



SUPERIOR COURT OF JUSTICE

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TOTAL PAGES (INCLUDING COVER PAGE): 30

RE: Rhonda Gayle Goodridge, Susan Dudley and Mark Dudley and
Pfizer Canada Inc. and Pfizer Inc.
Court File No.: 06-CV-307728CP

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CITATION: Goodridge v. Pfizer Canada Inc., 2010 ONSC 1095
COURT FILE NO.: 06-CV-307728CP
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**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN:

Rhonda Gayle Goodridge, Susan Dudley, and Mark Dudley

Plaintiffs

- and -

Pfizer Canada Inc. and Pfizer Inc.

Defendants

Counsel:

Michael Peerless, Michael Eizenga, Matthew Baer, Sabrina Lombardi, and Michael Dunn, for the Plaintiffs

Glen Zakaib and Peter Hencin, for the Defendants

Heard: January 18-21, 2010

REASONS FOR DECISION

PERELL, J.

Introduction and Overview

[1] Gabapentin is a synthetic version of gaba, which is a compound found in the brain that dissolves neurotransmitters and stops electrical impulses from being transmitted from one neuron to another. In Canada, the Defendant Pfizer Canada Inc., which is a pharmaceutical company, manufactures and markets gabapentin as a prescription drug under the brand name "Neurontin." The Defendant Pfizer Inc., which is an American pharmaceutical company and Pfizer Canada's parent corporation, manufactures and markets Neurontin in the United States.

[2] Competitors of the Defendants, who have been added as Third Parties, manufacture and market generic gabapentin in Canada.

[3] Rhonda Gayle Goodridge, Susan Dudley, and Mark Dudley, who are the current plaintiffs, and Brian Davidson and Jennifer Lauricella, who are proposed to be added as

plaintiffs, move for certification of a class action under the *Class Proceedings Act, 1992*, S.O. 1992, c. C.5 against Pfizer Canada and Pfizer Inc.

[4] In this proposed class action, the Plaintiffs and proposed new Plaintiffs seek to represent all persons resident in Canada (excluding Quebec) who were prescribed and ingested the drug Neurontin or its generic equivalent gabapentin, as well as, all persons who by virtue of a personal relationship to any of the persons described have a *Family Law Act* (or similarly applicable provincial statutory provision or the common law as applicable) claim for damages.

[5] There are five aspects to the claims being brought against the two Pfizer companies. First, the Plaintiffs allege that the Defendants were negligent and caused harm to Neurontin consumers by falsely and wrongfully promoting Neurontin for “off-label” uses, which is to say for uses for which the drug has not received Canadian regulatory approval. Second, it is alleged that the Defendants were negligent and caused harm to Neurontin consumers by designing and distributing a drug that was useless for its off-label uses. Third, it is alleged that the Defendants were negligent and caused harm to Neurontin consumers by designing and distributing a drug that had a harmful side effect; namely, propensity for suicidal behaviour. Fourth, it is alleged that the Defendants are liable not only for the harm caused to consumers of Neurontin but they are also liable for the harm caused to consumers of generic gabapentin that was manufactured and distributed by the Defendants’ competitors. Five, it is alleged that the family members of the Neurontin consumers and the generic gabapentin consumers have derivative claims under the *Family Law Act* or similar provincial statutory provisions.

[6] The Defendants oppose certification for numerous reasons, including the alleged absence of commonality of the proposed common questions and the alleged unmanageability and inefficiency of the proposed class action because of the complexity and incompatibility of the various aspects of the Plaintiffs’ claims and the alleged absence of ways to address important elements of the claims other than by individual trials.

[7] The Defendants make a motion of their own to strike portions of the Plaintiffs’ statement of claim on the grounds that in some instances, the Plaintiffs fail to plead a reasonable cause of action and in other instances, the Plaintiffs fail to properly or adequately plead a cause of action.

[8] For the reasons set out below, it is my opinion that the Defendants’ motion to strike out various parts of the Plaintiffs’ statement of claim should be allowed, in part, and on terms that I will describe below.

[9] It is also my opinion that although there are some problems with the Plaintiffs’ overly ambitious and overreaching claims and although several aspects of their claims should be struck out or not certified for the purposes of a class action, there remains a class action to be certified but on terms that I will describe below.

[10] As I will explain below, the class action that the court will certify will not involve claims or common issues about the Defendants wrongfully and falsely promoting Neurontin for “off-label” uses in Canada, nor will it involve claims or common issues about the Defendants being liable for generic drugs manufactured by their competitors. A collateral consequence of this narrower than proposed class action is that Susan Dudley and Mark Dudley will no longer be parties to this action. I shall, however, make an order adding Mr. Davidson and Ms. Lauricella as representative plaintiffs.

[11] To explain my conclusions, I will first describe the background facts. In discussing the facts, I will hold that there is no basis in fact to support certification of the common issues about the Defendants wrongfully and falsely promoting Neurontin for “off-label” uses in Canada. Next, I will address, the cause of action criterion for the certification of a class action along with the Defendants’ motion that attacks the Plaintiffs’ pleading and their argument that they do not have a duty of care with respect to the manufacturing and marketing of generic gabapentin. As a result of the pleadings motion, I shall, among other things, strike out the Plaintiffs’ allegations with respect to the generic sales of gabapentin for failure to show a reasonable cause of action. The discussion of the Plaintiffs’ causes of action and the duty of care issue will be followed by my analysis of the balance of the criteria for certification as a class action leading to my conclusion that the action should be certified as a class proceeding. I shall conclude with a summary and some directives about the future carriage of the action, including settling the terms of the litigation plan.

Factual Background

[12] Warner-Lambert was an American pharmaceutical company, and its Parke-Davis U.S. division developed Neurontin, of which the active ingredient is gabapentin. In 1993, Parke-Davis U.S. applied for and received the approval of the United States Food and Drug Administration (“FDA”) for the use of Neurontin in the United States as an adjunctive (i.e. secondary) treatment of epilepsy.

[13] In 1994, Parke-Davis Canada, a division of Warner-Lambert Canada, applied for and received the approval of Health Canada for the use in Canada of Neurontin as an adjunctive treatment for epilepsy. As with all Health Canada-approved pharmaceuticals, the product information for Neurontin was provided to healthcare professionals in a document called a product monograph, which is updated under the supervision and subject to the approval of Health Canada. Adverse drug reaction information identified during post-approval clinical trials and market surveillance is included in periodic updates to a drug’s product monograph.

[14] Physicians may lawfully prescribe a drug for other than its authorized use as set out in the product monograph. This practice is called “off-label” prescribing. Prescribing a drug for off label uses is not illegal, and it is a common practice of physicians. Medical practitioners are free to endorse or recommend off-label uses for medications and often do so, particularly when their patient’s ailments are proving resistant to approved drugs. (See: N. de Paulsen, “The Regulatory Gap: Off-Label Drug Use in Canada” (2005), 63 U.T. Fac. L. Rev. 183.) Apparently, Gabapentin’s benign side effect profile and lack of

contraindications for off-label conditions are characteristics that increase the likelihood that it will be prescribed for off-label uses.

[15] However, the manufacturer of a drug is prohibited from promoting the off label uses of a drug.

[16] Some 15 years ago, between April 1995 and August 1996, despite the prohibition against promoting the off-label uses of a drug, Warner Lambert U.S. through Parke-Davis U.S. began to overtly and covertly promote Neurontin for a host of off-label uses.

[17] These wrongful activities occurred in the United States. Warner Lambert U.S.'s sales representatives and agents unilaterally contacted physicians in the United States and advised them about off-label uses. The company's agents made false or misleading statements to health care professionals in the United States regarding Neurontin's efficacy and whether it had been approved by the FDA for off-label uses. "Medical Liaisons," who represented themselves (often falsely) as scientific experts in a particular disease, promoted off-label uses for Neurontin. Warner-Lambert U.S. paid doctors to attend so-called "consultants meetings," expensive dinners or conferences, during which presentations about off-label uses of Neurontin were made. Warner-Lambert U.S. arranged numerous teleconferences in which physicians were recruited by sales representatives to call into a pre-arranged number where they would listen to a doctor or a Warner-Lambert employee speak about an off-label use of Neurontin. It sponsored purportedly "independent medical education" events about off-label Neurontin uses.

[18] As I have said, these wrongful marketing activities took place in the United States. On this certification motion, there is, however, no basis in fact to find that in Canada, Parke-Davis Canada was a participant in any of the activities promoting the off-label use of Neurontin. There is no evidence of any Canadian doctor or health practitioner having been influenced by any promotional activities emanating from the United States, and there is no evidence of any promotional activities taking place in Canada. The one physician whose evidence was obtained (through production of the medical records of Ms. Goodridge) denies that he was influenced by or placed any reliance upon any alleged off-label marketing in his decision to prescribe Neurontin to Ms. Goodridge.

[19] Further, on this certification motion, there is no basis in fact for concluding that the Parke-Davis in the United States carried on any wrongful promotional activities in Canada. The Plaintiffs submitted that since Canadian doctors would have been aware of and have had available to them the publications and presentations in the United States, this amounted to the United States division of Parke-Davis promoting the off-label uses in Canada. I disagree, the marketing and promotion of Neurontin in Canada was conducted by and under the authority of Parke-Davis Canada, and there is no evidence of Parke-Davis Canada wrongfully promoting the off-label uses of Neurontin in Canada.

[20] While there is evidence that in Canada the vast majority of Neurontin's prescriptions and sales were for off-label uses, including the treatment of neuropathic pain, migraine, reflex sympathetic dystrophy, restless leg syndrome, attention deficit disorder, bipolar disorder, and other illnesses, there is no evidence of Parke-Davis U.S.,

Parke-Davis Canada, Pfizer Inc., or Pfizer Canada wrongfully promoting the off-label marketing of Neurontin for non-approved uses in Canada.

[21] Although no additional approvals have been sought in Canada, Neurontin came to be approved for the treatment of one or more various types of neuropathic pain in over 80 countries, including the U.S., where in May 2002, Neurontin was approved for the treatment of post-herpetic neuralgia, a type of neuropathic pain some people experience after suffering from shingles.

[22] In June 2000, Pfizer Inc. acquired Warner-Lambert, including its Parke-Davis division. At the same time, Pfizer Canada acquired Warner-Lambert Canada, including its Parke-Davis Canada division. Pfizer Canada and Pfizer Inc. operate autonomous and independent marketing departments.

[23] In 2000, **Brian Davidson** was prescribed Neurontin to treat back and leg pain from a herniated disk, and he took the drug intermittently for several years. The treatment was ineffective. On June 3, 2002, at a time when he was using the drug, Mr. Davidson attempted suicide. Mr. Davidson deposes that he would not have taken the drug if he had been told that it had not been approved to treat his health problems or if advised of the increased risk of experiencing suicidal behaviour.

[24] The Plaintiffs allege that the Defendants failed to warn about the risk of suicidal behaviour and misrepresented adverse drug reaction information about the incidence of suicidal behaviour.

[25] Relying on the evidence of Dr. Cheryl D. Blume, the Plaintiffs allege that gabapentin causes suicidal ideation or suicidal behaviour. Relying on the evidence of Dr. Anthony Rothschild, the Defendants submit that there is no reliable evidence from any well-controlled epidemiological study or clinical trial that supports this allegation.

[26] Whether gabapentin has the side effect of causing suicidal ideation or suicidal behaviour and whether Pfizer Canada provided misinformation about the incidence of adverse events are not matters that I can or should decide on this certification motion. In my opinion, there is some basis in fact for these allegations and that is all the Plaintiffs need establish at this juncture.

[27] **Jennifer Lauricella** is the daughter of Mr. Davidson and a putative class member and is prepared to act as the representative plaintiff on behalf of the family law claimants.

[28] On February 23, 2001, the Defendants' patent rights in Neurontin expired, and generic manufacturers sought and obtained approval to sell generic versions of gabapentin in Canada.

[29] To be approved by Health Canada, generic versions of a drug must have the same active ingredient as the brand-name drug with which they will compete. The review process for a generic drug is less rigorous than the review undertaken when the innovator of the drug obtains approval for the drug. Generic versions of innovator drugs are reviewed under an abbreviated process that focuses on whether the generic is

bioequivalent (acts in the same way) as the innovator drug, and, as such, is interchangeable. The regulatory assumption is that the safety and efficacy of the innovator's drug demonstrated in the original submission of the innovator and confirmed during the marketing period can be extrapolated to the generic drug.

[30] Generally, the generic versions of a drug have additional non-medicinal ingredients (such as fillers, dyes, and binders). Each generic version of a drug has its own product monograph. Generic manufacturers are subject to the same post-approval requirements as brand-name manufacturers and must maintain annual summaries and analyses of all adverse drug reactions reported. They must maintain updated product monographs.

[31] The Defendants were not involved in the pre-approval testing or regulatory filings, or in the post-approval manufacture, sale, marketing, distribution, or regulatory filings for any generic version of gabapentin.

[32] In April 2001, **Rhonda Gayle Goodridge** was prescribed Neurontin to treat neuropathic pain in her right arm. The treatment was not effective, and she discontinued use of the drug around June 28, 2001. Ms. Goodridge pleads that she would not have taken the drug if she had been told that it had not been approved to treat neuropathic pain or if advised of the increased risk of experiencing suicidal behaviour.

[33] In May 2002, the plaintiff **Susan Dudley** was prescribed generic gabapentin to treat nerve pain in her leg, and she used the drug for 6 or 7 weeks. While taking the drug she was taken to the emergency room of the Grey Bruce Regional Health Centre in Owen Sound because she was suicidal. The doctor in the emergency room discontinued Mrs. Dudley's use of gabapentin. Mrs. Dudley pleads that she would not have taken the drug if she had been told that it had not been approved to treat pain or if advised of the increased risk of experiencing suicidal behaviour.

[34] **Mark Dudley** is the spouse of Susan Dudley, and he advances a claim for special damages and for loss of care, guidance, and companionship.

[35] Pausing here, for the purposes of the certification motion, I do not need to describe the details, but the health situation and health histories of each of the Plaintiffs is unique, and I agree with the Defendants that the issues of what harm the individual Plaintiffs suffered and whether that harm was caused by their use of Neurontin or generic gabapentin are individual issues without commonality and the resolution of those individual issues would require individual trials.

[36] Returning to the narrative, in May 2004, an information was laid against Pfizer Inc. in the United States District Court, District of Massachusetts, concerning Warner-Lambert's promotion of Neurontin for off-label uses in the United States, and the following month, Pfizer Inc. agreed, on behalf of Warner-Lambert to plead guilty, and it agreed to pay a fine of more than \$240 million and to pay amounts in settlement of civil liabilities relating to Consumer Protection Divisions and Medicaid programs in the

United States. Including the criminal penalty, Pfizer Inc. paid more than \$430 million to resolve its criminal and some of its civil liabilities in the United States.

[37] On June 28, 2004, the action *Dunn v. Pfizer* (Court File No. 587012), which is a proposed class action about the selling of Neurontin, was filed in the Supreme Court of British Columbia.

[38] On August 5, 2004, Rhonda Gayle Goodridge commenced the proposed class that is now before the court against Pfizer Canada and Pfizer Inc.

[39] Pausing here, it may be observed that while the notoriety of the criminal plea in the United States in May 2004 would seem to have prompted the class action activity immediately following in Canada (there was also class activity in the United States), as I have already indicated above, there is no basis in fact that similar wrongful marketing activity occurred in Canada.

[40] I may also observe that while the addition of common issues about the wrongful marketing activities of Parke-Davis in the United States in the mid-1990s would add a great deal of colour to the proposed class action - and an enormous amount of complexity - it was conceded during argument of the certification motion that the class members do not need the marketing claim to advance their claims based on: (a) the Defendants' failure to warn of the propensity of suicidal behaviour; (b) gabapentin having actually caused suicidal behaviour; and (c) the alleged negligence of the Defendants' designing and distributing a drug that was useless and harmful for its off-label uses.

[41] For certification, the plaintiff in a proposed class proceeding must show "some basis in fact" for each of the certification requirements, other than the requirement that the pleading discloses a cause of action: *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at para. 25; *Taub v. Manufacturers Life Insurance Co.*, (1998) 40 O.R. (3d) 379 (Gen. Div.), aff'd (1999), 42 O.R. (3d) 576 (Div. Ct.). Because there is no basis in fact for the allegations of wrongful marketing activities in Canada, I am striking those allegations from the Plaintiffs' statement of claim. From the plaintiffs' prospective, a salutary effect of striking these allegations is that their removal goes a great distance in neutering the Defendants' argument that the action is too unmanageable for it to satisfy the preferable procedure criterion of the test for certification, and striking various paragraphs makes moot some of the Defendants' challenges to the Plaintiffs' statement of claim. From the Defendants' prospective, it is simply a matter of fairness to remove these allegations, leaving the Defendants to defend the remaining serious allegations that will be tried in the common issues trial. It follows from the above conclusions that the following words or paragraphs should be struck from the statement of claim: (a) the last sentence in para. 9; (b) para. 10; (c) paras. 12 - 18; (d) para. 22; (e) paras. 42 (a)-(b); and (f) the first sentence and the words "In addition," in para. 45.

[42] Once again returning to the narrative, on January 6, 2005, Joan Burgess commenced a second Neurontin class action in Ontario against Pfizer Canada and Pfizer

Inc. (Court File No. 46120 CP). The statement of claim made allegations similar to those made in the case at bar.

[43] On January 14, 2005, Options Consommateurs and Guy Campagna commenced a Neurontin class action in Quebec against Pfizer Canada and Pfizer Inc.

[44] In the case at bar, on November 2, 2006, a Fresh as Amended Statement of Claim (Court File No. 06-CV-307728CP) was delivered. The pleading consolidated the Goodridge and Burgess actions. However, sadly, Ms. Burgess had committed suicide, and she was replaced by Susan Dudley and her husband Mark Dudley as proposed representative plaintiffs.

[45] On or about November 27, 2007, it was discovered that Susan Dudley had never been subscribed Neurontin but rather had been prescribed a generic version of the drug, and in light of this fact, on December 21, 2007, an Amended Amended Fresh as Amended Statement of Claim ("Claim") was filed in which the Plaintiffs alleged that the Defendants were also liable for the generic sales of gabapentin.

[46] The parties spent about two years preparing for the certification hearing, and the Plaintiffs now move for certification and seek an order defining the class as:

(a) All persons resident in Canada (excluding Quebec) who were prescribed and ingested the drug Neurontin, or its generic equivalent, gabapentin; and

(b) All persons resident in Canada who by virtue of a personal relationship to one or more of such persons described in (a) above with a valid claim, have standing in this action pursuant to s.61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3, as amended (or an applicable provincial statutory provision or the common law as applicable).

[47] The Plaintiffs seek to certify the following common issues:

1. Did the Defendants actively market Neurontin for off-label uses for which there was no scientific evidence to support such use?
2. Can ingesting Neurontin and/or generic gabapentin cause an increased risk of suicidal behaviour?
3. Is Neurontin ineffective and/or defective or unfit for the purpose for which it was intended (including usages that ought reasonably to have been foreseen by the Defendants) as designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or both of the Defendants?
4. Did the Defendants breach a duty of care owed to the class by how Neurontin was marketed?

5. Did the Defendants knowingly, recklessly or negligently breach a duty to warn or materially misrepresent any of the risks of harm from Neurontin?
6. Are class members entitled to special damages for medical costs incurred in the treatment of health complications related to having ingested Neurontin?
7. Are the Defendants liable for damages resulting from the purchase and consumption of (a) Neurontin and (b) generic gabapentin?
8. Are the Defendants liable for the subrogated health care costs of class members incurred in the treatment of conditions related to taking Neurontin and/or generic gabapentin?
9. Should the Defendants pay exemplary or punitive damages?
10. By virtue of waiver of tort, are the defendants liable on a restitutionary basis:
 - (a) to account to any of the class, including the provincial insurers with subrogated claims, on a restitutionary basis, for any part of the proceeds of the sale of Neurontin? If so, in what amount and for whose benefit is such an account to be made? Or in the alternative,
 - (b) such that a constructive trust is to be imposed on the proceeds of sale of Neurontin for the benefit of the class, including provincial health insurers with subrogated claims, and, if so, in what amount, and for whom are such proceeds held?

[48] The Defendants, who have delivered a statement of defence, have commenced third party proceedings against 21 drug manufacturers of generic gabapentin, namely: (a) Pharmascience Inc.; (b) Dominion Pharmacal; (c) Apotex Incorporated; (d) Novopharm Limited; (e) Pharmel Inc.; (f) Nu-Pharm Inc.; (g) Genpharm Inc.; (h) Cobalt Pharmaceuticals Inc.; (i) Prempharm Inc.; (j) Laboratoire Riva Inc.; (k) Taro Pharmaceuticals Inc.; (l) Ratiopharm Inc.; (m) Baker Cummins Inc.; (n) Zymcan Pharmaceuticals Inc.; (o) Pro Doc Limitée; (p) Ranbaxy Pharmaceuticals Canada Inc.; (q) Aurobindo Pharma Limited Unit Iii.; (r) Sigmacon Lifesciences Inc.; (s) Auro Pharma Inc.; (t) Accel Pharma Inc.; and (u) Myland Pharmaceuticals ULC.

[49] The third party claims have not yet been served, but in light of my holdings below, the Defendants will not need to pursue these claims.

Disclosure of a Cause of Action

[50] For certification as a class action, the Plaintiffs' statement of claim must disclose a cause of action. As already noted, the Defendants make a motion to challenge whether the Plaintiffs have done so, most particularly, they challenge the allegations that they are liable for the harm caused by their competitors' manufacturing and selling generic

gabapentin. In this regard, the Defendants' submit that they have no duty of care to the consumers of gabapentin manufactured and sold by their competitors.

[51] The Defendants also submit that there are other deficiencies in the Plaintiffs' statement of claim. As I have already observed above, however, some of these problems have become moot because of the truncating of the Plaintiffs' pleading, which I have ordered because there is no basis in fact for the allegations.

[52] In that truncated statement of claim, apart from the allegations about liability for the sales of generic gabapentin, the main allegations against the Defendants are that:

- The Plaintiffs did not receive any warning from the Defendants of the potential side effect of suicidal behaviour and the Defendants provided false and misleading information with respect to the adverse event incidence of depression in clinical trials of Neurontin (para. 23 of the statement of claim).
- The Defendants caused individuals to receive unproven and ineffective treatment that excluded effective treatments and exposed the individuals to life-threatening risks for which no warning was given (para. 26 of the statement of claim).
- The Defendants had a duty of care: (a) to ensure that Neurontin was fit for its intended or reasonably foreseeable uses; (b) to only market Neurontin for approved uses; (c) to ensure that Neurontin was an effective treatment for the types of uses for which it was being marketed; (d) to conduct appropriate testing to determine whether and to what extent ingestion of Neurontin posed serious health risks, including the increased risk of suicidal behavior; and (e) to warn the Plaintiffs and their physicians that ingestion of Neurontin carries the increased risk of suicidal behaviour (para. 35 of the statement of claim).
- As a result of the Defendants' negligence, the Plaintiffs received unapproved and ineffective medication, were exposed to the risk of experiencing suicidal behaviour, and were harmed by not taking other medications that may have effectively treated their conditions (para. 44 of the statement of claim).
- As a result of the conduct of the Defendants, the Plaintiffs and other class members suffered and continued to suffer expenses and special damages (para. 38 of the statement of claim).

[53] Further, the Plaintiffs plead in the alternative that they are entitled to elect to waive the tort and claim a disgorgement of the Defendants revenue received from the sale of Neurontin in Canada (paragraph 42 of the statement of claim).

[54] I do not see the truncated statement of claim as pleading a negligent misrepresentation claim, and, therefore, the Defendants' arguments about the Plaintiffs having improperly pleaded such a claim need not be addressed. I shall address, however, other challenges made to the pleading, including the challenge that the Defendants do not have a duty of care to the consumers of generic gabapentin.

[55] The “plain and obvious” test for disclosing a cause of action from *Hunt v. Carey Canada*, [1990] 2 S.C.R. 959 is used to determine whether the proposed class proceeding discloses a cause of action; thus, a claim will be satisfactory unless it has a radical defect or it is plain and obvious that it could not succeed: *Anderson v. Wilson* (1999), 44 O.R. (3d) 673 (C.A.) at p. 679, leave to appeal to S.C.C. ref’d, [1999] S.C.C.A. No. 476; *176560 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.).

[56] In a proposed class proceeding, in determining whether the pleading discloses a cause of action, no evidence is admissible, and the material facts pleaded are accepted as true, unless patently ridiculous or incapable of proof. The pleading is read generously and a pleading will be struck out only if it is plain, obvious, and beyond a reasonable doubt that the plaintiff cannot succeed: *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at para. 25; *Cloud v. Canada (Attorney General) v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.) at para. 41, leave to appeal to the S.C.C. ref’d, [2005] S.C.C.A. No. 50 , rev’g (2003), 65 O.R. (3d) 492 (Div. Ct.); *Abdool v. Anaheim Management Ltd.*, (1995), 21 O.R. (3d) 453 (Div. Ct.) at p. 469.

[57] The Defendants submit that with respect to the claim of Ms. Goodridge, the statement of claim is deficient because it pleads the increased risk of harm from the side effect of a propensity for suicidal behaviour as if it were compensable damages. The Defendants submit, however, to ground a cause of action, the risk of harm must materialize into actual harm and no actual harm is alleged by Ms. Goodridge, and, therefore, her pleadings of suffering harm should be struck.

[58] I disagree with the Defendants’ argument. It seems to me that the increased risk of experiencing suicidal behaviour allegedly caused by Neurontin is a materialized actual harm just as much as, for example, would be the increased risk of a experiencing a heart failure caused by a drug that raised or lowered one’s blood pressure to dangerously high or low levels.

[59] In my opinion, putting aside the allegations with respect to liability for the manufacturing and selling of generic gabapentin by the Defendants’ competitors, the truncated statement of claim pleads causes of action against the Defendants: (a) in negligence for their manufacturing and selling a defective and harmful drug, (b) in negligence for failing to warn that the drug they manufactured and sold had harmful side-effects and would cause harm if used for off-label purposes, and (c) for waiver of tort, assuming that waiver of tort is a cause of action.

[60] Similar claims of products liability negligence with respect to drugs and medical appliances have satisfied the first criterion of the test for certification. See: *Wilson v. Servier Canada Inc.* (2000), 50 O.R. (3d) 219 (S.C.J.) at paras. 119-121 , leave to appeal ref’d (2000), 52 O.R. (3d) 20 (S.C.J.) , leave to appeal to S.C.C. ref’d [2001] S.C.C.A. No. 88; *Heward v. Eli Lilly & Co.*, [2007] O.J. No. 404 (S.C.J.), leave to appeal to Div. Ct. granted [2007] O.J. No. 2709 (S.C.J.), appeal dismissed [2008] O.J. No. 2610 (Div. Ct.); *Boulanger v. Johnson & Johnson Corp.*, [2007] O.J. No. 179 (S.C.J.), leave to

appeal ref'd [2007] O.J. No. 1991 (S.C.J.). See also N. de Paulsen, "The Regulatory Gap: Off-Label Drug Use in Canada" (2005), 63 U.T. Fac. L. Rev. 183.

[61] Therefore, apart from the claim about the harm caused by generic gabapentin, I am satisfied that the Plaintiffs' statement of claim satisfies the first criterion for certification as a class action.

The Claim that Pfizer Canada and Pfizer Inc. are Liable for the Harm Caused by Generic Gabapentin

[62] The Plaintiffs claim that Pfizer Canada and Pfizer Inc., as the innovators of Neurontin, have a duty of care to the consumers of generic gabapentin and are liable for the harm caused by the generic gabapentin manufactured and sold by its competitors.

[63] The Plaintiffs submit that it was reasonably foreseeable to the Defendants that Neurontin would be copied by their competitors, who would rely on the development work and regulatory approval obtained by the Defendants as the innovator of gabapentin. The Plaintiffs say that it was foreseeable to the Defendants that generic gabapentin would be prescribed and ingested to treat conditions for which the Defendants had negligently marketed Neurontin. Based on what they say was reasonably foreseeable to the Defendants, the Plaintiffs say that the Defendants have a duty of care to the consumers of generic gabapentin. Here, it is important to note that the Defendants' alleged duty of care would be in addition to and independent of the duty of care owned by the generic gabapentin manufacturers to their own consumers.

[64] The Defendants, however, submit that as the innovators of Neurontin they have no duty of care to the consumers of generic gabapentin manufactured by their competitors.

[65] I agree with the Plaintiffs that it was reasonably foreseeable to Pfizer Inc. and Pfizer Canada that harm would be caused by competitors manufacturing the allegedly defective drug gabapentin. However, for the reasons that follow, I agree with the Defendants that they have no duty of care for being the innovator of generic gabapentin. There is much more to the presence of a duty of care than whether harm was reasonably foreseeable to a defendant. There are elements of proximity and policy that must also be satisfied. As I will explain, in the case at bar there are policy reasons for concluding that the Defendants as innovators do not have a duty of care to the consumers of generic gabapentin.

[66] The contemporary Canadian approach to determining whether there is a duty of care has been developed in a series of Supreme Court of Canada decisions adapting and explaining the House of Lord's decision in *Anns v. Merton London Borough Council*, [1978] A.C. 728 (H.L.). See: *Kamloops (City of) v. Nielsen*, [1984] 2 S.C.R. 2; *Cooper v. Hobart*, [2001] 3 S.C.R. 537; *Odhavji Estate v. Woodhouse*, [2003] 3 S.C.R. 263; *Childs v. Desormeux*, [2006] 1 S.C.R. 643; *Syl Apps Secure Treatment Centre v. B.D.*, [2007] 3 S.C.R. 83; and *Mustapha v. Culligan of Canada Ltd.*, [2008] 2 S.C.R. 114.

[67] The first element of a tort claim for negligence is a duty of care. As Lord Esher stated in *Le Lievre v. Gould*, [1893] 1 Q.B. 491 (C.A.), at p. 497, "[a] man is entitled to be as negligent as he pleases towards the whole world if he owes no duty to them." The contemporary analysis of whether a duty of care exists begins by asking whether the plaintiff and the defendant are in a relationship that the law categorically recognizes as involving a duty of care or whether the relationship constitutes a new category of claim. If the claim falls within an established category, then precedent will have established that there is a duty of care associated with the relationship between the parties: *Childs v. Desormeaux*, [2006] 1 S.C.R. 643 at para. 14.

[68] If the case does not come within an established category, it is necessary to undertake a duty of care analysis. This approach harkens back to the seminal case of *Donnogoe v. Stevenson*, [1932] A.C. 512 (H.L.), where Lord Atkin stated at p. 580:

[T]here must be, and is, some general conception of relations giving rise to a duty of care, of which the particular cases found in the books are but instances ... The rule that you love your neighbour becomes in law, you must not injure your neighbour; and the lawyer's question, Who is my neighbour? receives a restricted reply. You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who then, in law is my neighbour? The answer seems to be – persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called into question.

[69] In *Anns v. Merton London Borough Council*, [1978] A.C. 728 (H.L.), the House of Lords adopted a two-step analysis to determining whether there was a duty of care between a plaintiff and a defendant: (1) Is there a sufficiently close relationship between the plaintiff and the defendant such that in the reasonable contemplation of the defendant, carelessness on its part might cause damage to the plaintiff? and, (2) Are there any considerations that ought to negative or limit: (a) the scope of the duty; (b) the class of persons to whom it is owed; or (c) the damages to which a breach of it may give rise.

[70] As developed by the case law in Canada, if the relationship between the plaintiff and the defendant does not fall within a recognized class whose members have a duty of care to others, then whether a duty of care to another exists involves satisfying three requirements: (1) foreseeability, in the sense that the defendant ought to have contemplated that the plaintiff would be affected by the defendant's conduct; (2) sufficient proximity, in the sense that the relationship between the plaintiff and the defendant is sufficient *prima facie* to give rise to a duty of care; and (3) the absence of overriding policy considerations that would negate any *prima facie* duty established by foreseeability and proximity. Thus, whether a relationship giving rise to a duty of care exists depends on foreseeability, moderated by policy concerns: *Anns v. Merton London Borough Council*, [1978] A.C. 728 (H.L.); *Mustapha v. Culligan of Canada Ltd.*, [2008] 2 S.C.R. 114 at para. 4.

[71] Proximity focuses on the type of relationship between the plaintiff and defendant and asks whether this relationship is so close that the defendant may reasonably be said to owe the plaintiff a duty to take care not to injure him or her: *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.). Proximate relationships giving rise to a duty of care are of such a nature as the defendant in conducting his or her affairs may be said to be under an obligation to be mindful of the plaintiff's legitimate interests: *Odhavji Estate v. Woodhouse*, [2003] 3 S.C.R. 263 at para. 49; *Hercules Managements Ltd. v. Ernst & Young*, [1997] 2 S.C.R. 165, at para. 24. The proximity inquiry probes whether it would be unjust or unfair to hold the defendant subject to a duty of care having regard to the nature of the relationship between the defendant and the plaintiff: *Syl Apps Secure Treatment Centre v. B.D.* 2007 SCC 38 at para. 26. The focus of the probe is on the nature of the relationship between victim and alleged wrongdoer and the question is whether the relationship is one where the imposition of legal liability for the wrongdoer's actions would be appropriate. See *Hill v. Hamilton-Wentworth Regional Police Services Board*, 2007 SCC 41 at para. 23.

[72] The proximity analysis involves considering factors such as expectations, representations, reliance, and property or other interests involved: *Cooper v. Hobart*, [2001] 3 S.C.R. 537 at para. 34; *Hill v. Hamilton-Wentworth Regional Police Services Board*, 2007 SCC 41 at para. 23; *Odhavji Estate v. Woodhouse* [2003] 3 S.C.R. 263 at para. 50. Proximity is not concerned with how intimate the plaintiff and defendant were or with their physical proximity, so much as with whether the actions of the alleged wrongdoer have a close or direct effect on the victim, such that the wrongdoer ought to have had the victim in mind as a person potentially harmed: *Hill v. Hamilton-Wentworth Regional Police Services Board*, 2007 SCC 41 at para. 29.

[73] It needs to be emphasized that the proximity analysis of the first stage of the *Anns* test involves policy issues because it asks the normative question of whether the relationship is sufficiently close to give rise to a legal duty: *Cooper v. Hobart*, [2001] 3 S.C.R. 537 at paras. 25-30.

[74] Moving on to the second stage of the duty of care analysis, if the plaintiff establishes a *prima facie* duty of care, the evidentiary burden of showing countervailing policy considerations shifts to the defendant, following the general rule that the party asserting a point should be required to establish it: *Childs v. Desormeaux*, [2006] 1 S.C.R. 643 at para. 13. Policy concerns raised against imposing a duty of care must be more than speculative, and a real potential for negative consequences must be apparent: *Hill v. Hamilton-Wentworth Regional Police Services Board*, 2007 SCC 41 at para. 48.

[75] This second stage of the analysis is not concerned with the type of relationship between the plaintiff and the defendant. At this stage of the analysis, the question to be asked is whether there exist broad policy considerations that would make the imposition of a duty of care unwise, despite the fact that harm was a reasonably foreseeable consequence of the conduct in question and there was a sufficient degree of proximity between the plaintiff and the defendant such that the imposition of a duty would be fair: *Cooper v. Hobart*, [2001] 3 S.C.R. 537 at para. 37; *Odhavji Estate v. Woodhouse*, [2003] 3 S.C.R. 263 at para. 51. The second stage of the analysis is about the effect of

recognizing a duty of care on other legal obligations, the legal system, and society more generally: *Cooper v. Hobart*, [2001] 3 S.C.R. 537 at para. 37; *Odhavji Estate v. Woodhouse*, [2003] 3 S.C.R. 263 at para. 51. An adverse effect may justify negating the defendant's duty of care.

[76] Applying the above principles to the case at bar, for the reasons that follow, I conclude that there is no *prima facie* duty of care between the innovator of a generic prescription drug and the consumers of the drug manufactured by a competitor and if there is a duty of care, it is negated by public policy considerations.

[77] I begin the duty of care analysis by noting that the case does not come within an established category of a duty of care. I was not referred to any Canadian cases where an innovator was held to have a duty of care to its competitors' consumers. Therefore, it is necessary to undertake a duty of care analysis of the nature of the relationship between the innovator of a drug and the consumers of a generic version of the drug.

[78] In their arguments for and against the existence of a duty of care, both parties referred to caselaw in the United States. For the most part, this law favoured the Defendants' arguments, but the applicability of any of it to the case at bar is problematic because some of the American cases involved allegations of fraudulent and negligent misrepresentations and wrongful marketing activities that will be removed as issues in the case at bar and the American law has a different approach than Canadian law to strict liability in negligence for product liability. In the result, in my opinion, it is not helpful to discuss the American jurisprudence, and I will confine my analysis to Canadian authorities.

[79] Beginning that analysis, as I have already stated, in my opinion, the foreseeability element of the first step of the *Anns* test has been satisfied. The issue for determination is whether the rest of the *Anns* test has been satisfied. Thus, the analysis should continue by considering the proximity and policy factors of the first step of the *Anns* test and then the policy factors of the second step. To do that for the case at bar, it is necessary to describe the duty of care that the Defendants have to consumers of Neurontin because it is that duty of care that the Plaintiffs submit should be extended to the consumers of generic gabapentin manufactured by other pharmaceutical companies.

[80] As already suggested above, the seminal case about duty of care, products liability, and negligence generally is *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.), where Lord ` stated at p. 599:

[A] manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable opportunity of intermediate examination, and with the knowledge that absence of reasonable care in the preparation or putting up of the products will result in the injury to the consumer's life or property, owes a duty to the consumer to take reasonable care.

[81] As the law of products liability has developed, it is now established that manufacturers have:

- a duty to consumers to see that there are no defects in manufacture that are likely to give rise to injury in the ordinary course of use: *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.);
- a duty to warn consumers of dangers inherent in the use of the product of which the manufacturer has knowledge or ought to have knowledge: *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 20; *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569 at p. 574; *Bow Valley Husky (Bermuda) Ltd. v. Saint John Shipbuilding Ltd.*, [1997] 3 S.C.R. 1210; and
- a duty to take care in designing the product to avoid safety risks and to make the product reasonably safe for its intended purposes: *Ragoonanan v. Imperial Tobacco Canada Ltd.* (2000), 51 O.R. (3d) 603 (S.C.J.) *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), *aff'd* [1994] O.J. No. 50 (C.A.).

[82] The manufacturer's duty of care not to manufacture a defective product is difficult to avoid. Professor Klar in *Tort Law* (4th ed) (Toronto: Thomson/Carswell, 2008) at pp. 365-366 suggests that it difficult to envisage circumstances where a manufacturer of a product that injures a person would not have a duty of care to that person. Whether the duty of care has been breached is, of course, a different issue; however, as Professor Waddams notes in *Products Liability* (4th ed) (Toronto: Carswell, 2004) at p. 67, where a product is manufactured with a defect that causes harm, the interference of negligence is practically irresistible.

[83] The manufacturer's duty to alert consumers about dangers associated with the use of a product 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: *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 20; *Rivtow Marine Ltd. v. Washington Iron Works*, [1974] S.C.R. 1189 at p. 1200.

[84] In *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 21, Justice La Forest explained the rationale for a manufacturer's duty of care to warn. He stated:

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.

[85] A manufacturer may discharge its duty to warn by providing an adequate warning to a "learned intermediary." In the case of prescription drugs, the duty of manufacturers to warn consumers is discharged if the manufacturer provides prescribing physicians, rather than the consumers, with an adequate warning of the potential dangers associated with the use of the drug: *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986), 54 O.R. (2d) 92 (C.A.) at paras. 23, 59. The legal theory here is that where a consumer places primary reliance on the judgment of a learned intermediary and not the manufacturer of the product, then the manufacturer will satisfy its duty to warn the consumer by adequately warning the learned intermediary of the risks inherent in the use of the product: *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at paras. 28-29; *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986), 54 O.R. (2d) 92 (C.A.) at para. 59.

[86] The manufacturer's duty of care not to design a product negligently is based on the theory that the manufacturer should be held responsible for the choices it makes that affect the safety of the product. The manufacturer has a duty to make reasonable efforts to reduce any risk to life and limb that may be inherent in its design: *Gallant v. Beitz* (1983), 42 O.R. (2d) 86 (H.C.J.) at p. 90; *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.).

[87] In the case of negligence in designing a product, the defendant is blamed for not designing its product in a safer manner. In *Nicholson v. John Deere Ltd.* (1986), 58 O.R. (2d) 53 at p.60, Justice Smith stated: a manufacturer does not have the right to manufacture an inherently dangerous article when a method exists of manufacturing the same article without risk of harm. Whether a manufacturer breaches its duty of care in designing a product is determined by a risk-utility analysis that measures whether the utility of the chosen design outweighs the foreseeable risks associated with the chosen design. See: *Ragoonanan v. Imperial Tobacco Canada Ltd.* (2000), 51 O.R. (3d) 603 (S.C.J.); *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, *supra*. Liability for a blameworthy design has greater scope than the liability for a defective product because a defective product may be a single aberration, but a design defect extends to all of the products manufactured with that chosen design.

[88] In *Rent-way v. Laidlaw*, *supra*, at p. 164, Justice Granger J. compiled a list of factors to consider when balancing the risks inherent in the product, as designed, against its utility and cost; namely: (1) the utility of the product to the public as a whole and to the individual user; (2) the nature of the product - that is, the likelihood that it will cause injury; (3) the availability of a safer design; (4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (5) the ability of the plaintiff to have avoided injury by careful use of the product; (6) the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff; and (7) the manufacturer's ability to spread any costs related to improving the safety of the design. By way of foreshadowing a point to be made again later, it should be noted at the heart of the duty to care in design is the availability of choices of design that should not be ignored.

[89] The Pfizer Defendants would have the duties described above to the consumers of Neurontin. In addition, they may also have a strict liability for breaching any warranties of quality associated with the contract of sale of Neurontin. And with that background about the nature of Pfizer Inc.'s and Pfizer Canada's duties to the consumers of Neurontin, I turn now to consider the nature of the Defendants' relationship with and duties, if any, to the consumers of generic versions of gabapentin.

[90] The first observation is that as a matter of proximity, the Defendants in their relationship with consumers of generic gabapentin do not have a relationship of manufacturer to consumer. The relationship to be considered is between an innovator that does not manufacture and a consumer from a manufacturer who copies but does not innovate. The relationship between the Pfizer Defendants and the consumers of generic gabapentin is more remote than the relationship between the consumers of generic gabapentin and the manufacturer of generic gabapentin. For the consumer of the generic drug, the more natural focus of his or her reliance and expectations would be on the physician that prescribed the drug and the manufacturer of the drug. The relationship between the consumer of the generic and the innovator of the drug being copied is less immediate.

[91] An innovator - who is not also the manufacturer of the drug - does not fit neatly within Lord Atkin's analysis in *Donoghue v. Stevenson* about product liability. Unlike the manufacturer, the innovator does not release a product into the stream of commerce. What the innovator of a drug releases to commerce is the idea that is copied by the generic drug manufacturer that releases the product into the marketplace. The proximity of the relationship and the attendant reliance between the innovator that does not manufacture the drug and the consumer of the drug while foreseeable is more remote than the relationship between manufacturer of the drug and the consumer of the drug, and the relationship between the innovator and the consumer is remoter still when the generic drug is prescribed by a physician for an off-label use, which, by definition, is not the use for which the product was developed by the innovator.

[92] However, in observing that the relationship between the innovator and the consumer of a generic version of the drug is more remote than the relationship between the manufacturer and the consumer, I wish to be clear that I do not regard the manufacture of generic gabapentin to be an intervening event that would disturb any duty of care that the innovator has to the consumers of generic gabapentin. I simply observe that the consumer of generic gabapentin has a closer relationship of reliance and expectations with the manufacturer or with the learned intermediary than the consumer does with the innovator of Neurontin. The question remains whether it is just and fair to impose duties of care on this less proximate relationship. In any event, as the above authorities indicate, the raw proximity factor is less important to the duty of care analysis than the question of whether it is fair and just to impose a duty of care on the particular defendant.

[93] In order to answer the fairness question in the case at bar, it is necessary to consider the nature of the harm alleged to have been suffered by the consumers of the generic gabapentin and the connection between that harm and the acts of the innovator of

Neurontin. Considering the harm suffered by the consumers in the case at bar, the consumers of the generic gabapentin suffered two harms. First, they consumed a drug that allegedly had a harmful side effect of a propensity of suicidal behaviour and second they consumed a drug that allegedly was useless for its off-label purposes and caused harm by delaying effective treatment. Since the innovator of Neurontin did not manufacture the generic gabapentin, the connection between these two harms and the innovator was the innovator's release of the idea for the drug that was copied by the generic manufacturer.

[94] Would it be fair to make the innovator of Neurontin liable for designing a drug copied by another manufacturer and harmful to its consumers? Perhaps, if the law were prepared to move to strict liability for harm, but Canadian law does not impose strict liability, and, in the case at bar, despite the Plaintiffs' characterizations and attempts to label the harm, the harm alleged to have been suffered by the consumers of generic gabapentin cannot be classified as a flaw in the design of Neurontin which would be the only basis for alleging misconduct against the innovator..

[95] Negligence in design involves the innovator making poor choices and managing risk poorly when deciding how a product should be planned or put together. But the harm caused to the consumers of generic gabapentin is not a result of a design choice. Neurontin was not designed for any use other than as an adjunct treatment of epilepsy. Neurontin was not designed by the Defendants choosing to accept the risk of a propensity of suicidal behaviour; rather, a propensity for suicidal behaviour was a side effect to watch for and, if observed, it was a side effect to be disclosed by giving adequate warnings to the users of the drug. There is no design flaw in the case at bar because design errors presuppose design choices. The Plaintiffs submitted that Neurontin was a drug with a fatal flaw. That remains to be proven, but assuming that the submission is true, its flaw was not a design flaw. The Defendants may have designed a drug that turned out to have a defect, but that is different than choosing to design a drug with a defect that could have been avoided by more careful decisions about how to design the drug. And, in any event, the Defendants made no design choices with respect to the off label uses of Neurontin.

[96] The case at bar is not a case like *Ragoonanan v. Imperial Tobacco Canada Ltd.* (2000), 51 O.R. (3d) 603 (S.C.J.), where tobacco manufacturers were sued by persons injured by fires resulting from their foreseeable careless smoking. Justice Cumming held that there was a reasonable cause of action that a cigarette manufacturer could be liable for designing a cigarette that was not fire safe. In *Ragoonanan*, it was alleged that the defendant's cigarettes could have been designed with reductions in circumference, paper porosity, and tobacco-packing density or with alternative nicotine delivery devices to produce a self-extinguishing cigarette. Nor is the case at bar like other design cases such as *Rent-way v. Laidlaw, supra*, where a truck was designed with the headlights on a single electrical circuit when separate circuits would make for a safer vehicle or *Nicholson v. John Deere Ltd.* (1986), 34 D.L.R. (4th) 542 (Ont. H.C.J.), var'd on other grounds (1989) 57 D.L.R. (4th) 639 (Ont. C.A.), where a lawn mower was designed dangerously because the gas tank was close to the battery. In those cases, the designer made design choices that were not justified based on a risk to safety analysis.

[97] In the case at bar, while the Plaintiffs' proposed common issues raise the issue of the adequacy of warnings about the use of Neurontin, the common issues do not raise the issue of whether a negligent design choice was made in developing the drug. The defects in Neurontin, namely that the drug has a side effect of propensity for suicidal behaviour and that the drug is useless for off label uses, are not a result of design choices. In truth, the case at bar is not a case about design flaws, and it would not be fair to find a duty of care based on an illusorily connection between the harm suffered by the Plaintiffs and the Defendants' conduct.

[98] Would it be fair to make the Defendants, as innovators, liable simply for releasing an idea that is copied? I think not, because once again this would be to impose strict liability and because the harm in releasing the idea is caused by releasing the idea without appropriate warnings about how the associated product may be used, but the innovator is not in a position to give any warnings about the uses being made by consumers of a copied version of the innovator's product. A drug innovator cannot issue warnings about the hazards of a drug manufactured and sold by another pharmaceutical company, particularly when the hazards may be associated with off-label uses. Although the drug innovator can control the manufacture of its own product, monitor for adverse reactions to its product and give warnings about its own product, the innovator is not in a position to stop the generic manufacturer from releasing the generic drug or to stop physicians from prescribing the generic drug for off label uses. This conduct is not the innovator's conduct, and, in my opinion, it would be unfair to impose a duty of care on the innovator for another's conduct when the innovator cannot control, qualify, or stop that conduct. In my opinion, it would not be fair or just to make the innovator liable for failing to do something that should and can only be done by others.

[99] Put differently, normally, an innovator of a prescription drug may discharge its duty of care by giving a warning about the risks associated with its own drug, but imposing a duty of care on the innovator for simply releasing the idea of the drug into the stream of commerce is to impose strict liability on the innovator and also to deny the innovator the defence of having given an adequate warning to a learned intermediary. In my opinion, such an imposition of liability would be unfair.

[100] I, therefore, conclude that it is plain and obvious that the Defendants do not have a duty of care to the consumers of generic gabapentin.

[101] Assuming, however, that I am incorrect and that *Pfizer Canada* and *Pfizer Inc.* do have a *prima facie* duty of care to all consumers of gabapentin, then the second stage of the *Anns* analysis asks are there any considerations that ought to negative or limit: (a) the scope of the duty; (b) the class of persons to whom it is owed; or (c) the damages to which a breach of it may give rise.

[102] In my opinion, in the case at bar about the duty of care between a drug innovator and the consumer of a drug manufactured by another pharmaceutical company, there are two public policy factors that ought to negative the scope of any duty of care and the class of persons to whom the duty is owed by the innovator of a drug. First, the imposition of a duty of care on the innovator to the competitor's consumer would be to

impose strict liability for defective products and to make an innovator an insurer against all harm from its innovation, which would be a radical change in Canadian law and one for the legislature and not the courts to make. Second, the imposition of liability on the innovator would discourage medical advances and innovative technologies that could be beneficial to society.

[103] In *Andersen v. St. Jude Medical Inc.*, [2002] O.J. No. 260 (S.C.J.), a proposed class action was brought against a manufacturer of an allegedly defective heart valve. The defendant moved to have a plea of strict liability struck from the statement of claim. In his judgment granting the defendant's motion, Justice Dambrot noted that Ontario courts had considered and rejected imposing strict liability for defective products and Canadian tort law preferred to subsume product liability under traditional negligence principles, requiring proof of negligence. At paras. 38 and 39 of his judgment, Justice Dambrot explained why the imposition of strict liability was a matter to be left to the legislatures. He stated:

38 There is good reason to leave to the legislatures the decision on whether to impose strict liability on manufacturers, and whether that should be done in all industries. In essence, strict liability makes the manufacturer an insurer of its products and shifts the burden from the individual who was injured to a broader sector of society. The additional costs to manufacturers are presumably passed on to all consumers of their products, assuming the manufacturer does not consider the cost or risk to be too great to carry on the particular business. If manufacturers take the latter view, goods or services may disappear from the market entirely. Although many American states have imposed strict liability, provincial legislatures may not see this to be appropriate or necessary in the Canadian context, where there is much greater social assistance available for those who are hurt. ...

39 Much has been written about the negative effects on product research and innovation that may result from the imposition of strict liability in tort, particularly in the health products field. The assessment of the effects of and the policy considerations underlying the imposition of strict liability is truly political in nature and should be left to the legislatures.

[104] I agree with the observations of Justice Dambrot, and I conclude that there are good public policy reasons for concluding that the Defendants do not have a duty of care to the consumers of gabapentin manufactured and sold by other pharmaceutical companies.

[105] It follows from the above conclusions that the following words or paragraphs should be struck from the statement of claim: (a) from para. 1(c), the words "and its generic, gabapentin, manufactured and sold by other manufacturers"; (b) paras. 19-21; (c) the last sentence of para. 22; (d) from para. 23, the words "or the generic gabapentin"; (e) the last sentence of para. 26; (f) paras. 30-33; (g) the words "Mark Dudley" from para. 34; (h) from para.36, the words "and thus generic gabapentin" in paragraphs c, d, and h; (i) the words "and generic gabapentin" and "and/or generic gabapentin" in para. 38; (j)

the words, “Mrs. Dudley” “and subsequently generic gabapentin” in para. 44; (k) the words “and generic gabapentin” in para. 46; and (l) the words “and generic gabapentin” in para. 47.

The Criteria for Certification

[106] I turn now to an analysis of whether the proposed class action satisfies the other criteria for certification set out in the Act.

[107] Pursuant to s. 5(1) of the *Class Proceedings Act, 1992*, 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.

[108] For an action to be certified as a class proceeding, there must be a cause of action, shared by an identifiable class from which common issues arise that can be resolved in a fair, efficient, and manageable way that will advance the proceeding and achieve access to justice, judicial economy, and the modification of behaviour of wrongdoers: *Sauer v. Canada (Attorney General)*, [2008] O.J. No. 3419 (S.C.J.) at para. 14, leave to appeal to Div. Ct. refused, [2009] O.J. No. 402 (Div. Ct.).

[109] On a certification motion, the question is not whether the plaintiff's claims are likely to succeed on the merits but whether the claims can appropriately be prosecuted as a class proceeding: *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at para. 16.

[110] The purpose of a certification motion is to determine how the litigation is to proceed and not to address the merits of the plaintiff's claim; there is to be no preliminary review of the merits of the claim: *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at paras. 28-9.

[111] Motions for certification are procedural in nature and are not intended to provide the occasion for an exhaustive inquiry into factual questions that would be determined at a trial when the merits of the claims of class members are in issue: *Lambert v. Guidant Corp.*, [2009] O.J. No. 1910 (S.C.J.) at para. 82

Identifiable Class

[112] I have already discussed the cause of action criterion above, and I turn now to the matter of the class definition.

[113] The definition of an identifiable class serves three purposes: (1) it identifies the persons who have a potential claim against the defendant; (2) it defines the parameters of the lawsuit so as to identify those persons bound by the result of the action; (3) it describes who is entitled to notice: *Bywater v. T.T.C.*, [1998] O.J. No. 4913 (Gen. Div.). There must be a rational relationship between the class, the causes of action, and the common issues, and the class must not be unnecessarily broad or over-inclusive: *Pearson*

v. Inco Ltd. (2006), 78 O.R. (3d) 641 (C.A.) at para. 57, rev'g [2004] O.J. No. 317 (Div. Ct.), which had aff'd [2002] O.J. No. 2764 (S.C.J.). Class membership identification is not commensurate with the elements of the cause of action; there simply must be a rational connection between the class member and the common issue(s): *Sauer v. Canada (Attorney General)*, [2008] O.J. No. 3419 (S.C.J.) at para. 32, leave to appeal to Div. Ct. refused, [2009] O.J. No. 402 (Div. Ct.).

[114] Subject to removing any references to the generic gabapentin and adding a temporal qualifier (the date of the commencement of Ms. Goodridge's action), which was absent from the originally proposed definition, I am satisfied that the Plaintiffs have satisfied the criterion of identifying a class. The class is:

(a) All persons resident in Canada (excluding Quebec) who were prescribed and ingested the drug Neurontin at any time before August 5, 2004; and

(b) All persons resident in Canada who by virtue of a personal relationship to one or more of such persons described in (a) above with a valid claim, have standing in this action pursuant to s.61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3, as amended (or an applicable provincial statutory provision or the common law as applicable).

[115] With an exception for Alberta, the above definition accommodates the subrogated claims of the provincial health insurers. The *Alberta Hospitals Act*, unlike other provincial legislation pleaded in Schedule B, does not provide for subrogated claims. This matter may be dealt with as it was in *Robinson v. Medtronic*, [2009] O.J. No. 4366 (S.C.J.) at paras. 77-82.

Common Issues

[116] I turn now to the matter of the common issues criterion.

[117] For an issue to be a common issue, it must be a substantial ingredient of each class member's claim and its resolution must be necessary to the resolution of each class member's claim: *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at para. 18.

[118] The focus of the analysis of whether there is a common issue is not on how many individual issues there might be but whether there are issues the resolution of which would be necessary to resolve each class member's claim and which could be said to be a substantial ingredient of those claims: *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.) at para. 55, leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g, (2003), 65 O.R. (3d) 492 (Div. Ct.).

[119] The fundamental aspect of a common issue is that the resolution of the common issue will avoid duplication of fact-finding or legal analysis: *Western Canadian Shopping Centres Inc. v. Dutton*, [2001] 2 S.C.R. 534 at para. 39.

[120] For an issue to be common, it is not essential that the class members be identically situated vis-à-vis the opposing party or benefit from the successful prosecution of the

action to the same extent: *Western Canadian Shopping Centres v. Dutton*, [2001] 2 S.C.R. 534 at paras. 39-40.

[121] The comparative extent of individual issues is not a consideration in the commonality inquiry, although it is a factor in the preferability assessment: *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.) at para. 65, leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g, (2003), 65 O.R. (3d) 492 (Div. Ct.); *Rumley v. British Columbia (sub. Nom. L.R. v. British Columbia)*, [2001] 2 S.C.R. 184 at para. 33.

[122] Because of my conclusion about the absence of any basis in fact for the allegations about wrongful marketing activities in Canada and my conclusion about the Defendants not having a duty of care with respect to the sales of generic gabapentin by its competitors, the scope of the proposed class proceeding has been substantially narrowed. Another consequence of this narrowing is that questions from the original list of proposed common issues should be removed or modified. The new list of questions is as follows:

1. Can ingesting Neurontin cause an increased risk of suicidal behaviour?
2. Is Neurontin ineffective and/or defective or unfit for the purpose for which it was intended (including usages that ought reasonably to have been foreseen by the Defendants) as designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or both of the Defendants?
3. Did the Defendants knowingly, recklessly or negligently breach a duty to warn or materially misrepresent any of the risks of harm from Neurontin?
4. Are class members entitled to special damages for medical costs incurred in the treatment of health complications related to having ingested Neurontin?
5. Are the Defendants liable for damages resulting from the purchase and consumption of Neurontin?
6. Are the Defendants liable for the subrogated health care costs of class members incurred in the treatment of conditions related to taking Neurontin?
7. Should the Defendants pay exemplary or punitive damages?
8. By virtue of waiver of tort, are the defendants liable on a restitutionary basis:
 - (a) to account to any of the class, including the provincial insurers with subrogated claims, on a restitutionary basis, for any part of the proceeds of the sale of Neurontin? If so, in what amount and for whose benefit is such an account to be made? Or in the alternative,

(b) such that a constructive trust is to be imposed on the proceeds of sale of Neurontin for the benefit of the class, including provincial health insurers with subrogated claims, and, if so, in what amount, and for whom are such proceeds held?

[123] I note that the original list of questions and the revised list of questions are similar to those considered by Justice Cullity in *Heward v. Eli Lilly & Co.*, [2007] O.J. No. 404 (S.C.J.), leave to appeal to Div. Ct. granted [2007] O.J. No. 2709 (S.C.J.), appeal dismissed [2008] O.J. No. 2610 (Div. Ct.), which was a class action that was based on the defendant manufacturing and selling an anti-psychotic drug that allegedly gave rise to an increased risk of diabetes. The Plaintiffs relied on the *Heward* case in making their argument that their questions were suitable for certification, and *Heward* does support their argument that their proposed list of questions have the appropriate commonality to be certified as common issues under the *Class Proceedings Act, 1992*.

[124] Subject to several qualifications, I am satisfied that the revised list of questions satisfy the common issues criterion for certification. The qualifications to the questions are: (a) the words “knowingly, recklessly or negligently” which are unnecessary and which suggest an unpleaded misrepresentation claim should be deleted from question 3; (b) the question about punitive damages should be removed from the list; and (c) the waiver of tort question should be certified but the issue of the entitlement to waiver of tort should be bifurcated from the issue of determining the amount to be disgorged by the Defendants.

[125] I am deleting the question about punitive damages as a common issue for the same reason that I did in *Robinson v. Medtronic*, [2009] O.J. No. 4366 (S.C.J.) and I rely on that analysis for the purposes of these Reasons for Decision.

[126] I am bifurcating the waiver of tort issues for the same reasons that I did in *Peter v. Medtronic*, [2009] O.J. No. 4364 (S.C.J.) and *Robinson v. Medtronic, supra*, and I rely on that analysis for the purposes of these Reasons for Decision.

Preferable Procedure

[127] The next issue is whether the preferable procedure criterion has been satisfied.

[128] For a class proceeding to be the preferable procedure for the resolution of the claims of a given class, it must represent a fair, efficient, and manageable procedure that is preferable to any alternative method of resolving the claims: *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.) at paras. 73-75, leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 50.

[129] Preferability captures the ideas of whether a class proceeding would be an appropriate method of advancing the claim and whether it would be better than other methods such as joinder, test cases, consolidation, and any other means of resolving the dispute: *Markson v. MBNA Canada Bank* (2007), 85 O.R. (3d) 321 (C.A.) at para. 69, leave to appeal to S.C.C. ref'd, [2007] S.C.C.A. No. 346; *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158.

[130] In considering the preferable procedure criterion, the court should consider: (a) the nature of the proposed common issue(s); (b) the individual issues which would remain after determination of the common issue(s); (c) the factors listed in the Act; (d) the complexity and manageability of the proposed action as a whole; (e) alternative procedures for dealing with the claims asserted; (f) the extent to which certification furthers the objectives underlying the Act; and (g) the rights of the plaintiff(s) and defendant(s): *Chadha v. Bayer Inc.* (2001), 54 O.R. (3d) 520 (Div. Ct.) at para. 16, aff'd (2003), 63 O.R. (3d) 22 (C.A.), leave to appeal to S.C.C. ref'd, [2003] S.C.C.A. No. 106.

[131] Whether a class proceeding is the preferable procedure is judged by reference to the purposes of access to justice, behaviour modification, and judicial economy and by taking into account the importance of the common issues to the claims as a whole, including the individual issues: *Markson v. MBNA Canada Bank* (2007), 85 O.R. (3d) 321 (C.A.) at para. 69, leave to appeal to S.C.C. ref'd, [2007] S.C.C.A. No. 346; *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158.

[132] In their factum, in submitting that the Plaintiffs' action does not satisfy the preferable procedure criterion, the Defendants advance numerous arguments that this action is not suitable for a class proceeding because of the complexity and incompatibility of the Plaintiffs' claims and the alleged absence of ways to address important elements of those claims other than by individual trials. Whatever the merits of those arguments, the sting of them is removed by the substantial reduction of the complexity of the lawsuit that is a result of the removal of the claims about the sales of generic gabapentin by the Defendants' competitors and the removal of the claims about the wrongful marketing activities that took place in the United States in the 1990s by a predecessor to Pfizer Inc.

[133] The gravamen of the Plaintiffs' remaining claim, for which there is undoubtedly some basis in fact, is a product's liability and failure to warn claim. This claim is based on the allegations that the Defendants' sold a drug that causes harm by its harmful side effects or by the drug's failure to provide therapeutic relief for its many off-label uses. After the reduction of claims, the gravamen of the Plaintiffs' claim resembles other products liability claims that have been found suitable for certification as a class proceeding.

[134] In my opinion, a class proceeding is the preferable procedure for the determination of the common issues of the Plaintiffs' remaining claim, and I am satisfied that the Plaintiffs' action satisfies the preferable procedure criterion of the test for certification.

Representative Plaintiffs

[135] The fifth criterion for certification is that 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.

[136] In the case at bar, because I am striking the claims with respect to the sales of generic gabapentin, the proposed representative plaintiffs are Ms. Goodridge, Mr. Davidson, and Ms. Lauricella

[137] The representative plaintiff must be a member of the class asserting claims against the defendant, which is to say that the representative plaintiff must have a claim that is a genuine representation of the claims of the members of the class to be represented or that the representative plaintiff must be capable of asserting a claim on behalf of all of the class members as against the defendant: *Drady v. Canada (Minister of Health)* [2007] O.J. No. 2812 (S.C.J.) at paras. 36-45; *Attis v. Canada (Minister of Health)*, [2003] O.J. No. 344 (S.C.J.) at para. 40, *aff'd* [2003] O.J. No. 4708 (C.A.).

[138] Provided that the Representative Plaintiff has his or her own cause of action, the Representative Plaintiff can assert a cause of action against a defendant on behalf of other class members that he or she does not assert personally, provided that the causes of action all share a common issue of law or of fact: *Boulanger v. Johnson & Johnson Corp.*, [2002] O.J. No. 1075 (S.C.J.) at para. 22, leave to appeal granted, [2002] O.J. No. 2135 (S.C.J.), varied (2003), 64 O.R. (3d) 208 (Div. Ct.) at paras. 41, 48, varied [2003] O.J. No. 2218 (C.A.); *Matoni v. C.B.S. Interactive Multimedia Inc.*, [2008] O.J. No. 197 (S.C.J.) at paras. 71-77; *Voutour v. Pfizer Canada Inc.*, [2008] O.J. No. 3070 (S.C.J.); *LeFrancois v. Guidant Corp.*, [2008] O.J. 1397 (S.C.J.) at para. 55.

[139] Whether the representative plaintiff can provide adequate representation depends on such factors as: his or her motivation to prosecute the claim; his or her ability to bear the costs of the litigation; and the competence of his or her counsel to prosecute the claim: *Western Canadian Shopping Centres Inc. v. Dutton*, [2001] 2 S.C.R. 534 at para. 41.

[140] In my opinion, putting aside the matter of the litigation plan, based on the other relevant factors mentioned above, Ms. Goodridge, Mr. Davidson, and Ms. Lauricella are suitable representative plaintiffs for the class as defined above.

[141] As for the litigation plan, for certification, the proposed representative plaintiffs must present a suitable litigation plan. The production of a workable litigation assists the court in determining whether the class proceeding is the preferable procedure and it allows the court to determine whether the litigation itself is manageable in its constituted form: *Carom v. Bre-X Minerals Ltd.* (1999), 44 O.R. (3d) 173 (S.C.J.) at p. 203, *aff'd* (1999) 46 O.R. (3d) 315 (Div. Ct.), varied on other grounds (2000), 51 O.R. (3d) 236 (C.A.), application for leave to appeal to the S.C.C. refused October 18, 2001.

[142] Litigation plans are something of a work in progress and may have to be amended during the course of the proceedings: *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.) at para. 95, leave to appeal to the S.C.C. refused, [2005] S.C.C.A. No. 50, *rev'g* (2003), 65 O.R. (3d) 492 (Div. Ct.).

[143] In the case at bar, the Defendants submit that there are numerous deficiencies in the proposed litigation plan. It is, however, not necessary to address most of the

Defendants' challenges to the plan because, once again, most of the problems arise from the claims associated with the sales of generic gapapentin and with the wrongful marketing activities that took place in the United States in the 1990s by a predecessor to Pfizer Inc., and these allegations are being removed from the proceeding.

[144] Ms. Goodridge, Mr. Davidson, and Ms. Lauricella have not had an opportunity to present a litigation plan that responds to the reshaped class proceeding that will emerge from their motion for certification. In what remains to be litigated by common issues trials and by individual issues trials, there would be, in my opinion, no insurmountable problems to settling an appropriate litigation plan.

[145] In these circumstances, I think it is appropriate to hold that the fifth criterion for certification has been satisfied but to impose a term that the Plaintiffs prepare a new litigation plan that shall be settled upon a motion or a case conference.

Conclusion

[146] In the result, I grant the Defendants' motion to strike various paragraphs from the Plaintiffs' statement of claim but with leave to amend the statement of claim to plead the claims of Mr. Davidson and Ms. Lauricella, who may be added as representative plaintiffs.

[147] Further, subject to the qualifications and terms noted in these Reasons for Decision, I grant the Plaintiffs' motion for certification.

[148] The precise terms of the certification order shall be settled after the litigation plan is settled. The litigation plan should include a notice plan, which can also be settled if the parties cannot come to an agreement.

[149] If the parties cannot agree with respect to the matter of costs of the two motions, they may make submissions in writing beginning with the Plaintiffs' submissions within 20 days of the release of these Reasons for Decision followed by the Defendants' submissions within a further 20 days.

[150] Order accordingly.



Percll, J.

Released: February 18, 2010

CITATION: Goodridge v. Pfizer Canada Inc., 2010 ONSC 1095
COURT FILE NO.: 06-CV-307728CP
DATE: February 18, 2010

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

**Rhonda Gayle Goodridge, Susan Dudley, and Mark
Dudley**

Plaintiffs

- and -

Pfizer Canada Inc. and Pfizer Inc.

Defendants

REASONS FOR JUDGMENT

Perell, J.

Released: February 18, 2010