group risk. As no class member in this case has yet had the opportunity to adduce individualized evidence of causation, had I found liability, I would not have made a determination that implicitly assumes that no such evidence would be probative.

This Approach Succeeds in Significantly Advancing the Litigation

561 The defendants suggested that to allow plaintiffs who suffered a complication for which the risk ratio was below 2.0 to proceed to the individual stage of these proceedings would fail to significantly advance this litigation and would result in the justice system being overwhelmed as every class member brought forward an individual claim. I disagree. I have described the evidentiary responsibility that such individuals would face. Proceeding with individual claims would be costly for those plaintiffs that did so both financially and personally. As such, they could only be expected to do so where they had the ability to present the court with probative

individualized evidence that had a real chance of overcoming the presumption against causation that flows from a risk ratio below 2.0. As such, in my view, the defendants' suggestion that to allow these claims to proceed to the individual stage would result in a "stampede" to the courts is without merit.

562 In addition, as the plaintiffs argued, this approach to materiality succeeds in substantially advancing the present litigation. Guided by American case law and the procedure of the WSIAT, I have outlined how triers of fact at the individual stage of these proceedings could properly utilize the risk ratios as ascertained by the epidemiological data in this case. I have also determined that the AVERT data is the most reliable and that the KM / life table analysis employed by Dr. Wells provides the best method of analyzing that data. Further, I have made determinations with respect to the parties' numerous arguments under each complication. Thus, I have analyzed and distilled all of the evidence before me regarding general causation, under both Common Issue 2 and this common issue, significantly advancing the litigation.

The Evidence does not Support an Inference of Causation

563 The plaintiffs direct me to a number of authorities which, they argue, support the proposition that, employing a "robust and pragmatic approach" to evaluating the evidence, I ought to find that the "totality of the evidence" supports an inference that Silzone causes medical complications. I am mindful of the Court of Appeal's reasoning in *Fisher v. Atack*, where the Court stated that "the robust and pragmatic approach does not shift the burden of proof away from the plaintiffs", but rather "offers a method for evaluating evidence", and "is not a substitute for evidence that the defendant's negligence caused the plaintiff's injury; nor does it change the amount of proof required to establish causation".[127]

564 Much of the plaintiffs' submissions regarding my authority to make inferences of causation are seemingly directed at circumstances where the statistical evidence demonstrates a lack of statistical significance. In such cases, the plaintiffs seek to demonstrate that positive findings of causation may still be made. They argue that the statistical evidence is only one part of the evidence, and that I must consider the totality of the evidence in making findings of causation. The plaintiffs place great emphasis in this regard on *Snell v. Farrell*, in which the court stated that "[c]ausation need not be determined by scientific precision".[128] *Snell* was cited with approval in *Athey v. Leonati*, in which the Court noted that "[a]lthough the burden of proof remains with the plaintiff, in some circumstances an inference of causation may be drawn from the evidence without positive scientific proof".[129] The plaintiffs also cite the Supreme Court's cautionary language regarding the use of statistical evidence in *Laferriere v. Lawson*:[130]

> It is perhaps worthwhile to repeat that a judge will be influenced by expert scientific opinions which are expressed in terms of statistical probabilities or test samplings, but he or she is not bound by such evidence. Scientific findings are not identical to legal findings... [P]roof as to the causal link must be established

> on the balance of probabilities taking into account all the evidence which is before [the court], factual, statistical and that which the judge is entitled to presume.

565 *Laferriere* was cited in *Goodman v. Viljoen*,[131] which the plaintiffs also cite for the proposition that statistical evidence ought not to be considered in a vacuum, but rather forms just one piece of the totality of the evidence.

566 In my view, the Court's reasoning in *Snell* does not support the plaintiffs' submission that it would be appropriate for me to make an inference of causation in this case. In *Snell*, the Court noted that "[w]hether an inference is drawn is a matter of weighing evidence... The legal or ultimate burden remains with the plaintiff, but in the absence of evidence to the contrary adduced by the defendant, an inference of causation may be drawn although positive or scientific proof of causation has not been adduced". In the present case, the defendants *have* adduced a considerable amount of evidence contrary to my making an inference of causation. For example, the defendants adduced expert evidence, including expert testimony on the 14 patient study, the sheep studies and the scientific literature, demonstrating that it is unlikely that Silzone impairs tissue healing, despite the finding in AVERT that Silzone materially increased the risk of PVL for some patients for some period of time post implant.

567 Further, the Court's reasoning in *Snell* with respect to the treatment of scientific evidence was driven largely by its other findings. In that case, the Court had already found that the plaintiff suffered blindness as a result of atrophy of the optic nerve caused by the loss of blood supply to the nerve; that the loss of blood supply was caused by a stroke; that a stroke is the destruction of a blood vessel due to interruption of the blood supply; and that there were two possible causes of the stroke, one of which was natural and the other due to the defendant surgeon's decision to continue an operation to remove a cataract from the plaintiff's eye in the face of obvious retrobulbar bleeding. It was this series of findings that gave the trial judge a factual basis to infer causation on the totality of the evidence, despite the lack of definitive scientific evidence.

568 In the present case, I have made no similar series of findings regarding how Silzone might cause medical complications that would permit such an inference. Under Common Issue 2, I have found that the plaintiffs have failed to demonstrate on a balance of probabilities that impaired tissue healing is the mechanism by which (or how) Silzone causes medical complications. I recognize that, as the plaintiffs point out, they do not have to demonstrate *how* Silzone causes medical complications in order to prove *that* it does so. However, reliable evidence as to how Silzone would cause medical complications would be able to support an inference that it does so. Here, however, there is none, as I have rejected the plaintiffs' theory of impaired tissue healing under Common Issue 2. Thus, while the epidemiological evidence demonstrates that Silzone causes PVL in some patients, unlike in Snell, we may never know, as the defendants argue, how it causes that or any other complication, if it does in fact do so. In *Snell*, the trial judge was able to reduce the number of possible causes of the plaintiff's injury down to two and it was established *that* the plaintiff had

suffered an injury. In the present case I have no reliable evidence upon which to make any findings about how Silzone causes medical complications, if it does indeed do so. Thus, unlike in *Snell*, other than the epidemiological evidence, I have no evidentiary basis upon which to make an inference of causation.

569 In the present circumstances, I believe the British Columbia Court of Appeal's words in *Moore v. Castlegar and District Hospital* are apposite.[132] In that case, the Court held that it is not open to a trial judge to draw a common sense inference of the cause of the medical complication where both parties have led expert medical evidence of causation. *Moore* was cited with approval in *Sam v. Wilson*, a case in which *Snell* was distinguished for similar reasons.[133]

570 In the present case, the two sides have adduced conflicting expert testimony. Further, there is simply no reliable evidence, other than the epidemiological evidence, upon which I could base an inference of causation. Thus, I cannot apply the robust and pragmatic approach as it was outlined in *Aristorenas v. Comcare Health Services* to draw an inference of causation. In that case, the court stated that "a series of facts and circumstances established by the evidence led at trial may enable the trial judge to draw an inference even though medical and scientific expertise cannot arrive at a definitive conclusion".[134] In the present case, the "series of facts and circumstances" upon which I could base such an inference is absent. The only reliable evidence of causation is epidemiological evidence, and I have interpreted that evidence consistently with how it is treated by qualified experts in the medical and scientific communities.

571 I also do not believe the court's decision in *Goodman* assists the plaintiffs' submissions in this regard. The plaintiffs note that in that case causation was found despite epidemiological evidence that did not reach statistical significance. However, I note that the epidemiological data in that case was derived from over 20 RCTs, as opposed to one in the present case, and it came very close to statistical significance. Further, the trial judge had the benefit of reliable clinical evidence of causation that was specific to the individual plaintiff, whereas in the present case I have rejected the plaintiffs' impaired tissue healing theory under Common Issue 2 and have not accepted any clinical evidence of causation as reliable.

572 Moreover, *Goodman* was an individual case, whereas in the present case I am assessing general causation. In an individual case, it makes sense that where epidemiological evidence falls short of statistical significance a trial judge could nonetheless find causation on the basis of individualized clinical evidence supportive of such a finding, as in *Goodman*. However, it does not follow that I may make a finding of *general* causation absent any reliable clinical evidence whatsoever. Further, had I found liability, there would be nothing in my reasons under this common issue to bar an individual plaintiff from bringing an individual claim in these proceedings. In such a case, where the individual suffered a complication for which no statistically significant increase in risk in Silzone valve patients was found, it would have been open to the trier of fact to nonetheless find that Silzone caused the particular plaintiffs' injuries on the basis of individualized clinical evidence combined with the epidemiological evidence - as occurred in *Goodman*. Outcomes such as

the one in *Goodman*, therefore, would still have been possible in respect of individual plaintiffs in the present case.

573 I also note that the plaintiffs' submissions with respect to my ability to draw inferences of causation were confusing and, in some cases, contradictory. For example, in their closing submissions, the plaintiffs acknowledge that "Common Issue 3 does not address whether the risks posed by Silzone would be considered significant in the eyes of a clinician",[135] a statement with which I agree. Yet, shortly thereafter, the plaintiffs again refer to informed consent case law and the importance of the seriousness of the injuries suffered by the plaintiffs. They state that

> [t]he concept of materiality ... is ... dependent on consideration of the seriousness of the injuries and whether the risk was sufficiently substantial that an implanting cardiac surgeon would consider the risk significant from a clinical perspective ... Even if there is only a slight chance of serious injury or death, a risk may be material. In contrast, a significant chance of a slight injury may not be material.[136]

574 In discussing the plaintiffs' one and one third standard for materiality, above, I explained why the informed consent case law and the relative seriousness of the complications at issue are not relevant to my determinations under Common Issue 3. The same analysis applies here. This line of case law does not assist the plaintiffs in establishing that, "on the totality of the evidence", an inference of causation ought to be drawn.

Conclusion under Common Issue 3

575 A Silzone coating on heart valves does not materially increase the risk of medical complications, with the exception of major PVL for two years post implant, and minor PVL for six years post implant.

THE REMAINING COMMON ISSUES

576 The remaining common issues address the plaintiffs' entitlement to the remedies of medical monitoring (Common Issues 4 and 5), 'waiver of tort' (Common Issues 7 and 8) and punitive damages (Common Issue 10(a)). In view of the conclusions I have reached on Common Issues 1, 2 and 3, the plaintiffs have no entitlement to these remedies and these questions must be answered in the negative.

577 I realize that there has been considerable anticipation that this trial, with the benefit of a full factual record, would finally decide whether or not there is a basis in Canadian law for applying the doctrine of waiver of tort in a product liability negligence case. As I have found no wrongdoing, any analysis I engage in would be academic. Nonetheless, due to the considerable interest in this issue, I will provide one or two comments that may be helpful in moving this vexing question closer to resolution.

The Waiver of Tort Debate

578 Our courts have had occasion to consider the question of whether waiver of tort exists as an independent cause of action, and if so, under what circumstances. The debate was neatly captured by Blair J.A. in the following passage from *Aronowicz v. Emtwo Properties Inc.*:[137]

> 80 Waiver of tort is a restitutionary remedy. There is considerable controversy over whether it exists as an independent cause of action at all or whether it is "parasitic" in the sense that it requires proof of an underlying tort and - since a tort requires damage - proof of harm to the plaintiff. By invoking waiver of tort, a plaintiff gives up the right to sue in tort but seeks to recover on the basis of restitution, claiming the benefits the wrongdoer has derived from the wrongful conduct regardless of whether the plaintiff has suffered damages or not. See, for example, *Serhan Estate v. Johnson & Johnson* (2006), 85 O.R. (3d) 665 (Div. Ct), at paras. 45-69, leave to appeal to S.C.C. dismissed, [2006] S.C.C.A. No. 494.
>
> 81 The claim is not so much "novel" - it has its roots in the ancient action of *assumpsit* - as it is "mysterious" or "mystical". In their text, *The Law of Restitution*, Maddaugh and McCamus describe it in this fashion:[138]
>
> > The doctrine known as "waiver of tort" is perhaps one of the lesser appreciated areas within the scope of the law of restitution. From the outset, it seems to have engendered an undue amount of confusion and needless complexity. The *almost mystical quality* that surrounds the doctrine is attested to by the following famous couplet penned by a pleader of old [J.L. Adolphus, "The Circuiteers - An Eclogue" (1885) 1 L.Q. Rev. 232, at p. 233]:
> >
> > Thoughts much too deep for tears subdue the Court
> >
> > When I *assumpsit* bring, and god-like waive a tort.
> >
> > One source of this confusion stems from the doctrine's very name. As one writer has pointed out, not entirely facetiously, it has "*nothing whatever to do with waiver and really very little to with tort*". [Emphasis added.]

> 82 While waiver of tort appears to be developing new legs in the class action field - see *Serhan Estate* and *Heward v. Eli Lilly & Co.* (2008), 91 O.R. (3d) 691 (Div. Ct.), for example - it is of no assistance to the appellants here. Whether the claim exists as an independent cause of action or whether it requires proof of all the elements of an underlying tort aside, at the very least, waiver of tort requires some form of wrongdoing. The motion judge found none here. No breach of contract. No breach of fiduciary duty, or duty of good faith or confidentiality. No oppression. No misrepresentation. No deceit. No conspiracy. As counsel for Mr. Grinshpan put it in their factum, "its eleventh hour insertion into the statement of claim does not provide the appellants' claim with a new lifeline given that the record discloses no wrongful conduct on the part of the respondents in respect of any of the causes of action pleaded."

579 As the above excerpt says, the primary debate about waiver of tort has been whether the doctrine exists as an independent cause of action in restitution (the independence theory) or is parasitic of an underlying tort (the parasitic theory). Under the parasitic theory, waiver of tort may only be invoked where all of the elements of the underlying tort have been proven, including damage to the plaintiff if that is an element of the tort. If, however, waiver of tort exists as an independent cause of action, by invoking the doctrine, a plaintiff can claim the benefits that accrued to the defendant as a result of the defendant's wrongful conduct, even if the plaintiff suffered no harm. It is also noteworthy that the independence theory of waiver of tort is not the same as an action for unjust enrichment, as the plaintiff does not have to demonstrate a deprivation that corresponds to the defendant's enrichment.

580 In *Serhan Estate v. Johnson & Johnson*,[139] an appeal from a Superior Court order certifying waiver of tort as a cause of action, the Divisional Court provided, at paragraphs 45 to 67, a detailed account of the contemporary academic and judicial debate on the issue. The court in *Serhan* noted that both the parasitic and independence theory of waiver of tort can claim the support of academic writings and case law, and the majority concluded, at paragraph 67, that while it had concerns about eliminating the need to prove loss in products liability cases (as is directed by the independence theory), the issue "should be considered and resolved on the basis of a full record". The court stated further, at paragraph 68, that "the resolution of the questions the defendants raise about the consequences of identifying waiver of tort as an independent cause of action in circumstances such as exist here, involves matters of policy that should not be determined at the pleadings stage". Finally, at paragraph 69, the court concurred with the certification judge's determination that "whether waiver of tort is an independent cause of action should be resolved in the context of a factual background of a more fully developed record".

581 Similarly, in *Heward v. Eli Lilly & Co.*,[140] in which waiver of tort was again certified as a common issue in a class proceeding, at paragraph 48, the certification judge, citing *Serhan*, noted that the consideration of whether and when waiver of tort should be an available remedy involves "important issues of policy ... that must surely be confronted on the basis of a full factual record".

582 Other courts have followed this pattern, and since *Serhan* waiver of tort has been routinely certified in most class actions. It has also found its way into pleadings in cases such as *Aronowicz* (a garden variety shareholders' dispute), presumably in the hope of avoiding the hammer of summary judgment on the basis that it is a novel and uncertain claim.

583 I could not agree more that it is time to decide the question.

584 There is no case law before me on waiver of tort that was not also before the courts in *Serhan* and *Eli Lilly*, although the related academic debate continues to develop.[141] Neither of those courts found that this was sufficient to determine the issue. In fact, both found that a full evidentiary record would be necessary. The Court of Appeal and the Supreme Court of Canada refused leave to appeal the decision in *Serhan* and as neither Court is obliged to give reasons for this, we do not know why. If these Courts did so because they agreed with the courts in *Serhan* and *Eli Lilly* that a full factual record is necessary to decide whether or not there is a basis in Canadian law for applying the doctrine of waiver of tort in a product liability negligence case, I must respectfully disagree.

585 The extensive factual record that was developed during a 138 day trial did not illuminate for me the important issues of policy that were meant to arise from the trial record. The written submissions of the parties did not rely on any evidence from the factual record in advancing arguments to support or oppose extending the waiver of tort doctrine to a negligence case. The plaintiffs did not lead any policy evidence to explain why waiver of tort should be available in a product liability negligence case.

586 In fact, the only policy evidence brought before the court was adduced by the defendants from Professor Michael Trebilcock, a law and economics scholar at the Faculty of Law, University of Toronto. The kind of analysis that Professor Trebilcock offered was certainly outside the experience and knowledge of the court, but I hasten to add that where the court is engaged in an analysis that may result in changes to the law, this kind of social science evidence is frequently brought before the court by way of application and is evaluated on the basis of affidavit evidence and cross-examination thereon.[142] The plaintiffs objected to the admissibility of the evidence of Professor Trebilcock and argued that waiver of tort is a matter for legal argument and does not require expert evidence on policy. If they are correct, the recognition (or not) of the waiver of tort doctrine can be determined under section 5(1)(a) of the *Class Proceedings Act*.

587 While generally, courts are reluctant to determine unsettled matters of law at a pre-trial stage and particularly on a pleadings motion, there is certainly precedent for doing this. It may be lost in the mists of time, but *Donoghue (or McAlister) v. Stevenson* reached the House of Lords on a pleadings motion.[143] No one can dispute that the outcome in that case represented a 'sea-change' in the law. As well, appellate courts have struck claims in regulatory negligence on pleadings motions based on an *Anns* analysis of whether there were policy reasons to negate a common law duty of care.[144] My experience from this trial suggests that deciding the waiver of tort issue does not necessarily require a trial and that it may be possible to resolve the debate in some other way.

Policy Considerations

588 The policy considerations did not arise from the factual record. The plaintiffs adduced no expert evidence on policy, but there is one policy consideration that they advance in their submissions that merits consideration. The plaintiffs argue that "[a]s a matter of policy, the courts should not encourage manufacturers to take unreasonable risks in circumstances where, *due to the complexities of establishing causation, it is unlikely that every individual harmed by a defective product will be able to successfully sue for compensation*" [emphasis added].

589 In the present case, had I found that the defendants had breached their duty of care, the defendants would have, through their negligence, exposed a population of Silzone valve patients to an increased risk of a serious medical condition (PVL). However, whether the defendant was required to pay for this - and thus, whether this would deter medical product manufacturers from engaging in negligent behaviour that puts populations at risk - would depend on whether individuals within that population could demonstrate that, on a balance of probabilities, Silzone caused their particular injuries. While epidemiological evidence can show that the defendant placed a group of people at risk, it is a more burdensome evidentiary hurdle to demonstrate that it is more likely than not that any one individual within the group suffered damages as a result of that increased risk. Tort law may be inadequate to the task of regulating the conduct of medical device manufacturers and other manufacturers whose products put populations at risk. Recognizing an independent tort based on wrongdoing, rather than proof of harm, can arguably overcome this problem and serve a useful social purpose.

590 When a population is put at risk, one might rightly ask whether this constitutes a *public* problem inviting public oversight, or a *private* problem the resolution of which can be left to a court applying private law. It bears noting that if the latter approach is taken, whether or not a person who puts a population at risk experiences any consequences will, in many cases, depend on whether a member of the bar sees fit to initiate a class action lawsuit. The factors that drive a lawyer's decision in this regard will be specific to that lawyer's practice, and generally will not include safeguarding the public interest. If putting populations at risk of serious medical complications is construed as a public problem, then it is unsurprising that private law constructs, such as the requirement that individual causation and damages be proven on a balance of probabilities, can become virtually insurmountable hurdles for those within the population who suffered from the risk and are seeking redress.

591 There are, of course, countervailing policy considerations. The defendants submit that the plaintiffs have fundamentally failed to explain why, as a matter of law and policy, waiver of tort should be extended to a product liability negligence case. Professor Trebilcock's law and economics public policy evidence indicates that the recognition of waiver of tort in this context will have a negative impact on product innovation and will over deter socially desirable behaviour on the part of health product manufacturers. Law and economics policy considerations strongly support the idea that damages for negligence should be calculated based on the injury suffered by the plaintiff,

rather than the gain realized by the defendant. Professor Trebilcock discussed the negative consequences that might be expected to arise from a "super-compensatory" regime in negligence law, that is, one where plaintiffs receive compensation in excess of their actual injuries. If waiver of tort were recognized as an independent cause of action, plaintiffs could be overcompensated in this manner as a defendant's gain from its wrongful conduct could exceed the damages suffered by plaintiffs. Professor Trebilcock noted there is considerable risk that overcompensating a plaintiff through waiver of tort in a negligence case would destabilize the deterrence and insurance functions of tort law. He testified that such a regime has the potential to deter socially productive activities. For example, allowing waiver of tort in negligence cases may:

* cause sellers to take socially excessive precautions on the market;
* cause sellers to take products off the market;
* cause sellers to under-invest in product innovation;
* cause sellers to charge higher prices for their products; and,
* cause consumers to have to pay more for products than they would prefer to pay.

592 While acknowledging their limitations, Professor Trebilcock cited empirical studies that suggest some negative consequences that might flow from a super-compensatory regime. A study by Steven Garber found that super-compensatory liability in medical products markets in the United States had the effect of causing companies to withdraw products from the market that had widespread support in the medical community.[145] He also found that the regime caused major price increases and deterred development efforts for socially valuable products. Another set of studies by Richard L. Manning suggested that exposure to super-compensatory liability caused manufacturers to increase prices for major childhood vaccines at a rate that outpaced increases in wholesale prices for drugs and pharmaceuticals generally.[146]

593 The debate between the independence theory and the parasitic theory engages fundamental philosophical questions about the nature of tort law. As Professor Trebilcock noted, negligence has been predicated on a system of compensation for actual loss for nearly 200 years. The requirement that a plaintiff demonstrate damages has long been considered a fundamental tenet of tort law. Does this requirement exist because the law only considers a person's conduct wrongful where it harms another person? If so, recognizing waiver of tort as an independent cause of action would result in punishing defendants for conduct that has never before been deemed wrongful. Under this view, the requirement that damages be demonstrated is meant to serve a foundational philosophical purpose. On the other hand, is it only the violation of the duty of care that makes a defendant's conduct wrongful? In that case, the requirement that the plaintiff demonstrate damages may merely perform some practical purpose and the philosophical foundations of tort law would not be offended by recognizing waiver of tort as an independent cause of action. Thus, the discussion surrounding the waiver of tort debate touches on questions as fundamental as what exactly it is that directs the law to deem certain conduct wrongful.

594 Given the philosophical and policy considerations mentioned above, it is my view that the

fundamental question for a court to answer is whether the recognition (or not) of the waiver of tort doctrine is within the capacity of a court to resolve, or whether it has such far-reaching and complex effects that it is best left to consideration by the Legislature.[147] On the basis of my experience, the answer to this and the other questions surrounding the waiver of tort doctrine is not dependent on a trial with a full factual record and may require no evidence at all.

ANSWERS TO THE COMMON ISSUES

Common Issue 1

The defendants exercised reasonable care in the design and testing of the Silzone valve and in the warnings of the risks inherent in their use.

Common Issue 2

A Silzone coating on a heart valve sewing ring has no different or adverse effect on tissue healing than uncoated Dacron.

Common Issue 3

A Silzone coating on heart valves does not materially increase the risk of medical complications, with the exception of major PVL for two years post implant, and minor PVL for six years post implant.

Common Issues 4 and 5

Silzone patients do not require additional or different medical monitoring than conventional heart valve patients. Common Issue 5 is moot.

Common Issue 6

The plaintiffs are not entitled to a presumption that explanted valves and tissue samples from the sheep studies would have been unhelpful to the defendants' case and helpful to the plaintiffs.

Common Issues 7 and 8

Members of the Class cannot elect to have damages determined through an accounting and disgorgement remedy. Common Issue 8 is moot.

Common Issue 10(a)

The defendants' conduct does not merit an award of punitive damages.

DISPOSITION

595 The action is dismissed. I encourage the parties to attempt to resolve the question of costs. If they are unsuccessful, they should arrange an attendance.

J.L. LAX J.

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SCHEDULE I

Certified Common Issues*

1. Did the defendants breach a duty of care owed to class members by reason of the design, pre-market testing, regulatory compliance, manufacture, sale, marketing, distribution and recall of Silzone-coated mechanical heart valves and annuloplasty rings implanted in such members?
2. What effect, if any, does such Silzone coating have on tissue healing?
3. Does a Silzone coating on heart valves, or annuloplasty rings, materially increase the risk of various medical complications including, but not limited to, paravalvular leakage, thrombosis, thromboembolism, stroke, heart attacks, endocarditis or death?
4. Do Silzone implanted-patients need additional or different medical monitoring than that for conventional mechanical heart valve patients?
5. Should the defendants be required to implement a medical monitoring regime and, if so, what should the regime comprise and how should it be established?
6. Is the burden of proof of causation or negligence affected by spoliation of evidence by the defendants?
7. Can all or a part of the Class elect to have damages determined through an accounting and disgorgement of the proceeds of the sale of the mechanical heart valves, or annuloplasty rings, coated with Silzone implanted in patients?
8. If part, but not all, of the Class can so elect, which part or parts of the Class can so elect?
9. If all or part of the Class can so elect, in what amount and for whose benefit is such an accounting to be made?
10. (a) Does the defendants' conduct merit an award of punitive damages?

    (b) Should an award of punitive damages be made against the defendants?

If so, in what amount?

* The common issues were certified by order of the Honourable Justice Cullity, dated January 16, 2004, and amended by order of the Honourable Justice Lax, dated January 20, 2010. Common issues 9 and 10(b) were bifurcated to the end of the trial of common issues.

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SCHEDULE II

The Expert Witnesses

[QL:GRAPHIC NAME="12OJ2921-6.JPG"/]

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SCHEDULE III

Scientific Articles

Akins et al. (2005), "Guidelines for reporting mortality and morbidity after cardiac valve interventions," *European Journal of Cardio-thoracic Surgery.*

Arom et al. (1996), "St. Jude Medical Prosthesis: Health Status of the Patients after 15 Years," *Annals of Thoracic and Cardiovascular Surgery.*

Bambauer et al. (2004), "Large Bore Catheters with Surface Treatments versus Untreated Catheters for Vascular Access in Hemodialysis," *Artificial Organs.*

Bambauer et al. (1996), "Scanning Electron Microscopic Investigation of Catheters for Blood Access," *Blood Purification.*

Bambauer et al. (1995), "New Surface Treatment Technologies for Catheters used for Extracorporeal Detoxification Methods," *Dialysis & Transplantation.*

Batt et al. (2003), "In situ revascularization with silver-coated polyester grafts to treat aortic infection: Early and midterm results," *Journal of Vascular Surgery.*

Boosalis et al. (1987), "Serum and urinary silver levels in thermal injury patients," *Surgery.*

Bradford Hill, A. (1965), "The Environment and Disease: Association or Causation?" *Proceeding of the Royal Society of Medicine.*

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* * * * *

SCHEDULE IV

Glossary of Medical Terms

Adsorption - molecules of gas or liquid adhere to the surface of a solid. It is different from "absorption" where molecules actually enter the absorbing medium.

Albumin - major blood protein.

Aliquot- a smaller portion of a sample taken for experimental purposes; fractional; pertaining to a part of the whole.

Anastomosis - to make such connection surgically.

Angstrom - unit of measurement; 1/100,000,000 of a centimetre.

Annular - related to the *annulus*.

Annuloplasty - surgical procedure involving repair of a heart valve.

Annulus (plural "annuli") - a ring of tough fibrous tissue at the base of a heart valve. This ring supports and anchors the heart valve(s) into the heart itself. There are 4 valve annuli: one each for the *tricuspid*, *mitral*, *aortic*, and *pulmonary* valves.

Anticoagulant - a drug that inhibits blood from clotting.

Antimicrobial- a substance that kills or inhibits the growth of microbes such as bacteria, fungi, or viruses.

Aorta - the largest artery in the human body, originating from the left ventricle of the heart and bringing oxygenated blood to all parts of the body.

Aortic Valve - a one-way valve that allows blood to flow only out of the left ventricle (left lower chamber) and into the *aorta*.

Bactericidal- capable of killing *bacteria*.

Bacteriostatic - inhibiting the growth or reproduction of bacteria.

Bileaflet Valve - a heart valve prosthesis consisting of a circular orifice to which are attached two semicircular occluding discs that swing open and closed to regulate blood flow.

Bioavailability - the extent to which a drug or other substance is absorbed by and becomes available to the body.

Biocompatibility - the ability of a material to perform with an appropriate host response in a specific application.

Biofilm - an aggregate of tiny organisms with a distinct architecture.

Clostridium - a kind of bacteria.

Coumadin - anticoagulant; also known as *Warfarin.*

Culture-negative Endocarditis - an infection and inflammation of the lining of one or more heart valves in which no *endocarditis*-causing germs can be identified on a blood culture.

Cytoskeleton- a network of proteins making up the internal skeleton of a cell.

Cytotoxic - any agent or process that is toxic to cells; ("cyto" denotes a cell).

Dacron - DuPont trade name for polyester.

Dehiscence - a rupture or opening of a sutured area or surgical wound, or of an organ or structure.

Duke Criteria - diagnostic criteria *for infectious endocarditis* originally proposed in 1994. The criteria are based on a combination of *echocardiogram*, laboratory and physical examination findings. These criteria include major and minor criteria. Clinical criteria for *infective endocarditis* requires: any of: (a) two major criteria; (b) one major criteria and three minor criteria; or (c) five minor criteria.

Echocardiogram- like an ultrasound, it provides a three dimensional view of the heart in real time.

Elution - in chemistry, separation of material by washing; the process of pulverizing substances and mixing them with water in order to separate the heavier components, which settle in solution, from the lighter.

Embolism- obstruction of a blood vessel by foreign substances or a blood clot.

Endocarditis - an infection of the lining of the heart (called the *endocardium*).

Endothelial - relating to the flat layer of cells lining the heart.

Endotheliazation - the growth of a layer of cells lining the circulatory system including the blood and lymphatic vessels of the heart.

Endothelium - protective cells that line the heart.

Epidemiology - the study of factors affecting the health and illness of populations.

Etiology - assignment of a cause, an origin, or a reason for something.

Explant - removal of an implanted prosthesis such as a heart valve or knee joint.

Fibrin - a stringy protein needed for blood to clot.

Fibroblasts - cells that help make up the support structure for tissues and organs; they are cells found in connective tissue.

Fibrous - containing, consisting of, or resembling fibres, for example, *collagen* is a fibrous protein.

Foreign Body Giant Cell - a collection of fused *macrophages* (giant cell) which are generated in response to the presence of a foreign body.

Free Radicals - compounds with an unpaired electron (and no charge). They may be involved as short-lived, highly-active intermediates in various reactions in living tissues, notably in photosynthesis.

Galvanic - electric; producing a direct current of electricity.

Galvanic Corrosion - Galvanic corrosion is an electromechanical process in which one metal corrodes preferentially when in electrical contact with a different type of metal and both metals are immersed in an *electrolyte*.

Glutathione - a tri-peptide found in plant and animal tissues that has various functions in a cell, which include acting as an antioxidant and protecting cells from toxins.

Hemolysis/Haemolysis - the destruction of red blood cells by the body.

In situ - Latin meaning "in place" or not removed, in its original position.

In vitro - in a test tube or a lab dish.

In vivo - in the living subject/the body.

Infection - a state in which the body is invaded by a disease-causing agent (like a microorganism or virus).

Infectious Endocarditis - an infection of the lining of the heart chambers and heart valves that is caused by bacteria, fungi, or other infectious substances.

INR or International Normalized Ratio - used to measure the effectiveness of blood thinning drugs such as warafin (Coumadin).

Interstices - a small area or gap in tissue or structure of an organ.

Ion Beam Assisted Deposition (IBAD) - a process of applying materials to a surface through the application of an ion beam.

Ischemic Stroke - a stroke in which blood supply to part of the brain is decreased leading to dysfunction of the brain tissue.

Leukocytes - white blood cells that help the body fight infections and disease.

LIMRA - Limited Initial Market Release Authorization.

Lymphocytes - white blood cells that are a major component of the immune system; they fight infection and disease.

Lysis - rupture, disintegration or destruction of cells.

Macrophages - large, white blood cells found at the site of infection or injury that are capable of engulfing and ingesting cells or particles.

Mammalian - any of the higher vertebrate animals comprising the class Mammalia.

Mechanical - in the context of heart valve prostheses, it means manufactured non-tissue prosthetics made to replicate the function of native heart valves.

Metallothionein - a small metal-binding protein, rich in sulphur-containing *amino acids*, that is synthesized throughout the body and in the liver, heart and kidney and important in ion transport. It is important in detoxification.

Microbiology - the study of all aspects of microorganisms, organisms which individually are generally too small to be visible other than by microscopy.

Micron - a unit of length equal to one millionth of a meter.

Microorganism - a minute living body not perceptible to the human eye.

Microvasculature - the portion of the circulatory system composed of the smallest vessels, such as the *capillaries*.

Mitral Valve - a valve of the heart located between the *left atrium* (receives oxygen-rich blood) and *left ventricle* (chamber on the left side of the heart that receives blood from the *left atrium* and pumps it into the *aorta*, a large artery of the heart); the mitral valve regulates blood flow between the left atrium and the left ventricle.

Monocytes - a type of *leukocyte* (white blood cell) and part of the human body's immune system.

Monocytes can move quickly to sites of infection in the tissues to elicit an immune response.

Necropsy - post-mortem examination/autopsy.

Necrosis- the death of one or more cells or a portion of tissue or an organ through injury or disease.

Neo-intimal - the inner lining of a vessel, artery or vein.

Pannus - fibrotic tissue which grows around a newly implanted prosthetic heart valve. The term may be used either to refer to such tissue generally, or refer to excessive tissue (*i.e.* pannus tissue that may grow to the point where it obstructs the leaflets of a prosthetic valve).

Paravalvular Leak - the leakage of blood through an opening between the upper and lower chambers of the heart around the outside of the valve.

Paravalvular Regurgitation - a complication associated with heart valve replacement surgery to which the blood leaks backwards between the native annulus and the prosthetic valve sewing ring.

Pasturella - a bacterium; many Pasturella species are zoonotic pathogens (meaning an infectious disease that is able to be transmitted from wild and domestic animals to humans or from humans to animals).

Pathology - the study of the characteristic causes and effects of disease.

Phagocyte - a cell, such as a white blood cell, that engulfs and absorbs waste material, harmful microorganisms, or other foreign bodies in the bloodstream and tissues.

Platelets - the part of a blood cell that helps prevent bleeding by causing blood clots.

Pledget - a small piece of material, usually felt, that is used to buttress or reinforce sutures during surgery.

Polyester - a category of *polymers* which contain the ester functional group in their main chain. Although there are many polyesters, the term "polyester" as a specific material most commonly refers to polyethylene terephthalate (PET).

Prosthetic Valve Endocarditis - infection based in the area of a prosthetic heart valve.

Prosthetic Valve Thrombosis - an obstruction of prosthesis by non-infective thrombotic material (blood clotting material).

Reversible Ischemic Neurologic Deficit ("RIND") - a temporary loss of functioning brain tissue caused by an interruption in the cerebral blood supply that lasts between 24 hours to three weeks.

Sewing Ring - a portion of a heart valve prosthesis that allows the valve to be sutured into place.

Silver Sulfadiazine - a topical antibacterial agent used primarily as a topical burn cream on second- and third-degree burns. The cream is applied to the burned skin for the duration of the healing period or until a graft is applied. It prevents the growth of a wide array of bacteria, as well as yeast on the damaged skin. Silver sulfadiazine is typically delivered in a 1% solution suspended in a water-soluble base.

Stroke - a stroke is the rapidly developing loss of brain functions do to a disturbance in the blood vessels supplying blood to the brain.

Thrombin - an enzyme formed in shed blood that converts *fibrinogen* into *fibrin* (proteins necessary in blood clotting), and forms the basis of a blood clot.

Thromboembolic - the blocking of a blood vessel by a blood clot dislodged from its site of origin.

Thromboembolism - the formation in a blood vessel of a clot (*thrombus*) that breaks loose and is carried by the bloodstream to plug another vessel.

Thrombogenicity- the tendency of a material in contact with the blood to produce a *thrombus* or clot.

Thrombosis - the presence or formation of a blood clot which obstructs veins (venous thrombosis) and *arteries* (arterial thrombosis).

Thrombus (plural "*thrombi*") - a blood clot within a blood vessel or within the heart.

Toxicity - the quality, state or relative degree of being toxic or poisonous.

Toxicology - the study of symptoms, mechanisms, treatments and detection of poisoning, especially the poisoning of people.

Transient Ischemic Attack or "TIA" - caused by the changes in the blood supply to a particular area of the brain, resulting in brief neurologic dysfunction that persists, by definition, for less than 24 hours.

Valve Thrombosis - an obstruction of a prosthesis by non-infective thrombotic material (blood clotting material).

Vascular graft - synthetic or biological materials used to patch injured or diseased areas of *arteries*, or for replacement of whole segments of larger *arteries* (such as the *aorta*), and for use as sewing cuffs (as with the heart valve).

Vegetation - in the medical context, an abnormal growth of tissue around a valve that can develop following the presence of bacteria in the blood. Vegetation is composed of blood *platelets*, the infecting *bacteria*, a few white blood cells, and *fibrin* (a protein involved in clotting).

Warfarin - a drug that prevents blood from clotting. Also called *anticoagulant* (blood thinner).

Zone of Inhibition - an area on an agar plate where growth of a control organism is inhibited.

cp/e/qljel/qlpmg/qlana

1 A list of the certified common issues is found in Schedule I.

2 This wording was formulated by Mr. Justice Cullity in his reasons on the certification motion and will be discussed in Common Issue 3.

3 The defendants' submissions state that this device was implanted in three Canadian class members, but I was unable to find evidence to support this. The plaintiffs led no evidence about the Sequin Ring.

4 At the time, a new prosthetic heart valve was licensed in Canada by a Notice of Compliance or NOC. In the United States, this was by way of a Pre-market Application or PMA.

5 In the United Kingdom, senior surgeons are referred to as "Mr." rather than "Dr."

6 'CERFS' is an acronym for Cardiff Embolic Risk Factor Study.

7 Sopinka, Lederman & Bryant: *The Law of Evidence*, 3rd ed. (Markham, Ontario: LexisNexis, 2009) at 6.449-6.450; *Lambert v. Quinn*, [1994] O.J. No. 3 at paras. 11-15 (C.A.).

8 *Ritchie v. Thompson*, [1994] N.B.J. No. 540 at paras. 9 and 15 (C.A.) [*Ritchie*].

9 The plaintiffs' written submissions also include Mr. Jonas Runquist in this group, although he does not appear on the list provided to the court during oral argument. Mr. Runquist was an engineer and Product Regulation Manager who reported to Dr. Flory.

10 At trial, the plaintiffs read in 79 excerpts from Mr. Runquist's deposition transcript, 71 excerpts from Ms. Schultz's deposition and 67 excerpts from Ms. Illingworth's deposition. In each case, they relied on portions of these read-ins in their written submissions.

11 *Miller v. Carley* (2009), 98 O.R. (3d) 432 at paras. 201-202 (S.C.J.).

12 *Levesque v. Comeau*, [1970] S.C.R. 1010 (see discussion in *Ritchie* at paras. 9-14); *Bernardi v. Guardian Royal Exchange Assurance Co.*, [1979] O.J. No. 553 at paras. 28-30

(C.A.); *Vieczorek v. Piersma*, [1987] O.J. No. 124 at para. 17 (C.A.); *Claiborne Industries Ltd. v. National Bank of Canada*, [1989] O.J. No. 1048 at paras. 47-51 (C.A.).

13 *Rothwell v. Raes* (1988), 66 O.R. (2d) 449, [1988] O.J. No. 1847 (H.C.J.) at para. 245 [*Rothwell*], aff'd (1990), 2 O.R. (3d) 332, [1990] O.J. No. 2298 (C.A.) [*Rothwell* (C.A.)], leave to appeal to the S.C.C. refused, [1991] S.C.C.A. No. 58.

14 *R. v. Mohan*, [1994] 2 S.C.R. 9 [*Mohan*].

15 *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579 at 592-595 (1993) [*Daubert*].

16 *R. v. J.-L.J.*, 2000 SCC 51, [2000] S.C.R. 600 at para. 33[*J.-L.J.*]; The Honourable Stephen T. Goudge (Commissioner), Report on the Inquiry into Pediatric Forensic Pathology in Ontario, vol. 3, (Toronto: Ministry of the Attorney General, 2008) ch. 18 ("Role of the Court") at 477-482 [The Goudge Report].

17 *J.-L.J.*, at para. 35.

18 The Goudge Report at 478-479.

19 *In Re Human Tissue Products Liability Litigation*, 582 F. Supp. (2d) 644 at 690 (D.N.J. 2008) [In Re Human Tissue].

20 See discussion in *Rothwell* at paras. 49 to 63.

21 *Rothwell* at para. 237.

22 At para. 89.

23 *Grass (Litigation guardian of) v. Women's College Hospital* (2001), 144 O.A.C. 298, leave to appeal to the S.C.C. refused, [2001] S.C.C.A. No. 372; *Meringolo v. Oshawa General Hospital* (1991), 46 O.A.C. 260.

24 *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1984), 46 O.R. (2d) 113, [1984] O.J. No. 3181 (H.C.J.) [*Buchan*]; aff'd (1986), 54 O.R. (2d) 92, [1986] O.J. No. 2331 (C.A.) [*Buchan* (C.A.)].

25 *Ryan v. Victoria (City)*, [1999] 1 S.C.R. 201 [*Ryan*].

26 *Ryan* at para. 28.

27 *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, 1989 CarswellOnt 23 at paras. 43-46, aff'd [1994] O.J. No. 50 (C.A.) [*Rentway*]; *Ragoonanan v. Imperial Tobacco Canada Ltd.*,

[2000] O.J. No. 4597 at paras. 103-104 (S.C.J.) [*Ragoonanan*].

28 The studies conducted by Dr. Bambauer are discussed in Common Issue 2.

29 Exhibits 954 to 959.

30 *Ryan* at para. 29.

31 Exhibit 335.

32 *Andersen v. St. Jude Medical*, 2010 ONSC 2436.

33 Dean F. Edgell, *Product Liability in Canada* (Markham, Ont.: Butterworths Canada, 2000) at 55.

34 *Willis v. FMC Machinery & Chemicals Ltd.*, [1976] P.E.I.J. No. 38 (S.C.) [*Willis*]; *Alie v. Bertrand & Frere Construction Co.*, [2000] O.J. No. 1360 (S.C.J.) at paras. 132 -155 [*Alie*], findings on liability aff'd, [2002] O.J. No. 4697 (C.A.).

35 Tweden et al. (1997), "Biocompatibility..." [JHVD article].

36 Dr. Cameron's pathology report records that "KTMV-2 was an early death, cause of death unknown".

37 Tweden et al (1997), "Silver Modification...".

38 Foreign body response is an inflammatory reaction to the presence of a foreign material.

39 Grunkemeier et al. (2006); Objective Performance Criteria or OPCs are performance criteria based on data from historical databases that are generally accepted as acceptable values. Exhibit 258, the U.S. Department of Health and Human Services' 1994 Draft Replacement Heart Valve Guidance, establishes OPCs for heart valves for 8 specific complications reported from heart valve trials over the prior 20 years.

40 Exhibit 258/6, the U.S. Department of Health and Human Services' Draft Replacement Heart Valve Guidance (1994).

41 *Attis v. Canada (Minister of Health)*, 2008 ONCA 660, [2008] O.J. No. 3766 at para. 78, leave to appeal to S.C.C. refused, [2008] S.C.C.A. No. 491.

42 C.R.C., c. 871, s. 38(a).

43 Avrom et al. (1996); Grunkemeier et al. (1997).

44 *Attis* at para. 75.

45 [1995] 4 S.C.R. 634 [*Hollis*].

46 *Buchan* (C.A.) at para. 54.

47 Bambauer et al. (2004).

48 Hemmerlein et al. (1997); Ellender and Ham (1989), "Connective tissue responses to some heavy metals..."; Ellender and Ham (1989), "Silver wire implant..."; Hidalgo and Dominguez (1998); Jansson and Harms-Ringdahl (1993); Chen et al. (1994); Kraft et al. (1999); Wataha et al. (1991); McCauley et al. (1989); McCauley et al. (1994); Hollinger (1996); Trerotola et al. (1998); Steffensen et al. (1994).

49 See e.g. Ellender and Ham (1989), "Silver wire implant...".

50 Lansdown et al. (2004).

51 Bambauer et al. (1995); Bambauer et al. (1996); Bambauer et al. (2004) [Together, "the Bambauer Studies"].

52 Kraft et al. (1999); Kraft et al. (2001).

53 Wright et al. (2002).

54 Lansdown et al. (1997).

55 Goodman et al. (1998).

56 Dr. Hirsh is Professor Emeritus, Department of Medicine (Haematology), McMaster University.

57 Trerotola et al. (1998).

58 Kathuria et al. (1996).

59 Sudmann et al. (1994); Garcés-Ortiz (1997).

60 Clark et al. (1974); Collinge et al. (1994); Lansdown et al. (1997); Wright et al. (2002); the Bambauer Studies; Batt et al. (2003); Hardes et al. (2007).

61 Lansdown (2004).

62 Ueberrueck et al. (2003), "Healing Characteristics...".

63 The plaintiffs rely on Dr. Rodricks' testimony in cross-examination at paragraphs 573 to 575 of their Reply submissions, but they do not fairly describe his evidence. I agree with the

defendants that the plaintiffs mischaracterize his testimony or provide incomplete references to the transcript. See defendants' further written submissions at paragraphs 35-36.

64 Ueberrueck et al. (2005) "Vascular Graft Infections...".

65 Zegelman et al. (2009).

66 Hardes et al. (2007).

67 R. Williams et al. (1989).

68 Oloffs et al. (1994).

69 Exhibit 1844/2.

70 Exhibit 1844/3.

71 *Glaxo Canada Inc. v. Canada (Minister of National Health & Welfare)*, [1988] 1 F.C. 422, [1987] F.C.J. No. 838, aff'd [1990] F.C.J. No. 275 (F.C.A.).

72 The animal care records show that KTMV-2 had 14 stitches as compared with KTMV-1 (16 stitches) and KTMV-3 (15 stitches).

73 Deitch et al. (1989); Boosalis et al. (1986).

74 Ueberrueck et al. (2005), "Vascular Graft Infections...".

75 *McDougall v. Black & Decker Canada Inc.* (2008), 440 A.R. 253 (C.A.), at para. 18; *St. Louis v. R.* (1896), 25 S.C.R. 649.

76 *Blais v. Toronto Area Transit Operating Authority* (2011), 105 O.R. (3d) 575 (Ont. S.C.), at para. 82; *Gutbir v. University Health Network*, 2010 ONSC 6752, at para. 18.

77 *Anderson v. St. Jude Medical*, 2010 ONSC 5768.

78 Marbarger and Clark (1981).

79 Bull and Braunwald (1971).

80 Vitale et al. (1997).

81 Butany et al. (2006).

82 *Rothwell* at para. 59.

83 At para. 92.

84 Patients 2, 3, 5, 6, 9, 10, 13, 14.

85 The defendants' clinical experts were Dr. Mizgala (Patients 1, 3, 4, 5, 7, 9, 11, 12, 13, 14); Dr. Hirsh (Patients 2, 6, 10); Dr. Sexton (Patient 2); and Dr. Snyder (Patients 6 and 10). Dr. Factor provided evidence on Patient 6. Dr. Schoen testified about each of the patients with the exception of Patient 6.

86 The Modified Duke Criteria are the most commonly accepted tool for the diagnosis of both native valve and prosthetic valve endocarditis. See, Li et al. (2000).

87 Tozzi et al. (2001); Butany et al. (2002); Butany et al, (2006).

88 Schaff et al. (2002) ["AVERT Annals Paper"].

89 See *Rothwell.*

90 At para. 51.

91 2010 ONWSIAT 2513.

92 At para. 42.

93 At para. 47.

94 At para. 42.

95 Bradford Hill, A. (1965) at page 299.

96 *Decision No. 646/00R2*, 2006 ONWSIAT 2526.

97 Medical and Occupational Disease Policy Branch and the Occupational Disease and Survivor Benefits Program, "Taking ODAP into the future: A protocol for occupational disease policy development and claims adjudication," Draft - March 2005 (Toronto: WSIB, 2005) at page 20.

98 Edmunds et al. (1996) [Edmunds Guidelines]; Akins et al. (2008) [Akins Guidelines].

99 See, Footnote 39.

100 Referring to exhibit 921, the defendants note that despite purporting to use a 90-day cut-off, Dr. Madigan included 17 patients in his study who suffered embolisms within *30* days of implant, casting further doubt on the reliability of Dr. Madigan's linearized rates analysis. The plaintiffs say this was a clerical error that was corrected in the final calculations,

but they present no evidence to support this assertion.

101 Exhibit#1443/14.

102 Man-Son-Hing et al. (2002).

103 See Plaintiffs' submissions at paragraphs 1515 and 1574. The plaintiffs' Reply submissions appear to take a different approach and are confusing. They submit at paragraphs 679-681 that "the question should be about minimal clinically important differences" and that Dr. Sackett "established a specific range for [the MCID], that is, any relative risk between 1 and 1/3 and a doubling..." I am unable to reconcile this contradiction and can find no testimony of Dr. Sackett to support the proposition that he established a specific range for the MCID between 1 and 1/3 and a doubling. Indeed, it is unclear that he selected any MCID.

104 Exhibit 641/1.

105 See e.g. The AVERT Annals Paper.

106 Exhibit 1444.

107 Exhibit 1443.

108 Exhibits 284 and 285.

109 Exhibit 1443.

110 Exhibit 1444.

111 Exhibit 1444.

112 Thrombogenic potential refers to the potential to produce thrombus that may cause a blockage either at the valve site or elsewhere in the body after breaking away and travelling through the bloodstream.

113 Exhibit 1443.

114 Exhibit 564.

115 [1980] 2 S.C.R. 192.

116 *Resurfice Corp. v. Hanke*, [2007] 1 S.C.R. 333 at paras. 21-23.

117 Federal Judicial Center, *Reference Manual on Scientific Evidence*, 2d ed. (Washington D.C.; Federal Judicial Center, 2000) [*Reference Manual*] at p. 362, footnote 82.

118 43 F. (3d) 1311 [*Daubert II*].

119 573 F. (3d) 233 (5th Cir. 2009).

120 292 F. (3d) 1124 [*Hanford Nuclear*].

121 *Hanford Nuclear* at 1137 [emphasis added].

122 *Hanford Nuclear* at 1137.

123 *Hanford Nuclear* at 1137.

124 *Decision No. 600/97*, 2003 ONWSIAT 2153, [2003] O.W.S.I.A.T.D. No. 2106 [*Decision No. 600/97*].

125 *Decision No. 600/97* at paras. 116-122.

126 *Anderson v. St. Jude Medical Inc.*, (2003) 67 O.R. (3d) 136 at para. 62.

127 2008 ONCA 759, at paras. 56-57.

128 [1990] 2 S.C.R. 311 at para. 29 [*Snell*].

129 [1996] 3 S.C.R. 458 at para. 16 [*Athey*].

130 [1991] 1 S.C.R. 541 at paras. 156-157 [*Laferriere*].

131 [2011] O.J. No. 463 (S.C.J.) at para. 198 [*Goodman*].

132 (1998), 49 B.C.L.R. (3d) 100 [*Moore*].

133 2007 BCCA 622 at paras. 139-146.

134 (2006), 83 O.R. (3d) 282 at para. 56.

135 At para. 1802.

136 At para. 1811.

137 2010 ONCA 96.

138 Peter D. Maddaugh and John D. McCamus, *The Law of Restitution*, looseleaf (Aurora: Canada Law Book, 2009), at p. 24-1.

139 (2006) 85 O.R. (3d) 665 (Div. Ct.), leave to appeal to C.A. ref'd Oct. 16, 2006, leave to appeal to S.C.C. ref'd. [2006] S.C.C.A. No. 494 [*Serhan*].

140 [2007] O.J. No. 404 (S.C.J.), leave to appeal to Div. Ct. granted, [2007] O.J. No. 2709 (Sup. Ct. J.), aff'd (2008), 91 O.R. (3d) 691, [2008] O.J. No. 2610 (Div. Ct.) [*Ely Lilly*].

141 H. Michael Rosenberg, "Waiving Goodbye: The Rise and Imminent Fall of Waiver of Tort in Class Proceedings" (2010) 6:1 Can. Class Action Rev. 36; The Honourable Mr. Justice Todd L. Archibald and Christian Vernon, "No Harm, No Foul? The Existence of Waiver of Tort as an Independent Cause of Action in Canadian Law" (2008) *Annual Review of Civil Litigation* 409; Shantona Chaudhury and Paul J. Pape, "Damages in Waiver of Tort" (Paper delivered at the Continuing Professional Development workshop on "The Law of Damages", 27 March 2012).

142 See, "Ruling on Admissibility of Evidence of Professor Michael Trebilcock", 2011 ONSC 2178.

143 [1932] All E.R. Rep. 1; [1932] A.C. 562 (H.L.).

144 See, for example, *Cooper v. Hobart*, [2001] S.C.J. No. 76, [2001] 3 S.C.R. 537 (S.C.C.); *Attis v. Canada*; but see *contra*, *Sauer v. Canada (Attorney General)* (2008), 225 O.A.C. 143 (C.A.), leave to appeal ref'd, [2007] S.C.C.A. No. 454.

145 Steven Garber, "Product Liability, Punitive Damages, Business Decisions and Economic Outcomes" (1998) Wis. L. Rev. 237.

146 Richard L. Manning, "Is the Insurance Aspect of Producer Liability Valued by Consumers? Liability Changes and Childhood Vaccine Consumption" (1996) 13 *Journal of Risk and Uncertainty* 37; Richard L. Manning, "Changing Rules in Tort Law and the Market for Childhood Vaccines" (1994) 37 J.L. & Econ. 247.

147 *Watkins v. Olafson*, [1989] 2 S.C.R. 750, [1989] S.C.J. No. 94 at paras. 13-15; see also *Friedman Equity Developments Inc. v. Final Note Ltd.*, [2000] S.C.J. No. 37 at paras. 42-49.

Case Name:

Osmun v. Cadbury Adams Canada Inc.

Between
David Osmun and Metro (Windsor) Enterprises Inc.,
Plaintiffs, and
Cadbury Adams Canada Inc., The Hershey Company, Hershey Canada Inc., Nestlé Canada, Inc., Mars, Incorporated, Mars Canada Inc. and ITWAL Limited, Defendants
PROCEEDINGS UNDER the Class Proceedings Act, 1992

[2010] O.J. No. 2093

2010 ONSC 2752

97 C.P.C. (6th) 169

2010 CarswellOnt 3350

Court File No. 08-CV-347263PD2

Ontario Superior Court of Justice

G.R. Strathy J.

Heard: April 21, 2010 and by written submissions.
Judgment: May 13, 2010.

(34 paras.)

Civil litigation -- Civil procedure -- Parties -- Class or representative actions -- Motion for approval of fees and disbursements of class counsel with respect to partial settlements reached in this action alleged -- Settlement was product of cooperation between class counsel in Ontario, BC and Quebec -- BC and Ontario counsel had entered into contingency fee agreement -- Class counsel's fee in the amount of $1,487,195 was approved -- Partial settlement was an excellent result for the class -- Considering legal complexity of the action, the degree of responsibility assumed by the solicitors, and the risks taken by the solicitors in taking on this case, the fees requested were reasonable.

Legal profession -- Barristers and solicitors -- Compensation -- Contingency agreements -- Fair and reasonable -- Motion for approval of fees and disbursements of class counsel with respect to partial settlements reached in this action alleged -- Settlement was product of cooperation between class counsel in Ontario, BC and Quebec -- BC and Ontario counsel had entered into contingency fee agreement -- Class counsel's fee in the amount of $1,487,195 was approved -- Partial settlement was an excellent result for the class -- Considering legal complexity of the action, the degree of responsibility assumed by the solicitors, and the risks taken by the solicitors in taking on this case, the fees requested were reasonable.

Professional responsibility -- Self-governing professions -- Remuneration -- Contingency fees -- Motion for approval of fees and disbursements of class counsel with respect to partial settlements reached in this action alleged -- Settlement was product of cooperation between class counsel in Ontario, BC and Quebec -- BC and Ontario counsel had entered into contingency fee agreement -- Class counsel's fee in the amount of $1,487,195 was approved -- Partial settlement was an excellent result for the class -- Considering legal complexity of the action, the degree of responsibility assumed by the solicitors, and the risks taken by the solicitors in taking on this case, the fees requested were reasonable.

Motion for approval of fees and disbursements of class counsel with respect to partial settlements reached in this action. The settlement was the product of cooperation between class counsel in Ontario, BC and Quebec. BC and Ontario counsel had entered into a contingency fee agreement. Class counsel in the three provinces had agreed to collectively request court approval of legal fees in a total amount equal to 25 per cent of the Cadbury settlement amount, plus disbursements and applicable taxes. The contingency fee permitted by the retainer agreements was 30 per cent.

HELD: Motion allowed. The settlement was fair and reasonable and in the best interests of the class. Class counsel's fee in the amount of $1,487,195 was approved. The partial settlement was an excellent result for the class, with major financial and non-financial benefits. The fee agreement in this case complied with the requirements of s. 32(1) of the Class Proceedings Act. There was jurisdiction to make an interim fee award and that it was appropriate to do so in this case. It was permitted by the retainer agreement. Since the settlement class is defined to include all persons in Canada who purchased chocolate products during the settlement period, regardless of whether they purchased from Cadbury or a non-settling defendant, there was no concern that the interim fee award would be an excessive or unfair burden on some members of the class. The payment of an interim fee award would help to promote early settlement. The payment of interim fees was in keeping with sound business practice. Significant time and money have been expended by class counsel in pursuing this litigation. Considering the legal complexity of the action, the degree or responsibility assumed by the solicitors, and the risks taken by the solicitors in taking on this case, the fees requested were reasonable.

Statutes, Regulations and Rules Cited:

Class Proceedings Act, 1992, S.O. 1992, c. 6, s. 32(1), s. 33(4), s. 33(7)(c)

prgmrgxking

Counsel:

Harvey T. Strosberg Q.C. and *Charles M. Wright*, for the plaintiff.

REASONS FOR DECISION - FEE APPROVAL

1 G.R. STRATHY J.:-- This is a motion for approval of fees and disbursements of class counsel with respect to partial settlements reached in this action. The settlements are conditional upon approval of the courts in each of Ontario, British Columbia and Québec. In reasons released on May 5, 2010, I approved the settlements. A motion for settlement approval will be heard by the Supreme Court of British Columbia on May 25, 2010 and by the Québec Superior Court on June 8, 2010.

2 The details of these proceedings, and of the settlements, are set out in my reasons on the settlement approval: *Osmun v. Cadbury Adams Canada Inc,* 2010 ONSC 2643. The key terms for present purposes are:

(a) Cadbury has paid $5,795,695.60 inclusive of pre-deposit interest for the benefit of settlement class members. Cadbury is also obligated to pay the costs of notice that exceed $250,000;
(b) Cadbury has agreed to cooperate with the plaintiffs in pursuing their claims against the non-settling defendants;
(c) ITWAL is required to assign to the settlement class its claims against the non-settling defendants and to pay the costs of notice up to $25,000; and
(d) ITWAL has agreed to cooperate with the plaintiffs in pursuing their claims against the non-settling defendants.

3 I have found that the settlement is fair and reasonable and in the best interests of the class. It is the product of cooperation between class counsel in Ontario, B.C. and Québec. Approval of a combined counsel fee, to be shared with B.C. class counsel, is being sought in this action and in the B.C. action, based upon the share of the settlement amount notionally allocated to these two proceedings. A separate counsel fee will be sought in the Québec action based upon the share of the settlement amount notionally allocated to that proceeding. Class counsel in Ontario and B.C. are seeking a combined fee award because they have pursued the proceedings on a national basis outside Québec, with the litigation being focused in Ontario. B.C. class counsel has assisted in the prosecution of the Ontario action.

4 By agreement amongst class counsel in Ontario, Québec and B.C., 7.2% ($414,383.31) of the settlement amount has been notionally allocated as the recovery of the Québec settlement class for the purpose of their fee request. The remaining 92.8% of the settlement amount, ($5,340,940.48), has been notionally allocated to the recovery of the Ontario and B.C. settlement classes for the purpose of this fees request. Class counsel in the three provinces have agreed to collectively request court approval of legal fees in a total amount equal to 25% of the Cadbury settlement amount (including accrued interest), plus disbursements and applicable taxes.

5 Class counsel also commenced actions in Alberta, Manitoba, Saskatchewan, Newfoundland, Nova Scotia, and New Brunswick, working with local counsel in each province. Other lawyers have also commenced actions in some of these provinces as well as in other provinces. Class counsel have worked cooperatively with the lawyers in those actions and it has been agreed that the plaintiffs is those actions will resolve their claims as part of the settlement agreements made in this action and the B.C. action.

6 From the outset, Ontario class counsel agreed to pursue this action on a contingent fee basis, accepting responsibility for all costs and seeking court approval for a fee if successful.

7 The retainer agreement entered into with the plaintiffs in this action as of December 1, 2007, provides that in the event of success in the action, Ontario class counsel will be paid any disbursements (not already recovered from the defendants as costs), plus applicable taxes and interest in accordance with s. 33(7)(c) of the *Class Proceedings Act, 1992,* S.O. 1992, c. 6 (*"C.P.A."*), plus the greater of:

(a) the base fee increased by a multiplier of 4, less any fees already recovered as costs, plus applicable taxes; or
(b) if a settlement is reached before examinations for discovery, 30% of the settlement, less any fees already paid, plus applicable taxes.

8 "Success" is defined in the retainer agreement to include "a settlement that benefits some or all of the Class members." Under the heading "Interim Distributions," the agreement provides that "The Court may authorize payments to the Solicitor and/or to the Class from time to time."

9 The retainer agreement entered between the plaintiff in the B.C. action and B.C. class counsel also provides for payment on a contingency basis. It provides that class counsel will be paid a fee calculated as 30% of the value of any settlement including any partial settlement and will be payable on all amounts, including prejudgment interest and post judgment interest.

10 The fee agreement in this case complies with the requirements of s. 32(1) of the *C.P.A.*

11 Class counsel in Ontario and B.C. request fees of $1,335,235.12 with respect to the settlement, plus disbursements of $81,231.04 and G.S.T. in the amount of $70,729.60, for a total of $1,487,195.76. The fee represents 25% of the portion of the settlement amount allocated to the

Ontario and B.C. settlement classes ($5,340,940.48) and is less than the 30% permitted by the retainer agreements entered into with the plaintiffs in this action and the B.C. action.

Analysis

12 The court has inherent jurisdiction to supervise the conduct of lawyers, including the jurisdiction to supervise the fees they charge to clients: *Glanc v. O'Donaghue,* 2008 ONCA 395, 90 O.R. (3d) 309. In class proceedings, the court exercises that supervisory jurisdiction over the fees charged by class counsel. Subsection 32(2) of the *C.P.A.* states that an agreement respecting fees and disbursements between a solicitor and representative party is not enforceable unless approved by the court. Subsection 32(1) sets out the terms that must be included in such an agreement.

Interim Fee Awards

13 I am satisfied that there is jurisdiction to make an interim fee award and that it is appropriate to do so in this case. It is permitted by the retainer agreement. Since the settlement class is defined to include all persons in Canada who purchased chocolate products during the settlement period, regardless of whether they purchased from Cadbury or a non-settling defendant, there is no concern that the interim fee award will be an excessive or unfair burden on some members of the class. This is similar to the form of settlement in *Catalyst Paper Corp. v. Atofina Chemicals Inc.,* 2009 BCSC 1659, [2009] B.C.J. No. 2409, in which an interim fee was approved on a partial settlement. The court noted, at paras. 59-60:

> All plaintiffs share in the success that has been achieved to date. Similarly, all plaintiffs share an interest in ensuring that the litigation continues to conclusion as against the non-settling defendants.
>
> As a result of this structure, no group of plaintiffs can say that legal fees fall disproportionately upon those whose claims have been settled early or those whose claims have not yet been settled.

14 I accept the submission of class counsel that the payment of an interim fee award is a salutary measure that will help to promote early settlement. Similar observations were made in *Catalyst Paper Corp. v. Atofina Chemicals Inc.,* at para. 63:

> In my view, the court should seek to establish a regime that is conducive to settlements generally. Permitting the payment of counsel fees on interim settlements is an important element of such a regime.

15 The payment of interim fees is in keeping with sound business practice. Most paying clients (and undoubtedly most defendants in class actions) expect to be billed and to pay on an ongoing basis.

16 There is precedent in this jurisdiction for the award of interim fees on partial settlement: *Nutech Brands Inc. et al* v. *Air Canada et al*, [2009] O.J. No. 710, above, (19 February 2009), London, 50389CP (S.C.J.); *Vitapharm Canada Ltd. v. F. Hoffmann-La Roche Ltd.*, [2005] O.J. No. 1117, [2005] O.T.C. 208 (S.C.J.).

Contingent Fee Arrangements

17 The *C.P.A.* expressly permits contingent fee arrangements - fees payable only in the event of success: s. 33(1). It is a common practice, indeed an almost invariable practice, for class counsel to enter into an agreement for a contingent fee based on a percentage of the recovery.

18 A number of cases have recognized that such arrangements reward results achieved rather than time spent: *Cogan (Re)* (2007), 88 O.R. (3d) 38, [2007] O.J. No. 4539 (S.C.J.) at paras. 37 and 50; *Crown Bay Hotel Ltd. Partnership* v. *Zurich Indemnity Co. of Canada* (1998), 40 O.R. (3d) 83 at 88, [1998] O.J. No. 1891 (Gen. Div.) at para. 11.

19 In the context of class proceedings, a contingent fee agreement focuses on the benefit achieved by the class: *Vitapharm Canada Ltd.* v. *F. Hoffmann-La Roche Ltd.*, above, at para. 107; *Endean* v. *Canadian Red Cross Society*, 2000 BCSC 971, [2000] B.C.J. No. 1254 (S.C.) at para. 74.

20 Section 33(4) of the *C.P.A.* provides that a contingent fee arrangement may include a provision that permits the lawyer to move to the court to have his or her fees increased by a multiplier. On such motion, the court is to determine a "base fee" (i.e., time multiplied by an hourly rate) and may apply a multiplier to the base fee that results in fair and reasonable compensation to the solicitor for the risk incurred in undertaking and continuing the proceeding under an agreement for payment only in the event of success. This "multiplier" approach has been regarded by some as encouraging inefficiency and discouraging early settlement: *Martin* v. *Barrett*, [2008] O.J. No. 2105, 55 C.P.C. (6th) 377 (S.C.J.) at para. 38-39; *Cassano* v. *The Toronto-Dominion Bank* (2009), 98 O.R. (3d) 543, 2009 CarswellOnt 4052 (S.C.J.) at paras. 55, 60, 63.

21 There is much to be said in favour of contingent fee arrangements. Litigants like them. They provide access to justice by permitting the lawyer, not the client, to finance the litigation. They encourage efficiency. They reward success. They fairly reflect the considerable risks and costs undertaken by class counsel, including the risk that they will never be paid for their work, the risk that their compensation may come only after years of unpaid work and expense, and the risk that they will be exposed to substantial cost awards if the action fails. Effective class actions simply would not be possible without contingent fees. Contingent fee awards serve as an incentive to counsel to take on difficult but important class action litigation.

22 It is appropriate to use other methods of measurement, such as time multiplied by hourly rate, or a multiplier, or the result, as a check against the reasonableness of the fees claimed; but, in my respectful view, courts should not be too quick to disallow a fee based on a percentage simply because it is a multiple - sometimes even a large multiple - of the mathematical calculation of hours

docketed times the hourly rate.

Factors to be considered

23 Some of the factors to be considered by the court in the determination of class counsel's fee include:

(a) the time expended by the solicitor;
(b) the legal complexity of the matters to be dealt with;
(c) the degree of responsibility assumed by the solicitor;
(d) the monetary value of the matters in issue;
(e) the importance of the matter to the client;
(f) the degree of skill and competence demonstrated by the solicitor;
(g) the results achieved;
(h) the ability of the client to pay;
(i) the client's expectations as to the amount of the fee;
(j) the risks undertaken by counsel in taking on the case, including the risk that the action may not be certified; and
(k) the position taken by any objectors.

24 In this case, the following factors are particularly important.

Time expended

25 Significant time and money have been expended by class counsel in pursuing this litigation. As of March 22, 2010, Class Counsel had docketed time worth $632,743.75 and incurred disbursements of $81,231.04 plus applicable taxes. A good deal of additional time has been docketed in preparation for the settlement and fee approval hearings.

26 Class counsel has funded all of the disbursements associated with the Ontario and B.C. actions. The plaintiffs in this action have not applied to the Class Proceedings Fund for assistance. If the class had received disbursements funding from the Fund, it would now be obligated to repay any financial support provided by the Fund and pay an additional 10% of the settlement funds.

Result achieved

27 I have concluded that the partial settlement is an excellent result for the class, with major financial and non-financial benefits. The result achieved is an important consideration in determining the reasonableness of the fee: *Parsons* v. *Canadian Red Cross Society* (2000), 49 O.R. (3d) 281, [2000] O.J. No. 2374 (S.C.J.), at paras. 15-17.

Complexity, importance and value of the litigation

28 This is legally and factually complex litigation. The issues are of significant private

importance to the class, but they also raise concerns of public importance. The amounts at issue are in the many millions of dollars. Counsel should be well compensated for bringing this stage of the litigation to a conclusion.

Skill and diligence

29 The settlement is the product of many months of negotiation. It is complex and it has been carefully crafted. It required negotiation with the settling defendants but it also required negotiation and discussion with numerous counsel across the country. Bringing all these lawyers, and their clients, on side was no small task. The settlement has been achieved relatively early in the litigation and it seems probable that it will substantially improve the plaintiffs' prospects in the litigation.

Reasonableness of contingent fee

30 The contingent fee permitted by the retainer agreements is 30%. Class counsel seeks a fee of 25%. I accept the submission of Mr. Wright that this is consistent with the terms of retainer agreements and fees awarded by the courts in other price-fixing conspiracy cases: *Nutech Brands Inc. et al* v. *Air Canada et al*, above, (25% plus disbursements) at paras. 7-8; *Bona Foods Ltd. et al.* v. *Ajinomoto U.S.A., Inc et al.,* [2004] O.J. No. 908, 2 C.P.C. (6th) 15 (S.C.J.) (25% plus disbursements) at paras. 40-42; *Minnema et al.* v. *Archer Daniels Midland Company et al.,* (28 February 2003), Barrie Court File No. G23495-99CP (S.C.J.) (25% plus disbursements) at pp. 4-5.

31 As I have noted, on a straight "time and hourly rate" basis, class counsel's charges would be $632,743.75, excluding disbursements. The effective multiplier being requested, therefore, is about two, which is not out of the reasonable range. That range has been expressed as being from slightly greater than one (at the low end) to four or higher in the most deserving cases: *Gagné* v. *Silcorp Ltd.* (1998), 41 O.R. (3d) 417 at p. 425, [1998] O.J. No. 4182 (C.A.) at paras. 16-27.

Absence of objection from class members

32 The notice to class members identified the fee being sought by class counsel. There has been no opposition from the class. Both representative plaintiffs support the proposed fee.

Conclusion

33 The amount claimed is in line with the fee agreement and, in fact, it is somewhat less. The partial settlement can be regarded as a successful piece of work by class counsel. It is a success in its own right and it may well pave the way for further settlements. If not, it provides the settlement class with both a reasonable recovery and a strategic advantage. In the result, class counsel's fee in the amount of $1,487,195.76 is approved.

34 In the event of future fee approval motions, the time spent by counsel to date will effectively be cleared off the ledger as covered by this award. This will not preclude class counsel from

referring to that time as a factor to be considered in the context of the overall fees claimed in the future.

G.R. STRATHY J.

cp/e/qllxr/qljxr/qlltl/qljxr/qljyw

Case Name:

Hislop v. Canada (Attorney General)

PROCEEDING UNDER the Class Proceedings Act, 1992
Between
George Hislop, Brent E. Daum, Albert McNutt, Eric Brogaard and Gail Meredith, plaintiffs, and
The Attorney General of Canada, defendant

[2004] O.J. No. 1867

[2004] O.T.C. 392

3 C.P.C. (6th) 42

130 A.C.W.S. (3d) 907

Court File No. 01-CV-221056CP

Ontario Superior Court of Justice

E. Macdonald J.

Heard: February 12, 2004.
Judgment: April 30, 2004.

(28 paras.)

Counsel:

J.J. Camp, Patricia LeFebour and Victoria Paris, for the plaintiffs.
Sheila R. Block, for the plaintiffs Counsel Group.

REASONS FOR DECISION

E. MACDONALD J.:--

Introduction and Background

1 This motion is brought by Roy Elliott Kim O'Connor LLP ("REKO") on behalf of the plaintiffs' counsel group ("PCG") under s. 32(2) of the Class Proceedings Act, 1992, S.O. 1992, c. 6 ("CPA") for approval of fees and disbursements (retainers). The retainers are in the form of written agreements with each of the representative plaintiffs. The retainers with George Hislop, Albert McNutt and Brent Daum provide for a contingency fee of 25% plus party and party costs. The retainers with Gail Meredith and Eric Brogaard provide for a contingency fee of 33 1/3%.

2 REKO seeks a fee based on a multiplier of at least 5 for all fees incurred up to and including the final disposition of the matter whether by court order or settlement. Ms. Block submitted that the appropriate multiplier is 6 times up to judgment and 4 times for the appeal. For the administration, the PCG proposes an hourly rate with no multiplier.

3 In the alternative, REKO seeks a fee of 25% on the total value of the award, plus applicable taxes, plus a 1% levy for a disbursement fund. In addition and in accordance with the retainer agreement, REKO asks that it be paid any amount awarded in costs.[1]

4 Each of the representative plaintiffs received notice of this motion. Each of them consents to the orders being sought. The Attorney General of Canada ("AGC"), not being affected by this order, is not entitled to notice. For the reasons set out below, I find that the multiplier approach is most appropriate to the unique circumstances of this case. I fix it at 4.8, which is at the high end of the range of multipliers in class action litigation in Canada. Before dealing with the factors that have influenced my determination of the appropriate multiplier, I refer to Gagne v. Silcorp Ltd. (1998), 41 O.R. (3d) 417, wherein Goudge J.A. observed the following after setting out s. 33 of the CPA:

> Another fundamental objective is to provide enhanced access to justice to those with claims that would not otherwise be brought because to do so as individual proceedings would be prohibitively uneconomic or inefficient. The provision of contingency fees where a multiplier is applied to the base fee is an important means to achieve this objective. The opportunity to achieve a multiple of the base fee if the class action succeeds gives the lawyer the necessary economic incentive to take the case in the first place and to do it well. However, if the Act is to fulfill its promise, that opportunity must not be a false hope.
>
> ....
>
> The multiplier is in part a reward to the solicitor for bearing the risks of acting in the litigation. The court must determine whether these risks were sufficient that together with the other relevant considerations a multiplier is warranted. While this determination is made after the class proceeding has concluded successfully,

> it is the risks when the litigation commenced and as it continued that must be assessed.
>
> ....
>
> I recognize that the selection of the precise multiplier is an art, not a science. All the relevant factors must be weighed. Here, while the risk of an adverse finding on liability was minimal, there was a material risk of non-certification. As well, as I have outlined, there were significant elements of success in the manner in which the solicitors conducted the proceedings. Weighed against these success factors is the fact that following the April 17, 1997 settlement, individual class members had to incur further legal fees to finally realize on their claims. [emphasis added]
>
> In the end, three considerations must yield a multiplier that, in the words of s. 33(7)(b), results in fair and reasonable compensation to the solicitors. One yardstick by which this can be tested is the percentage of gross recovery that would be represented by the multiplied base fee. If the base fee as multiplied constitutes an excessive proportion of the total recovery, the multiplier might well be too high. A second way of testing whether the ultimate compensation is fair and reasonable is to see whether the multiplier is appropriately placed in a range that might run from slightly greater than one to three or four in the most deserving case. Thirdly, regard can be had to the retainer agreement in determining what is fair and reasonable. Finally, fair and reasonable compensation must be sufficient to provide a real economic incentive to solicitors in the future to take on this sort of case and to do it well.

5 These are the considerations that have influenced my thinking on the choice of multiplier.[2] This case is in the category of "the most deserving case".

Factual Background

6 This action claimed Canada Pension Plan ("CPP")[3] survivors' pensions for surviving same sex partners of persons who died between April 17, 1995 and January 1, 1998. The action was framed under s. 15 of the Canadian Charter of Rights and Freedoms.[4] It also claimed equitable relief that was dismissed in my reasons for judgment released on December 19, 2003. The judgment was in favour of the class members on the s. 15 claims. Interest was awarded on the arrears beginning in February 1992.

7 Ms. Block stated that these class proceedings are the largest class action award after trial in

Canadian legal history. The award has the potential value of $81 million.[5] This is the first class action judgment in the world that addressed an infringement of the rights of lesbians and gay men. The appeal from the judgment is being heard in June 2004.

8 Under ss. 32 and 33 of the CPA, a retainer between counsel and the representative plaintiff or plaintiffs cannot be enforced without the approval of the court. Cullity J., appointed as the case management judge, directed that the trial judge approve the form of the retainer. If the retainers are approved as requested by the PCG, the net recovery to the class members should be about 70% of their individual claims after legal fees and all applicable taxes and disbursements are deducted. Each of the representative plaintiffs consents to the approval of the retainers. Each has filed an affidavit in which he/she expresses appreciation for the extraordinary efforts of their counsel and for the results achieved at trial.

Plaintiffs' Counsel Group (PCG)

9 I note the following about the PCG. They are an outstanding group of men and women from across Canada, all of whom have a high level of expertise in class actions and same sex equality rights litigation.

10 Mr. Elliott, lead counsel for the class members, has extensive experience in Charter litigation, especially in cases involving equality rights for gay men and lesbians. Mr. Camp and Ms. Matthews are also very experienced in class proceedings and were the lead counsel in the B.C. action. Ms. Matthews was co-counsel at the trial. The other members of the counsel team from coast to coast were selected by Mr. Elliott because of their past experience and their willingness to work in a national team environment.

11 Because of the nature of the claims being advanced, it was difficult to identify lesbians and gay men who were willing to serve as representative plaintiffs. Many people who would otherwise be eligible as representative plaintiffs were shy about the publicity of this action and the potential for invasion of the privacy of their sexual orientation and their relationships. They knew that this case would attract significant media attention. These factors made it difficult to identify persons who would come forward and who were prepared to endure the glare of publicity that was inevitable from being a representative plaintiff.

The Risks In This Class Action

12 In this case there were significant risks for the PCG. These risks infuse the determination of the appropriate multiplier. Any lawyer, considering a retainer in an action such as this would know that he/she faced the burden of accumulating very significant work in progress without compensation for a long period of time.[6] As the court remarked in Endean v. Canadian Red Cross Society, [2000] B.C.J. No. 1254, this was "bet your firm" litigation.

13 Aside from the financial burden and risk undertaken by the PCG, there are other risks that are

set out in paragraph 18 of PCG's factum. Rather than paraphrase these risks, I reproduce them exactly as they appear in the factum:

a. Chance of having the equitable claims struck - There was a risk that the Crown would succeed in having these claims struck in the Rule 21 motion. If this were the case, it could have had the effect of weakening the chances of certification. This risk no longer exists.
b. Failure to certify the equitable claims - There was a risk that even if the equitable claims survived the Rule 21 motion of the Crown, these claims would be unsuccessful on certification. This risk no longer exists.
c. Failure to certify the Charter claims - There was a risk that certification would not occur in B.C. because of the Auton[7] decision. In Ontario, the chances of certifying a class proceeding on a Charter issue alone were significantly less. This risk no longer exists.
d. Failure to succeed at trial - There was a risk that the class members would not succeed on any of the claims advanced. The Crown argued consistently that this Class Action was concerned with Parliament's ability to select an effective date of legislation and was not concerned with discrimination. If the class members were entirely unsuccessful at trial, there would have been no recovery to them and counsel would have received nothing according to the Retainer. This risk no longer exists.
e. Failure to succeed on any of the common issues at trial - There were 17 common issues identified for the trial of this action. There was a material risk that the plaintiffs could have failed on any or all of those common issues. In fact, the plaintiffs did:

    i. Fail to establish any of the equitable claims: This risk materialized. Since there is no cross-appeal there is no hope of an alternate outcome.
    ii. Fail to win full interest: For the period since February 1992, the plaintiffs were successful in winning interest. However, since this aspect of the judgment is under appeal, there is still a risk that may materialize. With respect to interest prior to that time, the plaintiffs were unsuccessful. Since there is no cross appeal, there is no hope of an alternate finding on that point.
    iii. Fail to win symbolic damages for the class members. This risk materialized. Since there is no cross-appeal there is no hope of an alternate outcome.
    iv. Fail to win damages pursuant to s. 24 of the Charter. This risk materialized. Since there is no cross-appeal there is no hope of

an alternate outcome.

f. Failure to win the equitable claims at trial - There is a risk that, if the equitable claims were unsuccessful at trial, the class members would have to succeed on the Charter claims, including entitlement to the arrears of the CPP survivor pension, in order to be fully successful. This risk materialized. Since there is no cross-appeal there is no hope of an alternate outcome.

g. Risk of having certain provisions of the CPP struck and others remain - It was possible that the trial judge could have found certain provisions of the CPP, whether or not they were of general application, to be constitutional, while finding others to be in violation of s. 15(1). This could have produced a pyrrhic victory for the class members. This risk still exists because of the appeal.

h. Risk of application of statutes of limitations - If the Crown were successful on having various statutes of limitation apply in this Class Action, the amount recoverable by the class members would be reduced. For example, the arrears could be limited to one year. This risk is extant because of the appeal by the Crown.

i. Risk of application of CPP insulating clause - Section 65 of the CPP precludes any payment from being attached or assigned. If the Court were to rule that these provisions applied, there would be restrictions on the ability of counsel to collect their fees. This risk continues to exist.

j. Failure to succeed on remedy at trial - There was a significant risk that, even if the class members were successful at establishing a s. 15(1) Charter breach which was not saved by s. 1, the court would award the CPP survivor pensions only on a prospective basis, without interest. This outcome would have reduced the recovery to the class members by a considerable degree and would also have had a negative impact on the fees to counsel. This risk existed up to and including the trial and still exists on the appeal.

k. Risk of having the trial decision overturned on appeal - There is a material risk that, because of the appeal by the Crown from the trial decision, the class members' recovery and payment of counsel's fees will be delayed. Moreover, there is always a risk that the trial decision will be overturned in whole or in part, which will mean either no recovery for the class members or a significantly reduced recovery and accordingly no recovery for counsel. There is also a risk that the defendant will, if unsuccessful at the Court of Appeal, seek leave to appeal to the Supreme Court of Canada.

l. Use of notwithstanding clause - There has always been and continues to be a material risk that if the Crown does not wish to accept a court ruling, it

can invoke the notwithstanding clause. In this event, the class members would be powerless and would receive nothing.

14 The AGC put forth a vigorous and able defence to these claims. It brought motions to strike the claims in Ontario and British Columbia. It opposed certification of the class proceeding in British Columbia. There were examinations for discovery of all representative plaintiffs prior to trial. There was documentary production of approximately 3,500 documents. In summary, the AGC was a well-funded opponent. In this high profile case, excellent counsel fought hard on behalf of the AGC.

15 The reality is that there is no vehicle other than a class proceeding by which these claims could have been advanced. Individual class members could not afford to mount a legal challenge on their own to obtain a CPP survivors' pension. Proceeding by way of this class action provided the representative plaintiffs with the opportunity to advance their claims with no financial exposure to them as individuals.

Section 33 of the CPA

16 Under s. 33 of the CPA, a solicitor and a representative party may enter into an agreement which provides for the payment of fees and disbursements only in the event of success in a class proceeding, where success is defined as judgment on common issues or a settlement for the benefit of the class members. A pattern has developed that supports the concept that counsel are to be paid a premium on their base fees in the event of success. A judge hearing a motion such as this selects the method of calculating the fees whether by way of a percentage of the recovery or a multiplier on the base fee amount.

PCG's Approach

17 The PCG have submitted that the percentage approach provided in the retainers is not the preferable method for compensation in this case. I agree. The percentage approach could result in unfairly low compensation if the class size is smaller than anticipated or the "take up rate" is low. It is estimated that there are a maximum 1500 class members. If this were so, the total fees would be approximately $20 million using the percentage approach. This is based on the application of 25% to Chief Actuary Menard's calculation of a total award of approximately $81 million plus costs. However, the reality is that there has never been a class proceeding that has had 100% participation by class members. Class proceedings where there is a high level of participation generally involve cases where there is a known finite group such as patients of a physician. In those cases, class members are readily identified and contacted. Even in cases with high participation rates such as Nantais v. Telectronics Proprietary (Canada) Limited (1996), 28 O.R. (3d) 523 and Anderson v. Wilson (1997), 32 O.R. (3d) 400 (certification motion), the participation rates did not exceed 75%. I accept Ms. Block's submission that it is rare that a class action has more than a 75% "take-up" rate. To date, despite a well-funded notification campaign and the notoriety of the trial judgment in this case only 500 class members have come forward.

18 In addition, section 65 of the CPP provides that pensions are not to be attached or assigned. This is a consideration that underlies the proposal of the plaintiffs. It is suggested, that in the context of this motion, s. 65 of the CPP has no application to: (a) costs awarded, (b) pre-judgment interest or (c) post-judgment interest. Given the current numbers of class members, there is a risk that these three items will not be sufficient to protect the accounts of the PCG. In order to afford some protection to the PCG and at the same time ensure fairness to the class members, the PCG proposed the following steps once the fee is set:

a. All costs will be paid and applied directly against the amount;
b. All pre-judgment interest will be paid and applied directly against the amount;
c. All post-judgment interest will be paid and applied directly against the amount;
d. The ACG or administrator of the Class Action will withhold 50% of the arrears pending the hearing specified below;
e. On or about September 16, 2004, the situation will be reviewed on notice to the defendant and the representative plaintiffs. At that time, a determination will be made as to whether the balance of the arrears can be released or, alternatively, whether there is a need for argument on s. 65 of the CPP Act.[8]

19 The method of payment proposed by the PCG advantages the class members in the following ways:

a. it ensures that the future monthly pension cheque is available in full in total to meet the needs of class members so long as they live;
b. it provides the class members with certainty, finality and the psychological comfort of paying legal fees at one time when they are receiving a larger lump sum cheque for arrears and interest and without encumbering their future stream of survivor pensions; and,
c. it simplifies administration because once class members are "in pay", they can be paid directly by the Government with no further involvement by class counsel or the Court.

20 This process is fairest to the class members. Class members who have large claims for arrears and reduced expectations of a long stream of future income, (particularly those older class members whose partners died early in the class period), could pay a disproportionately higher burden of the fees compared to the younger class members whose partners died later in the class period. However, all class members will receive some arrears and some interest so all will make a contribution to fees. With the exception of George Hislop, there are no other known class members, who could potentially be affected by this approach. George Hislop has consented to this approach.

Compensation To The Representative Plaintiffs

21 The representative plaintiffs are entitled to payment for their work on the preparation of this case. The amounts that they request are modest. These amounts are to be treated as a disbursement and are recoverable from the class members. I agree that George Hislop should receive the highest amount of compensation with Gail Meredith and Albert McNutt receiving the second highest amounts and Eric Brogaard and Brent Daum receiving the third highest amounts.

22 For George Hislop, the amount is fixed at $15,000. For each of Gail Meredith and Albert McNutt, the amount is fixed at $10,000. For each of Eric Brogaard and Brent Daum the amount is fixed at $5,000. All five agree to the amounts as fixed. These amounts do not in any way compensate the representative plaintiffs for the enormous amount of their personal time and energy devoted to the advancement to these proceedings. It signals recognition of the value of their contributions to the other class members and to their counsel.

The Determination Of The Appropriate Multiplier

23 There have been various choices of appropriate multiplies in class proceedings. In Gagne, supra, the court indicated that in cases where certification is contested, the minimum multiplier that should be awarded is 2 times the hourly rate. The court has also indicated that rarely should the multiplier exceed 4 times the hourly rate.

24 The average multiplier for cases in Ontario that are settled prior to trial is approximately three times. The highest multiplier known in Ontario for a settlement in a class proceeding was 3.8 in Parsons v. Canadian Red Cross Society, [2001] O.J. No. 214, aff'd [2001] O.J. No. 214 (C.A).

25 In the United States multipliers in the range of 2 to 4 are common. Higher multipliers have been awarded in exceptional cases, such as cases that were tried or were exceptionally risky.[9]

26 My choice of a 4.8 times multiplier reflects fair compensation for very devoted and experienced counsel who carried enormous financial burden and risk in their commitment to access justice for the class members. I set out sample calculations of the range of fees that result from the use of multipliers at different levels. Based on total fees as at February 2004, of $3,067,352.15, these sample calculations are:

a. a 3 times multiplier would yield a fee of $9,202,056.45;
b. a 4 times multiplier would yield a fee of $12,269,408.60;
c. a 4.8 times multiplier would yield a fee of $ 14,723,290;
d. a 5 times multiplier would yield a fee of $15,336,760.75; and
e. a 6 times multiplier would yield a fee of $18,404,112.90.

27 The highest fee approved in Canada was in Parsons, supra and Endean, supra. Counsel submitted that in Parsons, the equivalent team was awarded a total of $30 million in a case that did

not reach trial.

28 4.8 shall be the multiplier for the trial and for the appeal. Fees for the administration will be at counsel's hourly rate.

E. MACDONALD J.

cp/e/nc/qw/qlrme/qlhcs

1 After I heard this motion I was advised by counsel that the parties were successful in reaching settlement on the quantum of costs to be paid by the AGC as a result of my judgment released December 19, 2003 which awarded costs to the plaintiffs.

2 I am also influenced by the recent decision in Christian Brothers of Ireland in Canada (Re), 68 O.R. (3d) 1, [2003] O.J. No. 4249, (O.C.A.) in which the court allowed a significant premium on fees, and held that a premium provides incentive to counsel to take on difficult litigation and to do it well. As in this case, "the litigation was complex, difficult and time consuming, its outcome uncertain." (See para. 3).

3 Canada Pension Plan, ss. 2(1) and 8(1).

4 Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act, 1982 (U.K.), 1982, c. 11, (the "Charter").

5 This is based on the assumption that there are approximately 1500 people who would be entitled to benefits as a result of the judgment but so far the "take-up" rate is 1/3 of the eligible class members.

6 This risk is so significant that one highly respected plaintiff's lawyer and one large Bay Street firm declined continued involvement in the case. Counsel for the class members also incurred significant disbursements in the course of the action, none of which has been reimbursed by the plaintiffs.

7 Auton v. British Columbia (2001), 197 D.L.R. (4th) 165 (B.C.S.C.); aff'd (2002) 220 D.L.R. (4th) 411 (B.C.C.A.), leave to appeal to the Supreme Court of Canada granted May 15, 2003, [2002] S.C.C.A. No. 510.

8 The PCG are content to have all of the fees awarded paid from the interest and costs on an interim basis with the result that it is premature to resolve the application of s. 65 of the CPP

to the solicitors lien on arrears at this time. If need be, I will be available to deal with this matter at some future point.

9 See: H. Newberg, A. Conte, "Newberg on Class Actions, 3rd ed". (1992), Footnote 21 which refers to two American decisions. One is a personal injury class action where a multiplier of 5 was fixed for lead counsel for contingency and superior trial skills. In another American decision, in the California Superior Court in August 1982 non-contingent hourly rates were fixed at up to $150 an hour with a multiplier of up to 10 times the hourly rate.

Case Name:

Wilson v. Servier Canada Inc.

PROCEEDING UNDER the Class Proceedings Act, 1992
Between
Sheila Wilson, plaintiff, and
Servier Canada Inc., Les Laboratoires Servier, Servier Amerique, Institut de Recherches Internationales Servier ("I.R.I.S."), Science Union et Cie, Oril S.A., Servier S.A.S., Arts et Techniques du Progres, Biologie Servier Institut de Developement et de Recherche Servier, Oril Industrie, Bio Recherche Servier, Instituto di Ricerca, Idux, Biopharma Artem, Science Union S.A.R.L., Laboratoires Servier Industrie, I.R.I.S. et Cie Developement, Information Servier, Servier Monde, Servier International, I.R.I.S. Services S.A.R.L., Adir, Servier R&D Benelux, Dr. Jacques Servier and Biofarma S.A., defendants

[2005] O.J. No. 1039

252 D.L.R. (4th) 742

[2005] O.T.C. 217

9 C.P.C. (6th) 83

137 A.C.W.S. (3d) 1104

140 A.C.W.S. (3d) 27

Court File No. 98-CV-158832

Ontario Superior Court of Justice

P.A. Cumming J.

Heard: October 18-19 and November 1-2, 2004.
Judgment: March 21, 2005.

(100 paras.)

Civil procedure -- Settlements -- Approval -- Legal profession -- Barristers and solicitors -- Compensation.

Application by the representative plaintiff, Wilson, for approval of a proposed settlement and for the approval of counsel fees. The class action involved a national class comprising all residents in Canada, except Quebec, and a British Columbia subclass. Counsel for the national class and subclass worked cooperatively. The action related to individuals who had ingested certain diet drugs. They claimed the diet drugs caused primary pulmonary hypertension and valvular heart disease. Scientific studies had verified a causal connection between the drugs and diseases. There had been at least 35 motions in the action. A nine-month trial had been anticipated before a mediation resulted in a settlement agreement three days before trial. Examinations for discovery took 11 weeks and occurred mainly in France. The settlement agreement provided for the defendant Servier Canada to establish a settlement fund of $25 million. A further $15 million was to be made available in the event the fund was insufficient to satisfy the claims made by class members. Any money not exhausted would revert back to Servier. Class counsel sought fees of $13 million.

HELD: Application allowed. The settlement agreement was fair and reasonable and in the best interests of all the class members. The very extensive cost in time and resources in the prolonged litigation was largely due to Servier's refusal to deal with the claims until immediately before trial. Class counsel fees were fixed at $10 million plus $2,619,536 in disbursements. The final amount of class counsel fees could not be determined before the settlement was implemented.

Statutes, Regulations and Rules Cited:

Class Proceedings Act, 1992, S.O. 2002, c. C.6, ss. 29(2), 32, 33.

France Civil Code, Article 15.

Counsel:

Joel Rochon, Vincent Genova and Sakie Tambakos for the National Class

David Klein and Gary Smith for the B.C. Sub Class

William W. McNamara, Stephen A. Scholtz, and Seana Carson for the Defendants

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REASONS FOR DECISION

P.A. CUMMING J.:--

The Motions

1 These Reasons for Decision deal with motions brought by class counsel under the Class Proceedings Act, 1992, S.O. 1992, c. C.6 as am. ("CPA") in respect of this class action: first, for approval of a proposed settlement; and second, assuming settlement approval, approval of the counsel fees.

2 This class action involves a national class comprising all residents in Canada (except for Quebec) and a British Columbia subclass. The national class and B.C. subclass have each made discrete motions but they are conveniently treated together as one. I shall refer to Rochon Genova as National Class Counsel and Klein Lyons as B.C. Class Counsel and collectively, the two firms simply as "class counsel." (Capitalized terms employed in these Reasons are found in the definition section of the Settlement Agreement.)

3 This was a cooperative effort by the two law firms and both gained significantly by the contribution of the personnel and resources of the other in this very demanding and protracted litigation. The two law firms have determined and agreed to a division between the two firms of the global class counsel fees approved by the Court. Thus, on the matter of the second motion as to the approval of class counsel fees, the Court will address the matter as though there is a single class counsel law firm.

4 At the conclusion of the hearing in respect of the first motion, approval of the settlement was granted orally, so that implementation could be expedited, with reasons to follow. These are the Reasons for Decision in respect of that settlement approval and these are the Reasons for Decision in respect of the second motion, being the matter of the determination and approval of class counsel fees.

The Motion for Settlement Approval

5 The representative plaintiff, Ms. Sheila Wilson, moves for approval of the Settlement Agreement in this national class action commenced November 17, 1998 on behalf of all residents in Canada, except for those individuals resident in Quebec, who had ingested the diet drugs Ponderal, Ponderal Recaps and/or Redux (collectively, the "diet drugs" or "Products"). Representative plaintiff Ms. Beverley Greenlees moves for approval on behalf of the B.C. subclass.

6 Fenfluramine, and later dexfenfuramine, the active ingredients in the diet drugs, were anorexigens introduced in Europe in the 1960s and in Canada in the 1970s. The claim alleges that the diet drugs caused primary pulmonary hypertension ("PPH") and/or valvular heart disease ("VHD") in some users of the diet drugs.

7 Ms. Wilson ingested diet drugs between August, 1995 and August, 1996. She became ill in late

1996 and was ultimately diagnosed in March, 1998 as having PPH. This disease reportedly results in diminished right-heart function and leads ultimately to heart failure and death. The reported mean survival period from the onset of symptoms to death for PPH patients is about two to three years.

8 VHD involves the failure of one or more of the valves of the heart to open or close properly. This results in regurgitation or the backwards flow of blood. This can lead to severe and potentially fatal complications, including congestive heart failure, shortness of breath, arrhythmias and bacterial endocarditis. Surgery may be necessary to repair or replace the defective valves.

9 Ms. Greenlees consumed Ponderal and developed VHD. Her daughter also consumed Ponderal. She developed PPH and had a double lung transplant but has died.

10 The first case report of a claimed association between PPH and the use of fenfluramine was published in the scientific literature in 1981. Ultimately, a multi-centre case-controlled epidemiologic study (known as the International Primary Pulmonary Hypertension Study ("IPPHS") led by Dr. Lucien Abenheim published its findings in the New England Journal of Medicine in August, 1996, concluding that there was a "causal relationship" between the use of fenfluramine derivatives and PPH. Several later scientific reports reached the same conclusion, being that a person's use of the diet drugs added definite risk factors for the development of PPH.

11 The diet drugs were withdrawn from the Canadian market and other markets around the world in September, 1997. The claim alleges that the diet drugs increased the risk of developing PPH and VHD, were unfit for the purpose for which they were intended as designed and that the defendants negligently failed to adequately disclose the risks to physicians and consumers and negligently misrepresented the safety of the drugs.

12 The defendant Servier Canada Inc. ("Servier") was the Canadian distributor of the diet drugs. The defendant Biofarma S.A. ("Biofarma"), a corporation in France, is the parent of Servier. Ultimately, several foreign corporations affiliated with Biofarma as well as its founder, Dr. Jacques Servier, were named and added as defendants. It is claimed that one or more of these foreign corporations manufactured and marketed the Products.

13 The certification motion was granted pursuant to written reasons released September 13, 2000. Wilson v. Servier Canada Inc. (2000), 50 O.R. (3d) 219 (Sup. Ct.); motion for leave to appeal to Divisional Court denied November 21, 2000, 52 O.R. (3d) 20; leave to appeal to Supreme Court of Canada dismissed, [2001] S.C.C.A. No. 88.

14 It is believed this class action has involved more court appearances than any other class action seen to date in Canada. There have been countless case conferences with at least thirty-five motions, and fifteen stay and leave applications and related appeals, including: (2000), 50 O.R. (3d) 219 (Sup. Ct.); [2000] O.J. No. 3722 (Sup. Ct.); (2000), 52 O.R. (3d) 20 (Sup. Ct.); [2001] S.C.C.A. No. 88; [2001] O.J. No. 1615 (Sup. Ct.); [2001] O.J. No. 4636 (Sup. Ct.); [2001] O.J. No. 4947 (Sup. Ct.); [2001] O.J. No. 5278 (Div. Ct.); [2001] O.J. No. 4636 (Sup. Ct.); [2001] O.J. No. 4626 (Sup.

Ct.); [2001] O.J. No. 4716 (Div. Ct.); [2001] O.J. No. 4717 (Sup. Ct.); [2001] O.J. No. 4947 (Sup. Ct.); [2002] O.J. No. 60 (Div. Ct.); [2002] O.J. No. 1021 (Sup. Ct.); (2002), 58 O.R. (3d) 753 (Sup. Ct.); [2002] O.J. No. 1663 (Div. Ct.); (2002), 213 D.L.R. (4th) 751 (Sup. Ct.); [2002] O.J. No. 2138 (Sup. Ct.); [2002] O.J. No. 3470 (Sup. Ct.); [2002] O.J. No. 3722 (Sup. Ct.); [2002] O.J. No. 3723 (Sup. Ct.); (2002), 220 D.L.R. (4th) 191 (C.A.); [2002] O.J. No. 4566 (Div. Ct.); [2003] O.J. No. 155 (Sup. Ct.); [2003] O.J. No. 156 (Sup. Ct.); [2003] O.J. No. 157 (Sup. Ct.); [2003] O.J. No. 179 (Sup. Ct.); [2003] O.J. No. 280 (Sup. Ct.).

15 The common issues trial was scheduled to commence February 24, 2003. A nine-month trial, conducted largely in the French language, was anticipated. A Court-ordered formal mediation under the supervision of Mr. Justice W. Winkler resulted in a settlement agreement-in-principle, reduced to writing February 21, 2003, three days before the scheduled commencement of the trial. An included provision stipulated that if agreement could not be reached on an implementing specific term, that the issue would be submitted to Winkler J. for a determination. He appointed Mr. Randy Bennett, a Toronto lawyer, as a Court-appointed Monitor, to facilitate the resolution of disputes in the process to achieve a final settlement agreement. A Settlement Agreement was ultimately accomplished with finality after more than 18 months, on September 17, 2004.

The Settlement Agreement

16 Information and detailed particulars as to the Settlement Agreement can be found on the web sites of class counsel: www.rochongenova.com and www.kleinlyons.com. Important matters and details pertinent to the motion for settlement approval at hand are dealt with in affidavits in the motion records of the plaintiff class and subclass, including the affidavits of: Ms. Sheila Wilson, Ms. Beverley Greenlees, Ms. Annelis Thorsen, Mr. Dana Graves, Dr. John Granton, Dr. Stephen Raskin and Mr. Kerry F. Eaton (of the claim administrator, Crawford Class Action Services).

17 The Settlement Agreement provides for a payment by the defendant, Servier Canada Inc. ("Servier"), to establish a Settlement Fund of $25 million. This Fund is to be administered by Crawford Class Action Services as Settlement Administrator. A further $15 million in "Additional Settlement Funds" is to be made available in the event that the Fund is insufficient to satisfy the claims made by class members. In addition, Servier is obliged to pay the administration costs and the costs of the two notice programs.

18 The Settlement Agreement provides for a reversionary interest in the $25 million Fund whereby, if the claimants' take-up does not exhaust the Fund, the residual unused amount will largely revert to Servier, and an additional amount will revert to provincial health providers.

19 If the $25 million is exhausted by claimants but the entirety of the guaranteed Additional Settlement Funds of $15 million is not necessary for claimants, any residual amount of this committed amount remains with Servier.

20 Given the reversionary interests of Servier in respect of the settlement monies, defendants'

counsel asked to make submissions relating to the determination of the question of approved class counsel fees.

21 The Court welcomed this submission. In the usual course of events, a court is left alone when it comes to considering the reasonableness of the requested class counsel fees. Defendants have agreed to a settlement and want it approved in the interest of their own clients and are indifferent to the fees paid to class counsel by class members.

22 Given the reversionary interest of Servier in the instant situation, defendants seek the Court's determination of "reasonable" class counsel fees that accord with their own view of reasonableness.

23 While the Court welcomes the submission of the defendants on this matter as a positive, constructively critical aid, this Court does not view the intervention of the defendants as a "right." The defendants have a clear "interest" in the outcome of the motion for the approval of class counsel fees. They are permitted to make submissions for that reason. But, in my view, they do not have the "right" to intervene in the determination of class counsel fees.

24 In Parsons v. Canadian Red Cross Society, [2001] O.J. No. 214 (C.A.), leave to appeal to Supreme Court of Canada denied, [2001] S.C.C.A. No. 190, the Court of Appeal found at para. 13 that "[t]he settlement agreement ... was the place where the defendants, if they intended to participate in the subsequent fixing of the fees and disbursements of class counsel, could have reserved their rights in this regard. There is no provision in the settlement agreement to this effect." The present case differs slightly in that paragraph 11(c) of the Settlement Agreement provides that the defendants are entitled to notice of a motion to determine "any further amount of Class Counsel Fees." The defendants submit that paragraph 11(c), on its face, clearly permits them to participate fully at the hearing of the motion to approve Class Counsel Fees. I disagree. On its face, the provision entitles them to reasonable notice of the hearing. That provision should not be extended to include a right to make submissions. As in Parsons, the defendants could have, but did not, ensure their right to make submissions by specifically including words to that effect in paragraph 11(c).

25 The defendants further submit that to deny them full participation in the hearing would be contrary to fundamental principles of justice and fairness, given their interest in the issue. They submit that theirs is the only interpretation of paragraph 11(c) that is consistent with the Settlement Agreement. The Settlement Agreement does not require that paragraph 11(c) be interpreted to include a right to standing and a right to make submissions. A contractual right to notice can be consistent with the lack of a corresponding right to full participation. Under various provisions of the Claims Administration Procedures, the defendants have a right to review all information and correspondence regarding approved claims, but no standing with regard to their determination by the claims adjudicators. I note that the defendants cannot challenge a claims adjudicator's determination. The defendants' various rights to information and notice reflect their role in the overall implementation of the settlement, but do not automatically include full participation rights in every hearing.

26 In Parsons, supra, the Ontario Court of Appeal found at para. 12 that having made submissions to assist Winkler J. in approving counsel fees did not mean that the defendants were parties to the motion since they did not seek, and were not granted, party status. While finding that the defendants were not parties, the court went on to say at para. 19 that "[n]othing we have said, of course, is intended to reflect a view on whether or not defendants in some class proceedings should have the right to participate as parties with rights of appeal in fee-fixing motions or applications. Much will depend on the facts of the particular case." In this case, the defendants attempt to distinguish Parsons based on the fact that they have "a clearly-defined contractual" interest in any residual Settlement Funds, and control of the Additional Settlement Funds. At para. 17 of Parsons the Court of Appeal recognized that the defendants had an interest in the fund surplus, but that the interest was "highly speculative and contingent." In my view, and I so find, the defendants' interest in the present case is similarly contingent and speculative. That the contingent, speculative interest is a contractual one does not sufficiently distinguish the facts of Parsons.

27 Finally, Servier is committed to pay $3 million in respect of partial indemnity costs to the plaintiff class plus $1 million in compensation for the plaintiffs' litigation disbursements. It is noted parenthetically as well that class counsel was awarded some $626,000 in party and party (or partial indemnity) costs resulting from the plaintiffs' success in motions throughout the course of litigation. Servier has also agreed to pay all reasonable costs of the notice programs and the costs of settlement administration. Thus, the overall global benefits to the plaintiff class from the settlement approximates a potential total of some $45 million.

28 The Settlement Agreement is subject to the express stipulation that there is not any admission on the part of any of the defendants as to liability. In particular, there is no admission that the defendants' products are the cause of any of the injuries for which the class members may claim.

29 Payment from the Fund of a total $1 million is to be made to Canada's provincial and territorial health ministries in satisfaction of their subrogated claims. If monies remain in the fund at the expiration of the Administration Period (a period of five years commencing immediately upon the expiration of the Claim Period - being in turn the period of 15 months following first publication of the Approval Notice) the public health insurers are entitled to a share of such remaining monies.

30 Medical experts have prepared a Medical Conditions List (Exhibit "E" to the Settlement Agreement) ("MCL"). A roster of Canadian physicians with the requisite medical expertise has been created to act as Claims Adjudicators. They will review a claimant's submitted Claim Package and determine whether the claimant is entitled to benefits from the related medical records. An appeal process allows a claimant to challenge in writing before the Court any final determination regarding a claimant's eligibility for benefits.

31 The MCL stipulates specific eligibility criteria in respect of benefits for a range of levels of disease severity for claimants who have ingested the defendants' Products and who suffer from VHD. Benefits are accorded to a matrix which identifies varying levels of VHD severity. Product

Recipients with PPH can also make claims pursuant to the eligibility criteria.

32 The compensation values for Matrix level benefits are incorporated into the Matrix Grid (Exhibit "F" to the Settlement Agreement) and vary based on the level of disease severity and the Product Recipient's age at diagnosis.

33 One level of benefit under the Settlement Agreement is for FDA Positive valvular regurgitation. There will be a per capita payment up to $2,500.00 in recognition of an individual FDA Positive Benefit, subject to an overall ceiling of $3 million for such claimants. An FDA Positive is a defined physiological condition. Product Recipients who qualify for an FDA Positive or greater VHD benefit and whose VHD worsens during the Administration Period can submit a progressive claim such that the initial benefit may be increased accordingly.

34 The estimated class is one of approximately 160,000 members, being the estimated number of individuals who consumed the Products, whether or not any injury has been sustained.

35 National Class Counsel advise they have been contacted by some 886 individuals to date, with 126 of that number providing information regarding injuries or diseases they believe are related to the ingestion of the Products. National Class Counsel estimates on the basis of an initial review that 69 of the 126 have provided medical information which allows a claim to be advanced. Of these 69 class members, 27 may qualify for FDA Positive Benefits with the remaining 42 perhaps qualifying for Matrix-level benefits because of having VHD or PPH.

36 B.C. Class Counsel estimate 29 class members within the B.C. subclass suffer from PPH (15 primary and 14 secondary to VHD) and 86 class members who have VHD (including the 14 who appear to have PPH) with 45 of this number having FDA positive levels as defined in the MCL and the remaining 41 having Matrix level conditions as defined in the MCL.

37 Class members asserting claims which are derivative to the claims of Product Recipients and are based upon the loss of care, guidance and companionship of the Product Recipient may be compensated within a range of $1,000 to $10,000 if the Product Recipient's claim is other than a FDA Positive of Matrix Level I claim.

38 Claimants must submit a Claim Package (which includes a Claim form and Medical diagnosis form along with instructions) to the Settlement Administrator within the Claim Period.

39 A settlement of a class proceeding is not binding unless approved by the Court. In order to approve a settlement, the Court must find that it is fair, reasonable, and in the best interests of the class. See CPA s. 29(2); Dabbs v. Sun Life Assurance Co. of Canada (1998), 40 OR. (3d) 429 at 444 (Gen. Div.), aff'd at (1998), 41 O.R. (3d) 97 (C.A.), leave to appeal to Supreme Court of Canada dismissed, [1998] S.C.C.A. No. 372.

40 In general terms, the Court must be assured that the settlement secures appropriate

consideration for the class in return for the surrender of litigation rights against the defendants. However, the Court must balance the need to scrutinize the settlement against the recognition that there may be a number of possible outcomes within a "zone or range of reasonableness":

> all settlements are the product of compromise and a process of give and take and settlements rarely give all parties exactly what they want. Fairness is not a standard of perfection. Reasonableness allows for a range of possible resolutions. A less than perfect settlement may be in the best interests of those affected by it when compared to the alternative of the risks and costs of litigation: Dabbs v. Sun Life Assurance Co. of Canada, supra, at 440 (Gen. Div.); H. Newberg, A. Conte, Newberg on Class Actions, 3d ed., looseleaf (Colorado: Shepard's/McGraw-Hill Inc., 1992) at 11-104.

41 The representative plaintiffs for both the national class and for the British Columbia sub-class have approved the settlement. There were only two class members who have raised any objections or queries.

42 In determining whether to approve a proposed settlement a court takes into its assessment several factors, including:

(a) the likelihood of recovery or likelihood of success if the action were to proceed to trial;
(b) the amount and nature of discovery, evidence or investigation;
(c) the settlement terms and conditions;
(d) the recommendation and experience of class counsel;
(e) the future expense and likely duration of on-going litigation;
(f) the number of objectors and the nature of objections;
(g) the presence of arms-length bargaining and the absence of collusion; and
(h) the degree and nature of communications by class counsel and the representative plaintiff(s) with class members during the litigation.

See Dabbs v. Sun Life Assurance Co. of Canada, [1998] O.J. No. 1598 at para. 13 (Gen. Div.); Parsons v. Canadian Red Cross Society, [1999] O.J. No. 3572 at paras. 71-72 (Sup. Ct.).

43 As stated above, the litigation in respect of the subject class action has been a very lengthy process with extensive discovery evidence. Settlement was only achieved through the office of an effective mediator at the last moment with a nine-month trial scheduled to commence shortly.

44 Class counsel had significant information about the case and a good understanding of liability and damages issues before embarking upon the settlement negotiation process. Class counsel's grasp of these issues was assisted by medical experts and by experienced American counsel, familiar with like litigation involving diet drugs in the United States.

45 Given that the settlement was achieved only some three days before the scheduled trial, there was considerable trial preparation time required of class counsel. Some 20 expert reports had been exchanged.

46 Given the information available to class counsel, they were well situated to negotiate, and ultimately to agree to a settlement for the resolution of the class action.

47 There is sufficient evidence before the Court to allow it to exercise an objective assessment of the fairness of the proposed Settlement Agreement.

48 There is the risk that if the matter had proceeded to trial, any judgment against Servier might exceed its exigible assets. Servier has $15 million in insurance coverage but that amount is subject to reduction for defence costs which, while unknown, might well have exhausted the coverage. Finally, there are uncertainties regarding any eventual judgment being effectively enforceable in France where the defendants' major assets are located.

49 The function of the Court in reviewing a settlement is not to reopen and enter into negotiations with litigants in the hope of possibly improving the terms of the settlement. It is within the power of the Court to indicate areas of concern and afford the parties an opportunity to answer those concerns with changes to the settlement. However, the Court's power to approve or reject settlements does not permit it to modify the terms of a negotiated settlement. See Dabbs v. Sun Life Assurance Co. of Canada, [1998] O.J. No. 1598 at para. 10 (Gen. Div.); Manual for Complex Litigation, Third ss. 30.42 (1995).

50 Possible concerns, as raised by the Court during the course of submissions, include: that there will be sufficient funds to meet all proper claims, that sufficient and effective notice is given to prospective claimants, that the process for claiming is straightforward and expeditious, and that the latency period for the diseases or injuries alleged to arise from the ingestion of the Products has already passed such that all medical problems will be known by Product Recipients or, at least known well before the end of the Claim Period. Class counsel have provided explanations and assurances in respect of these queries.

51 The Product Recipient class members with viable claims in this class action, such as Ms. Wilson and Ms. Greenlees, have suffered grievous and serious injury and illness (indeed, in some cases, death), because of the defendants' allegedly defective Products.

52 The path to a resolution of the litigation has been long and extremely arduous. Taking into account all the circumstances, in my view and I so find, the Settlement Agreement is fair and reasonable and in the best interests of all the class members.

The Motion for Approval of Class Counsel Fees

53 Class counsel (including Ontario, British Columbia and United States counsel) seek approval

of class counsel fees of $13 million at this time. They do this with the express proviso that they will seek additional fees to a maximum of $5 million if at the conclusion of the Claim Period it appears "there will be sufficient funds remaining." About $626,000 in party and party (partial indemnity) costs (an estimated $500,000 toward fees and $126,000 for reimbursement of disbursements) has been paid by the defendants in the course of the proceedings of the litigation to date.

54 Affidavit evidence in support of the motion by class counsel for the approval of fees includes the affidavits of Ms. Annelis Thorsen, Ms. Sheila Wilson, Mr. Dana Graves, and Ms. Beverley Greenlees.

55 Public notice was given in advance of this hearing as to the quantum of fees being requested by class counsel. There has not been any objection by class members to the fees requested.

56 A United States law firm, Lieff Cabraser Heimann & Bernstein, with considerable expertise in product liability class actions, has been joined in the application for class fees by the submission of the Canadian class counsel. The factum of class counsel of Rochon Genova includes the U.S. firm, together with the B.C. subclass counsel, Klein Lyons.

57 I do not question the value of the contribution of the U.S. firm to the conduct of the class action and its successful conclusion. However, in my view, the U.S. firm is properly to be paid from the counsel fees awarded to class counsel. The U.S. law firm was not appointed as class counsel by the Court nor is there anything on record to indicate the firm is licensed to provide legal services directly to the public and to represent the class in court in Ontario.

58 The U.S. firm has provided legal advice to class counsel and it is the responsibility of class counsel to meet their obligation of payment to the U.S. firm, whatever that commitment might be. The services provided by the U.S. firm are, of course, legal services indirectly for the benefit of the class but it is not an obligation of the class to pay this charge. Hence, my use of the term "class counsel" embraces only the counsel for the national class, Rochon Genova, and the counsel for the B.C. subclass, Klein Lyons.

59 Class counsel assumed a truly daunting task in pursuing this class action given that it became quickly apparent the defendants were certain to challenge them in every way possible at every single step of the litigation process.

60 The efficacy of the underlying three policy objectives to the CPA are seen in the litigation at hand. The first policy objective is 'access to justice.' The individual class members most certainly could not realistically have had access to justice if forced to pursue their claims individually. The short answer, in effect, of the defendants throughout the course of the litigation to the Canadian class members' claims (in respect of allegedly defective drugs marketed by the defendants in Canada) was that each claimant should come to France and individually sue the defendants.

61 The second policy objective is to achieve 'efficiency in the use of resources' necessary to the

litigation process. By combining all claimants in one class action there is obvious greater efficiency and economy for all participants (including the courts) in the adjudication of common issues. One cannot realistically imagine a nine-month trial for each of a vast multitude of claimants to determine issues common to all, in particular, whether the defendants' Products cause VHD or PPH.

62 Finally, the third policy objective is 'behaviour modification.' There are limited public resources available to ensure that defective drugs are not brought into or maintained in the Canadian market upon it being realized there are possible problems. The public regulator is assisted greatly by the private sector through the CPA enabling class actions. In exchange for the possibility of sizeable legal fees through a class action on behalf of a private group of claimants, class counsel indirectly serves a public purpose. The drug industry knows that it is more likely to be held accountable for unlawful behaviour in the marketplace. Hence, it is more likely that drug companies will act responsibly in the first instance in researching, manufacturing and marketing drugs and in advising and disclosing to the public known risk factors in using drugs.

63 As stated above, there was a plethora of pre-trial motions and appeals (about 50 in total). These included, to give a few examples, several motions by the defendants challenging jurisdiction, challenging the constitutionality of a national class action, asserting the purported 'blocking' provisions of Article 15 of France's Civil Code, and asserting non-compliance with the service rules of the Hague Convention. Court orders were also required for the discovery of representatives from the Health Protection Branch of Health Canada.

64 Class counsel were obliged to bring several motions to add defendants as knowledge of the defendants' large corporate empire gradually unfolded. To gain meaningful access to documentary production, some seven motions were necessary for answers to undertakings given and for answers which had been improperly refused.

65 There was voluminous documentary production. The initial production was reportedly some 2,895 documents without an index nor a searchable database or electronic coding. Some 80,000 individual documents were reportedly delivered by the defendants unbound (albeit each separated by a blue sheet of paper) on April 2002 in 122 banker's boxes without being organized according to chronology or subject matter. A later agreement between counsel for production of electronic copies with a searchable index was in fact reportedly not searchable by keyword.

66 Class counsel was required to bring a motion to force the release of relevant documents produced in the U.S. Multi-District Litigation Re: Diet Pills. Another motion was required to gain access to the non-privileged documents in the defendants' electronic database of over 300,000 documents.

67 Class counsel were required to develop a database maintained by a California-based document management company.

68 The oral discovery took place mainly in France. Discovery had to be conducted to a

considerable extent before there was any meaningful production. Examinations for discovery took an approximate total of 11 weeks. There were hundreds of thousands of pages of production. Court orders were required for consular authority to gain access to the release of documents.

69 There were extreme difficulties in piercing the corporate maze of the defendants' business empire consisting of dozens of privately-held companies whose interconnectivity was not readily apparent. An order was required to force the defendants to produce a meaningful organizational chart identifying the various corporate entities involved in bringing the Products to the Canadian market. This ultimately resulted in the plaintiff class moving successfully to add 19 new defendants.

70 Two excerpts from decisions of this Court in the course of the litigation are illustrative, as examples, of the nature of the litigation faced by class counsel. The first is from Wilson v. Servier, [2001] O.J. No. 4717 at paras. 22-23 (Sup. Ct.):

> It is fundamental to the administration of justice in Canada that plaintiff consumer users of an alleged defective product which allegedly has caused very severe health problems (and allegedly death for some class members) have a determination of the common issues on the merits through their certified class action in a timely way. Even if they are successful in the trial of the common issues there will then remain a lengthy process to determine individual issues.
>
> Our society's concept of justice dictates that fairness is inherently fundamental to our court processes. Timeliness in the determination of claims on their merits is critical to achieving fairness to the parties. Justice must be done and it must be seen to be done in a timely way and manner. It is prejudicial to plaintiffs to deny them fairness through further substantial delays by granting Servier's motion. To grant Servier's motion would inevitably have the result of delaying and frustrating a determination of the common issues on their merits. A basic objective of the judicial system is access to justice. Indeed, that is an express policy objective underlying the CPA [citation omitted]. Access to justice means access to timely justice. A fair judicial process requires much more than simply an endless war of attrition waged by defendants with considerably greater resources than an individual representative plaintiff and the plaintiff class.

71 The second excerpt is from Wilson v. Servier, [2003] O.J. No. 157 at paras. 31-33 (Sup. Ct.):

> The record establishes that the defendants resist providing any fulsome understanding as to the role of Dr. Servier and the nature of the vast and complex structure of the Servier enterprise which manufactured and marketed the subject diet drugs sold in Canada. The defendants have volunteered nothing and have confronted the plaintiff with a confusing, complex and extensive corporate enterprise which is largely situated in France. Plaintiff's counsel has been forced

> to comb through more than 100,000 documents and endure a multitude of discoveries with many objections, simply to try to establish incrementally the nature of the Servier enterprise and the structure of decision-making in respect of the subject diet drugs. See (2000), 50 O.R. (3d) 219 at 228 (Sup. Ct.), leave to appeal denied (2000), 52 O.R. (3d) 20, leave to appeal to S.C.C. denied September 6, 2001; [2002] O.J. No. 1002 (Sup. Ct.) at para. 10.
>
> The approach of the defendants could have been to elucidate voluntarily and in a straightforward manner upon the true nature of the Servier enterprise and its relationship to the subject diet drugs in Canada, and proceed to meet the issues in this class action directly on their merits.
>
> However, the defendants have chosen to resist the plaintiff at every stage in this proceeding on every procedural and asserted legal basis imaginable, through seemingly endless motions. The defendants have attempted to try to throw up an impenetrable defensive wall whereby plaintiff's counsel has been forced to expend extensive resources and time simply to attempt to determine the factual history and corporate structure underlying the manufacturing and marketing of the subject drugs in Canada.

72 The technical subject matter involved emerging, complex and unsettled areas of medicine and medical science. Topics requiring expert reports included: whether epidemiological principles supported a conclusion of causation between the use of the Products and the development of PPH and VHD; the incidence, diagnosis, latency period, treatment options and prognosis for patients suffering form PPH or VHD; the issue of progression in the disease process of VHD; the applicable regulatory and industry standards relating to adverse reaction reports and whether the defendants complied with such standards; whether there was adequate disclosure of known risks associated with use of the Products and whether potential benefits from the use of the Products outweighed the attendant risks.

73 The fixing of counsel fees is governed by sections 32 and 33 of the CPA. The essential criterion is whether the requested fees are fair and reasonable.

74 Factors to consider include the time expended by class counsel, the legal and factual complexity of the matters dealt with, the risk of success or failure assumed by class counsel in pursuing the litigation, the degree of skill and competence demonstrated by class counsel, the degree of responsibility assumed by class counsel, the results achieved, the benefits achieved for class members through a settlement, the importance of the matter to the class members, and the client's expectation as to the quantum of fees to be paid.

75 The fairness and reasonableness of the requested fee is commonly measured by several

standards. One is the use of a multiple of the base fee for the docketed time expended, that is, for the opportunity cost to class counsel of not being able to bill for his/her time as would be done in the normal course in respect of a fee paying client.

76 The retainer contingency fee agreement of National Class Counsel with Ms. Wilson in the first instance set forth a 25 percent fee plus any award of costs, disbursements and applicable taxes. Ms. Wilson has signed a revised retainer authorizing an award of legal fees to class counsel in accordance with the amount now sought in total.

77 The retainer contingency fee agreement with Ms. Greenlees in respect of the B.C. subclass provides for 40 percent of the recovery; however, B.C. Class Counsel have agreed to request fees on the same basis as National Class Counsel. That is, class counsel as a single group, seek for fees 25 percent of the settlement amount of $40 million plus applicable taxes plus the $3 million in the partial indemnity costs and $1 million in disbursements contributed by the defendants, plus an additional $5 million if there are funds which remain after all claims are met.

78 Rochon Genova state that they have docketed time of some 14,800 hours (this includes 2,000 hours in respect of discovery, 2500 hours in reviewing documentary productions, 5,500 hours in respect of court appearances and some 1,500 hours in respect of settlement negotiations and drafting) resulting in docketed fees of about $5 million. Rochon Genova spent some 11 weeks in examinations for discovery of representatives of the defendants in France, Canada and Belgium. They say they have disbursements of $720,883.32, inclusive of G.S.T. They advise that their American legal advisers, Lieff Cabraser, have docketed time of some 3,661.5 hours with docketed fees of about CDN $1.5 million and disbursements totaling $465,926.61.

79 The defendants question two aspects of the base fee as calculated by Rochon Genova. First, they say that 700 hours of time up to the successful certification motion was not included in an earlier Bill of Costs given to defendants' counsel. Rochon Genova answer that the earlier lesser calculation was an error. Second, defendants question the hourly rates employed, asserting that 2004 rates are used retrospectively.

80 As an aside, it is noted that defendants' counsel do not volunteer their own docketed time, fees and disbursements in support of this class action. They are, of course, under no obligation to do so. Yet their own fees would offer an additional rough standard by which to measure the reasonableness of class counsel's base fee and requested counsel fees.

81 B.C. Class Counsel put their docketed time at some 8700 hours, including more than 3000 hours by Mr. Gary Smith of the Klein Lyons firm. The defendants say that these rates are higher than prevailing market rates. They also assert that some of the time charges relate to administrative matters for which costs have been awarded and paid.

82 The defendants hired KPMG Forensic Inc. ("Forensic") to thoroughly analyze the charges comprising the asserted base fee by class counsel. That analysis would reduce the base fee to

$3,005,681 from the base fee calculated by Rochon Genova of $4,997,884. Forensic's analysis would reduce the base fee of Klein Lyons from $3,753,270 to $2,452,811. Thus, the two base fees would be reduced in the range of some 35 to 39 percent by the analysis of Forensic.

83 Taking the combined reduced base fee from the analysis of Forensic of $5,458,492 one is in all events left with a very substantial base fee. Moreover, this omits a notional revised base fee of CDN $1,349,732 as calculated by Forensic for the value of the contribution by Lieff Cabraser.

84 It is not necessary for me to deal with the differences in the calculation of the base fee and determine which figure is more probably accurate. I say this because, in my view, the counsel fee approved in this case, taking into account all the circumstances (putting aside for the moment the factor of the total amount of recovery), could certainly justify a multiplier of 4 times the base fee.

85 It is enough to say that the record establishes a base fee of class counsel of at least $5,458,492. The defendants themselves submit that a reasonable base fee would be this figure of $5,458,492.

86 As class counsel are seeking maximum fees of $18 million, if approval of this amount were to be granted, it would imply a multiplier of only 3.3 upon the base fee (i.e., 3.3 times $5,458,492).

87 The defendants also have done an analysis of the claimed disbursements. The defendants take the position that $2,619,536 represents the total reasonable disbursements (this includes the notional base fee of $1,349,732 of Lieff Cabraser being treated as a disbursement).

88 The defendants propose a formula for class counsel fees which would cap the overall fees at a maximum of $9.4 million. The defendants propose that class counsel receive an interim payment of fees at this time of $6.4 million, $2.6 million for disbursements and the right to apply for additional fees when the 'take-up' by claimants is known. The defendants would fix such additional fees at an amount equal to the lesser of 10 percent of the settlement take-up by claimants or $3 million. By this approach, the maximum in additional fees would be $3 million.

89 By the defendants' formula, the maximum possible fees of $9.4 million would imply a multiplier of only 1.72 on the base fee (said by the defendants to be reasonable) of $5,458,492. If the take-up was less than $30 million the effective multiplier would be even less.

90 The defendants submit in their factum that "even when fees are awarded on the basis of a fixed sum or a multiplier basis, the percentage of the potential fee awarded as compared to the quantum of the settlement or judgment becomes a significant factor in determining the fee awarded" (Gagne v. Silcorp Ltd. (1998), 41 O.R. (3d) 417 at 425). Certainly, the amount of the settlement or judgment is one important factor to be taken into account. If the base fee as multiplied constitutes an excessive portion of total recovery, the multiplier may be too high. As I have said above, leaving this single factor of total recovery aside, a multiplier of 4 is appropriate in this case, given all other factors.

91 But other significant factors must also be kept in mind given the idiosyncratic nature of this class action. Class counsel could not reasonably estimate the total number of class members actually injured by ingestion of the defendants' diet drugs. Even if it is determined ultimately it is only a relatively few of the total users who have been injured, their injuries are severe (including death in several instances) and these persons would not have achieved any redress at all but for the efforts of class counsel.

92 Finally, the very extensive cost in time and resources in respect of this prolonged litigation has been largely because the defendants refused to deal with their customers' claims (notwithstanding cogent evidence suggesting a foundation to the claims) until just immediately before trial, but rather 'circled the wagons' and imposed every hurdle imaginable (as was their legal right, if not the preferred moral position) at every step of the legal process to block the claimant customers and their counsel in seeking to gain justice.

93 As an aside, I mention that one can argue that any provider for profit of prescription drugs to consumers in the marketplace, as a responsible corporate citizen, should want to see a neutral, independent process established immediately upon any plausible medical problems surfacing, whereby the medical/scientific issues of causation and effect are addressed expeditiously, seriously and authoritatively with an administrative/arbitral regime then established to provide appropriate compensation if suggested by the results of the medical/scientific inquiry.

94 It is hardly an appropriate answer for an off-shore multinational, global enterprise drug provider to say, in effect, to individual Canadian consumers 'if you claim our drug has seriously injured you, come to France and prove it.' Nor is it arguably an appropriate answer for the Canadian Government, as the public health regulator through Health Canada, to remove a drug from the market when serious medical problems for consumers surface, and not then also require the drug seller to agree to an appropriate mechanism to address immediately in a cost-effective and fair manner the consequences of the medical problems left in the wake of the marketing.

95 National Class Counsel requests a separate payment for Ms. Wilson from the Settlement Fund of $15,262 as compensation on a quantum meruit basis based on some 230 hours at $65 per hour. I do not dispute Ms. Wilson's significant contribution to the carriage of this class action. However, National Class Counsel can deal with this add-on claim by making the requested payment to her out of their pocket.

96 Class counsel have stipulated that there will not be any additional fees payable by class members for their services beyond those awarded pursuant to the motion at hand. In particular, this means that even if there might be separate contingency fee agreements with individuals who are now in the B.C. subclass there will be no extra fees charged to such individuals. (That is, there will be no so-called double-dipping.)

97 The individual class members have a maximum fund available for their claims of $43 million (provincial health authorities receiving $1 million from the $40 million Fund). I consider the $3

million added in the settlement for partial indemnity of costs and the $1 million added for partial indemnity of disbursements to be properly considered as part of the global fund available for class members.

Disposition

98 In my view, and I so find, class counsel fees in the amount of $10 million plus applicable G.S.T. of $700,000 plus $2,619,536 (inclusive of any taxes on disbursements) are approved and to be paid at this time. (The disbursement calculation includes $619,699 allocated for Rochon Genova, $203,566 for Klein Lyons and $1,796,271 to Rochon Genova on account of Lieff Cabraser.) (The party and party costs awarded throughout the litigation process, about $700,000, are apart from, and over and above, the $10 million in fees awarded. However, the $4 million in partial indemnity costs paid as part of the settlement are credited to the global Fund or considered otherwise, are credits against the $10 million in fees and $2,619,536 for disbursements hereby awarded.)

99 It is appropriate for the Court to know how the claims process has worked for claimants, the actual take-up by claimants, and the overall achievement of the settlement for class members before determining with finality the full and final amount of class counsel fees.

100 Without implying any appropriate overall final quantum of class counsel fees at this time, I will remain seized of the motion for approval of class counsel fees. The hearing is adjourned for a continuance to a date to be fixed by the Court. A further hearing on the matter is appropriate after the Settlement Administrator, Crawford Class Action Services, has provided a comprehensive report on the implementation of the settlement. Such report should not be provided until after at least a year following the expiry of the Claim Period i.e., until after at least a full year has been completed in the Administration Period. Given the reversionary interest of Servier in respect of the settlement monies, the defendants are permitted to make such submissions as they consider appropriate at the continued hearing to assist the Court in its determination of the appropriate overall final quantum of class counsel fees.

P.A. CUMMING J.

cp/e/qlalc

Case Name:

Robinson v. Rochester Financial Ltd.

RE: Kathryn Robinson and Rick Robinson,
Plaintiffs/Moving Parties, and
Rochester Financial Limited et al., Defendants/Respondents

[2012] O.J. No. 534

2012 ONSC 911

[2012] 5 C.T.C. 24

2012 CarswellOnt 1368

212 A.C.W.S. (3d) 20

Court File No. 08-CV-349792 CP

Ontario Superior Court of Justice

G.R. Strathy J.

Heard: January 17, 2012.
Judgment: February 7, 2012.

(45 paras.)

Counsel:

David Thompson and Matthew G. Moloci, for the Plaintiffs.

Glenn Smith and Sean O'Donnell, for the Defendant Fraser Milner Casgrain LLP.

John Finnigan, for the Monitor, Grant Thornton Limited.

ENDORSEMENT

(Settlement Approval and Class Counsel Fee Approval)

1 **G.R. STRATHY J.**:-- This endorsement sets out my reasons for approving the settlement of this class action and approving the fees and disbursements of class counsel, an Order to that effect having been issued on January 17, 2012.

2 The action relates to a tax shelter called the Banyan Tree Foundation Gift Program, which operated in 2003-2007. It has been referred to as a "leveraged" charitable donation program because, in return for a proportionately small out-of-pocket payment, a taxpayer was purportedly entitled to ratchet-up his or her donation and to receive a charitable tax receipt equivalent to 3 1/2 times the amount of his or her cash outlay.

3 The leverage was supposed to be provided by a "loan" to the participant, made by one of the defendants, Rochester Financial Limited, secured by a promissory note. Part of the participant's cash payment was described as a "security deposit", which was supposed to be invested so that it would pay off the loan before the taxpayer was ever called upon to pay it.

4 The effect of this was to allow the taxpayer to profit from his or her donation -- in the case of a taxpayer in the highest bracket, a payment of $2,700 would secure a tax credit of $4,600, resulting in a profit of about $1,900.

5 The program was promoted by the Banyan Tree Foundation through a network of salespeople who were paid substantial commissions.

6 Canada Revenue Agency ("C.R.A.") disallowed the charitable donation tax credits claimed by participants in the Gift Program. It took the position that the "donation" made by the taxpayer was not a gift for the purposes of the *Income Tax Act*, because the loan was not *bona fide* and there were nothing more than book-keeping entries to give an aura of respectability to the transaction. It said that the participants were never at risk to repay their loans and that the program was a sham, designed to have the appearance of a legitimate charitable donation, when the real purpose was to enrich the taxpayer rather than benefit a charity. It therefore disallowed the charitable donation tax credits, and the participants were required to repay the taxes they had deducted, with interest.

7 Not only did the participants lose their deductions, their security deposits have disappeared, apparently due to defalcation by the investment manager.

8 In January 2010, Justice Lax certified this action as a class proceeding: *Robinson v. Rochester Financial Ltd.*, 2010 ONSC 463, [2010] O.J. No. 187.

9 There is no realistic prospect of recovery from any of the parties directly responsible for the Gift Program. This leaves the defendant law firm, Fraser Milner Casgrain LLP ("FMC"), as the last party standing. It provided legal opinions that the Gift Program complied with the applicable tax

legislation and that the tax receipts issued by the Banyan Tree Foundation should be recognized by C.R.A.

10 As a result of mediation before a former judge of this Court, class counsel negotiated a settlement, subject to Court approval, of class members' claims against FMC for the total sum of $11 million. Approximately $7.75 million of this amount will be paid to class members in proportion to the charitable contributions they made, under a distribution plan that will be administered by class counsel. The balance will be used to pay the fees and disbursements of class counsel and the costs of administration of the settlement. In addition to this cash distribution, the plaintiffs asked the Court to make a declaration that the promissory notes executed by class members in connection with the Gift Program are unenforceable.

11 The proposed settlement, and the order I have granted, are somewhat unusual in that all individuals who have previously opted-out of this action, will have the opportunity to opt back in and to enjoy the benefits of the settlement. One of the reasons for this is that, following certification, Banyan Tree Foundation engaged in a misinformation campaign, designed to encourage class members to opt-out of this proceeding, suggesting that class members who opted out would be unable to challenge their C.R.A. reassessments. When this was brought to my attention by class counsel, I issued an order dated June 25, 2010, providing for further notice to class members and an opportunity to revoke their opt-outs. I am satisfied that, in the particular circumstances of this case, it is appropriate to extend this relief in connection with the settlement.

12 Those class members who have previously opted-out, and wish to remain outside the Class, need not do anything further.

13 There were approximately 2,825 participants in the Gift Program. They have received extensive individual notice of the proposed settlement. Approximately 500 objections to the settlement have been delivered. Almost all of these objectors have sent a standard form letter that appears to have been authored by Mr. Tim Millard, an accountant who was also a salesman for the Gift Program and who had approximately 40 clients who are class members. Mr. Millard and two other class members, Mr. Harrington and Dr. Maier, attended the hearing and made submissions. About seven or eight other class members attended the hearing but made no submissions.

14 The uniform concern expressed by Mr. Millard, Mr. Harrington and Dr. Maier, who spoke at the hearing, and by those class members who sent in the standard form letter, related not to the amount of the settlement, but rather to the proposed term of the settlement that would declare the "loan" portion of the taxpayer's contribution to the Gift Program (i.e., the leveraged portion), void and unenforceable. These objectors were concerned that a declaration to this effect would potentially adversely affect any future appeals they may make of their tax assessments or re-assessments.

15 This issue was raised at the hearing and, as a result of further discussions between class counsel and the objectors, a revised form of order, satisfactory to Messrs Millard, Harrington and

Maier, was approved. That form of order, simply declares that the loan agreements and promissory notes executed by class members in connection with the Gift Program are unenforceable by the defendants, their successors and assigns.

16 A handful of objectors who sent written communications were concerned about the relatively modest amount they would receive under the settlement in comparison to the loss of their contributions, the loss of their anticipated deductions and any penalties and interest they may be required to pay. I will discuss this issue below.

17 In order to approve a settlement, the court must be satisfied that it is fair, reasonable and in the best interests of the class: *Nunes v. Air Transat A.T. Inc.*, [2005] O.J. No. 2527, 2005 CarswellOnt 2503 (S.C.J.) at para. 7; *Vitapharm Canada Ltd. v. F. Hoffmann-La Roche Ltd.*, [2005] O.J. No. 1118 (S.C.J.). The "fairness and reasonableness" analysis will vary from case to case, but courts frequently turn to the factors set out in *Dabbs v. Sun Life Assurance Company of Canada*, [1998] O.J. No. 1598 at 13 (Gen. Div.); and (1998), 40 O.R. (3d) 429 at 440-444 (Gen. Div.); aff'd (1998), 41 O.R. (3d) 97 (C.A.); leave to appeal to S.C.C. denied [1998] S.C.C.A. No. 372:

(a) the presence of arm's length bargaining and the absence of collusion;
(b) the proposed settlement terms and conditions;
(c) the number of objectors and nature of objections;
(d) the amount and nature of discovery, evidence or investigation;
(e) the likelihood of recovery or likelihood of success;
(f) the recommendations and experience of counsel;
(g) the future expense and likely duration of litigation;
(h) information conveying to the court the dynamics of, and the positions taken by the parties during the negotiations;
(i) the recommendation of neutral parties, if any; and
(j) the degree and nature of communications by counsel and the representative plaintiff with class members during the litigation.

18 I am satisfied that most of these factors have been addressed in this settlement. The settlement is clearly the product of hard bargaining at arms' length, facilitated by an experienced mediator. It comes with the recommendation of highly qualified and reputable counsel, who have engaged the assistance of expert tax counsel. The concerns of the overwhelming majority of objectors have been satisfied. The settlement is clearly a compromise, but liability of FMC was a very contentious issue. FMC would argue, if the matter proceeded to trial, that its opinions were consistent with the state of the law as it existed at the time and that the subsequent hardening of the position of C.R.A. and, it would appear, the appellate case law, was not something that could have been foreseen at the time. There were other issues that would also be brought into play by FMC, including whether class members relied on its opinions. A significant discount of the claim was warranted to reflect the real risk that the claim against FMC would not succeed.

19 While a very small number of objectors have expressed concerns about the amount of the settlement, the vast majority of the objectors were concerned only with the issue of the proposed relief in relation to their loans. Over eighty percent of class members have made no comment on the settlement. I acknowledge, however, that some class members think that the settlement amount is too low. Every settlement is necessarily a compromise. It reflects the possibility that the class may recover nothing if the action goes to trial and that there is a benefit to early resolution.

20 For the purposes of a settlement approval motion, I should assume that if the settlement is not approved, the action will proceed to trial. In effect, I would be substituting my view of the prospects of success for the views of class counsel, who have lived with this action since its outset and who are familiar with the risks and benefits of continuing with the action. While I can, in appropriate cases, appoint *amicus* to assist my examination of the settlement, I have in this case a high level of confidence in the fairness and reasonableness of the settlement and I approve it.

Fee of Class Counsel

21 Class counsel entered into a contingency fee retainer agreement with the representative plaintiffs that provided for a contingent fee of 25% of the total value of any settlement. They request approval of the payment of $3,252,682.65 for their fees, disbursements and taxes.

22 I find that the fee agreement meets the requirements of s. 32(1) of the *Class Proceedings Act,* S.O. 1992, c. 6 (the "*C.P.A.*") and that it is fair and reasonable, having regard to the factors set out in the case law, as summarized in *Vitapharm Canada Ltd. v. F. Hoffmann-LaRoche Ltd.*, [2005] O.J. NO. 1117 (S.C.J.) at para. 67.

23 In this case, I consider the following circumstances of particular significance:

(a) this action would never have been commenced, let alone successfully resolved, had it not been for the initiative, tenacity and persistence of class counsel in the face of widespread apathy on the part of all class members;
(b) class counsel funded disbursements of almost $200,000, making it unnecessary to apply to the Class Proceedings Fund;
(c) class counsel have gone without any compensation at all through four years of litigation;
(d) class counsel gave an indemnity to the representative plaintiffs with respect to any adverse costs award -- the assumption of a significant risk of not only receiving no fees and disbursements, but the possibility of a substantial six figure costs award against them;
(e) the matter was complex and the outcome was far from certain;
(f) the result achieved is financially significant and every class member will receive actual cash compensation;
(g) in addition to the cash value of the settlement, class members will receive the added benefit of a declaration that their loans and promissory notes are

unenforceable, a matter of some concern to class members;

(h) the time spent by class counsel was about 4,600 hours with a face value of about $1.8 million, and the proposed fee represents a multiplier of less than 2;

(i) there has been no real opposition to class counsel's fee by class members, whose only significant objection related to the scope of the proposed declaration; and

(j) the payment of the proposed fee does not significantly dilute the recovery by class members, and their ability to pay the fee is not an issue.

24 Having supervised this proceeding for more than two years, I am satisfied that class counsel have demonstrated commendable diligence, perseverance and skill in pursuing a very challenging piece of litigation and bringing it to a successful conclusion.

25 I do not propose to repeat the observations I made in *Baker Estate v. Sony BMG Music (Canada) Inc.*, [2011] O.J. No. 5781, concerning the value of contingency fees in the fair compensation of class counsel. In my view, with the benefit of hindsight, it is fair and reasonable that class members should pay the fee requested by class counsel and I approve that fee.

Compensation for the Representative Plaintiffs

26 Class counsel have made a request for compensation in the amount of $5,000 for each of the representative plaintiffs, relying on the authority of *Windisman v. Toronto College Park Ltd.*, [1996] O.J. No. 2897 (Gen. Div.), on the basis that the plaintiffs have rendered "active and necessary assistance" in the prosecution of the case.

27 In *Baker Estate v. Sony BMG Music* (Canada Inc.), 2011 ONSC 7105, [2011] O.J. No. 5781, I set out the principles applicable to this request at para. 93:

> The payment of compensation to a representative plaintiff is exceptional and rarely done: *McCarthy v. Canadian Red Cross Society* [2007] O.J. No. 2314 (S.C.J.) at para. 20; *Windisman v. Toronto College Park Ltd.*, [1996] O.J. No. 2897 (Gen. Div.); *Sutherland v. Boots Pharmaceutical plc*, [2002] O.J. No. 1361 (S.C.J.); *Bellaire v. Daya* [2007] O.J. No. 4819 (S.C.J.) at para. 71. It should not be done as a matter of course. Any proposed payment should be closely examined because it will result in the representative plaintiff receiving an amount that is in excess of what will be received by any other member of the class he or she has been appointed to represent: *McCutcheon v. Cash Store Inc.* [2008] O.J. No. 5241 (S.C.J.) at para. 12. That said, where a representative plaintiff can show that he or she rendered active and necessary assistance in the preparation or presentation of the case and that such assistance resulted in monetary success for the class, it may be appropriate to award some compensation: *Windisman v. Toronto College Park Ltd.*, [1996] O.J. No. 2897 (Gen. Div.) at para. 28.

28 Class counsel says that this is one of those exceptional cases in which compensation should be paid. As I have noted, class counsel faced considerable apathy on the part of class members and it was exceedingly difficult to find someone prepared to take on the role of representative plaintiff until Mr. and Mrs. Robinson stepped up to the plate. Taking on that role required that they expose private personal financial information, including their income tax returns for the years they participated in the Gift Program. They each spent more than 300 hours in assisting class counsel in the prosecution of the action. In comparison, they will receive a modest award of about $6,000 under the settlement.

29 In *Windisman*, above, Sharpe J. observed, at para. 28:

> Ordinarily, an individual litigant is not entitled to be compensated for the time and effort expended in relation to prosecuting an action. In my view, there is an important distinction to be drawn with reference to class proceedings. The representative plaintiff undertakes the proceedings on behalf of a wider group and that wider group will, if the action is successful, benefit by virtue of the representative plaintiff's effort. If the representative plaintiff is not compensated in some way for time and effort, the plaintiff class would be enriched at the expense of the representative plaintiff to the extent of that time and effort. In my view, where a representative plaintiff can show that he or she rendered active and necessary assistance in the preparation or presentation of the case and that such assistance resulted in monetary success for the class, the representative plaintiff may be compensated on a quantum meruit basis for the time spent. I agree with the American commentators that such awards should not be seen as routine. The evidence here is that Ms. Windisman took a very active part at all stages of this action. It seems clear that the case would not have been brought but for her initiative. She assumed the risk of costs and she devoted an unusual amount of time and effort to communicating with other class members, acting as a liaison with the solicitors, and assisting the solicitors at all stages of the proceeding. She kept careful records of her time and effort.

30 In that case, the representative plaintiff had kept docketed time entries showing 81.2 hours of time and estimated a further 25 hours of undocketed time. Sharp J. awarded compensation of $4,000, to be deducted from the net recovery of the class.

31 This issue brings into play some conflicting values. On the one hand, we do not wish to create a conflict of interest between the representative plaintiffs and the class, by giving the former more substantial contribution. This was discussed by Winkler J. in *Sutherland v. Boots Pharmaceutical Plc.*, [2002] O.J. No. 1361 (S.C.J.):

> In the present circumstances the work of the Representative Plaintiffs was unnecessary to the preparation or presentation of the case. Indeed, their work did

> not begin until after the settlement had been structured. Their work did not result in any monetary success for the class. If they were to be compensated in the manner requested they would be the only class members to receive any direct monetary compensation. The entire settlement is in the form of Cy-pres distribution. The representative plaintiffs are seeking some $80,000 in total which is to be deducted from the settlement. By way of contrast, in Windisman, the representative plaintiff took an active part at all stages of the proceeding, the case would not have been brought except for her initiative, she assumed the risk of costs, and devoted an unusual amount of time communicating with class members and assisting counsel. The class members received a direct monetary benefit due in part to her efforts.
>
> While the work of the representative plaintiffs is commendable, to compensate them for the work when the settlement funds for the entire class are being donated to research without a single penny finding its way into the hands of a class member would be contrary to the precept of the Cy-pres distribution in particular and to a class proceeding generally. Compensation for representative plaintiffs must be awarded sparingly. The operative word is that the functions undertaken by the Representative Plaintiffs must be "necessary", such assistance must result in monetary success for the class and in any event, if granted, should not be in excess of an amount that could be purely compensatory on a quantum meruit basis. Otherwise, where a representative plaintiff benefits from the class proceeding to a greater extent than the class members, and such benefit is as a result of the extraneous compensation paid to the representative plaintiff rather than the damages suffered by him or her, there is an appearance of a conflict of interest between the representative plaintiff and the class members. A class proceeding cannot be seen to be a method by which persons can seek to receive personal gain over and above any damages or other remedy to which they would otherwise be entitled on the merits of their claims. This request is denied.

32 In *Hislop v. Canada (Attorney General)*, [2004] O.J. No. 1867 (S.C.J.), an action claiming CPP survivor's pensions for same sex partners, E. Macdonald J. awarded compensation of $15,000 to one representative plaintiff, two others received $10,000 each and two others received $5,000 each.

33 In *Garland v. Enbridge Gas Distribution Inc.*, [2006] O.J. No. 4907, Cullity J. awarded the representative plaintiff $25,000 for his efforts, which he described as an "exceptional contribution". He made the following observations at paras. 45 and 46:

> ... Mr Garland has, in my judgment, made out a strong case for compensation. He took the initiative in seeking legal advice with respect to the legality of late

payment penalties and in instructing counsel to commence the proceedings. He was instrumental in keeping the legal team together when members of the class counsel sought to withdraw from the proceedings on the ground of a business conflict, and he accepted a large part of the responsibility for communicating with class members personally or through interviews with representatives of the media. He also played an active part in the settlement negotiations and, in particular, in obtaining agreement to the nature and details of the *cy pres* distribution -- one of the matters for which he found it desirable to retain separate counsel.

The litigation was commenced, and continued, by Mr Garland in the public interest and, I am satisfied, that throughout it his primary concern has been to protect and serve the interests of the class. It was on this ground that he firmly opposed counsel's proposal to replace the method of calculating their fee under the 1998 fee agreement with the application of a multiplier to be applicable irrespective of the gross recovery.

34 In *McCutcheon v. Cash Store Inc.*, [2008] O.J. No. 5241, Cullity J. approved a payment of $10,000, stating at paras. 22 and 23:

Although I am not oblivious to the risk of engendering expectations that such payments will be approved as a matter of course, the request in this case is strongly supported by class counsel who have sworn to the significant amount of time expended by Mr McCutcheon in advancing the interests of the class. His efforts were not confined to meetings with class counsel but extended to communicating with other class members, monitoring developments in the pay-day loan industry and providing input and assistance to class counsel in the settlement negotiations. Counsel have testified to his active part in all stages of the litigation and his time and energy spent in liaising between them and class members. They have sworn that he accepted the personal exposure to an adverse costs award and, to the benefit of the class, that he did not choose to seek assistance from the Class Proceedings Fund. They have stated that the request for compensation was made entirely at their suggestion. While I consider the amount requested to be on the high side, I am satisfied that, independently of this payment and the payment of counsel fees, the settlement merits approval and that the total amount of class counsel fees and the representative plaintiff's compensation could be justified if, as in *Garland*, it consisted of counsel fees from which the representative plaintiff's compensation was to be paid. On the basis of the strong support provided by class counsel, I will approve the amount of $10,000. I will, however, reiterate what I have said in other cases that, as a general rule, all benefits and payments to be made by defendants should be

> treated as a single package when considering the fairness and reasonableness of a settlement from the viewpoint of a class. This, I believe, should be accepted whether or not there are expressed to be separate agreements for fees to be paid directly by defendants rather than out of a settlement amount otherwise earmarked for the benefit of the class. As in other parts of the law, substance must prevail over form.

35 In *Fakhri v. Alfalfa's Canada Inc.*, 2005 BCSC 1123, [2005] B.C.J. No. 1723, Gerow J. of the British Columbia Supreme Court awarded $5,000 as compensation for the representative plaintiff. In that case, the defendant had agreed to pay the amount directly to the representative, with the result that it would not dilute the recovery of the class. It was found that the plaintiff had delivered multiple affidavits, reviewed pleadings, provided instructions, attended the mediation and court hearings, and helped shape the final settlement. The judge found that the plaintiff's efforts on behalf of the class had an impact on the successful resolution of the proceeding.

36 In *Walker v. Union Gas, Ltd.*, [2009] O.J. No. 536, Cumming J. approved a payment of $5,000 to the representative payment, out of the fees of class counsel. He observed that the plaintiff had spent more than 70 hours in the conduct of the litigation, including reviewing some 10 bankers' boxes of documents, cross-referencing documents and isolating bills, and traveling to Toronto for the meeting with the Class Proceedings Committee.

37 In the recent case of *Smith Estate v. National Money Mart Co.* 2011 ONCA 233, [2011] O.J. No. 1321, the Court of Appeal affirmed the motion judge's decision to award $3,000 compensation to the representative plaintiff. It suggested that generally such a fee should be paid out of the settlement fund, rather than out of class counsel's fees, to avoid any spectre of fee-splitting. In that case, the Court of Appeal observed, at para. 134, that judges of this court have taken different approaches with respect to the payment of fees for the representative plaintiffs. It noted that it had not previously dealt with the issue. We can take from the Court of Appeal's decision that the court may award compensation to a representative plaintiff in an "appropriate case".

38 In *McCarthy v. Canadian Red Cross Society* [2007] O.J. No. 2314 (S.C.J.) there was a request for fees and disbursements to be paid to the representative plaintiff, in the amount of $75,000. In dismissing the request, Winkler J. observed at para. 20:

> Mr. McCarthy has fulfilled his obligation to the class as their representative. However, a distinction must be drawn between the professional advisors to the class and the representative plaintiff with respect to fees. Where it is necessary for the representative plaintiff to incur out-of-pocket expenses in acting in that capacity, such as attendance at discoveries as one example, it may be appropriate for class counsel to reimburse such amounts and claim it as a disbursement subject to recovery on approval by the Court. While each case turns on its facts, in my view, it is not generally appropriate for a representative plaintiff to receive

> a payment for fees or for time expended in the pursuit of the action. Further, any payment made to a representative plaintiff in connection with the action, whether directly or indirectly, and whether for reimbursement or otherwise, must be disclosed to the Court.

39 It would appear that judges in British Columbia have been less reluctant to award compensation for representative plaintiffs. In addition to *Fakhi v. Alfalfa's Canada Inc.*, above, I will mention *Reid v. Ford Motor Co.*, 2006 BCSC 1454, in which a payment of $3,000 was approved on a *quantum meruit* basis, to be paid from class counsel fees and *MacKinnon v. Vancouver City Savings Credit Union,* 2004 BCSC 1604, 34 B.C.L.R. (4th) 322 in which a payment of $5,000 was approved to be paid as a disbursement.

40 In a recent decision of the British Columbia Court of Appeal in *Parsons v. Coast Capital Savings Credit Union,* 2010 BCCA 311, [2010] B.C.J. No. 1184, the representative plaintiff appealed an order of the settlement approval motion judge refusing to award compensation to the representative plaintiff in the amount of $10,000. The motion judge had concluded that British Columbia law only permitted compensation to be paid to the representative plaintiff where he or she has made a contribution that is over and above the contribution expected of a representative plaintiff, although it need not be an extraordinary contribution.

41 After a thorough review of the authorities in both Canada and the United States, the Court of Appeal concluded that it was not necessary for the class representative to show that he or she performed services of special significance. It said that where the representative plaintiff has fulfilled his or her duties, and a favourable settlement has been achieved, a "modest award in recognition of the effort expended on behalf of the class" would be appropriate. The Court stated, at paras. 20-3:

> I consider it is too narrow to say, as the judge did here, that services of special significance beyond the usual responsibilities under the *Act* are required for a separate award to the representative plaintiff. Where the representative plaintiff has fulfilled his or her duties, which will include attendance for examination in discovery, providing instructions on all steps taken in the litigation and on the settlement (which necessarily requires immersion in the substance of the case), and where a monetary settlement in favour of the class members is achieved, a modest award in recognition of the effort expended on behalf of the class members is consistent with restitutionary principles and recognition of the principle of *quantum meruit.* This expectation is further justified by the exposure to costs assumed by the representative plaintiff in commencing the action. While that risk is mitigated upon certification, there is a real exposure to costs assumed on commencing the action. Other intangible costs also are borne by such a plaintiff, including the sometimes not inconsiderable weight of being the leader of the claimants.

> In other words, I do not consider exceptional service is required. Rather competent service accompanied by positive results should be sufficient for recognition in this way, weighing in this factor the quantum of personal benefit achieved by the representative plaintiff with the overall benefit achieved for the class.
>
> In considering the quantum of such a payment, where the representative plaintiff's personal benefit is small but the collective benefit is great, there may be disproportion between personal benefit on the one hand and effort and responsibility on the other, so as to weigh in favour of a somewhat larger award. Nevertheless, in no case should the award be so large as to create the impression that the representative plaintiff was put into a conflict of interest. The outer bounds of what could be an appropriate compensatory award may vary from case to case, depending on factors such as the terms of settlement or award at issue and the personal circumstances of the representative plaintiff.
>
> In this case Ms. Parsons was a representative plaintiff in another action, and in the course of that proceeding her counsel observed the overdraft payment that grounded this action. In other words, Ms. Parsons did not initiate the claim. Nonetheless she exposed herself to costs in any proceedings that might have arisen prior to the certification application, she assumed responsibility for deriving benefit for others, she attended at an examination for discovery, she was available for conversation during the mediation, and in the end result she fronted an action that was significantly successful. In my view these features of the case, while not extraordinary, militate in favour of payment to her of a modest sum, described by her counsel as an honourarium.

42 The Court held that an award of $3,500, payable as a disbursement, would be appropriate. I note that one of the factors the Court of Appeal considered was the representative plaintiff's exposure to costs, a factor not relevant in this case due to the indemnity agreement.

43 In this particular case, while I acknowledge the contribution made by Kathryn Robinson and by Rick Robinson, and commend them on the work they have done to bring this matter to a successful conclusion on behalf of their fellow class members, I am not prepared to award such compensation. In my respectful view, requests for compensation for the representative plaintiff are becoming routine, as Sharpe J. anticipated in *Windisman*, above. I agree with those who have expressed the opinion that compensation should be reserved to those cases where, considering all the circumstances, the contribution of the plaintiff has been exceptional. The factors that might be appropriate for consideration could include:

(a) active involvement in the initiation of the litigation and retainer of counsel;
(b) exposure to a real risk of costs;
(c) significant personal hardship or inconvenience in connection with the prosecution of the litigation;
(d) time spent and activities undertaken in advancing the litigation;
(e) communication and interaction with other class members; and
(f) participation at various stages in the litigation, including discovery, settlement negotiations and trial.

44 I conclude, with some regret, that in this particular case the application of these factors, considered as a whole, do not dictate payment of compensation.

Conclusion

45 The settlement is therefore approved, as are the fees and disbursements of class counsel. I have also issued an order, on consent, discharging the Monitor, Grant Thornton Limited.

G.R. STRATHY J.

cp/e/qlrxg/qlvxw/qlced/qlcas

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, c. C-36, AS AMENDED, AND IN THE MATTER OF A PLAN OF COMPRISE OR ARRANGEMENT OF SINO-FOREST CORPORATION

Commercial Court File No.: CV-12-9667-00CL

The Trustees of the Labourer's Pension Fund of Central and Eastern Canada, et al.

Plaintiffs

and

Sino-Forest Corporation, et al.

Defendants

Superior Court File No: CV-10-414302

ONTARIO
SUPERIOR COURT OF JUSTICE
Commercial List
Proceeding under the *Class Proceedings Act, 1992*
Proceeding commenced at Toronto

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