

June 29/07
Pursuant to
CONFORMEMENT A
 Rule 1.01
 The Order of
the Court
DATE: _____

Court File No.: 07-CV-331344CP

**ONTARIO
SUPERIOR COURT OF JUSTICE**

REGISTRAR
SUPERIOR COURT OF JUSTICE
BETWEEN:

MARIA FODOR and LESLIE FODOR

Plaintiffs

- and -

JANSSEN-ORTHO INC., JOHNSON & JOHNSON INC.,
JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH &
DEVELOPMENT, L.L.C., f/k/a R. W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE,
and ORTHO-McNEIL PHARMACEUTICAL, INC.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

AMENDED STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs.
The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date July 28, 2006

Issued by M. Burnett *MB*
1 Local registrar

Address of ~~London Court House~~
court office ~~Civil, Landlord/Tenant Section~~
~~Group Floor, Unit "A"~~
~~80 Dundas Street~~
~~London, ON N6A 6A3~~

TO: JANSSEN-ORTHO INC.
19 Green Belt Drive
Don Mills, ON M3C 1L9

SUPERIOR COURT
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330 UNIVERSITY AVE
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COUR SUPÉRIEURE
DE JUSTICE
330 AVE UNIVERSITY
TORONTO
TORONTO, ONTARIO
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AND TO: JOHNSON & JOHNSON INC.
7101 Rue Notre Dame Est
Montreal, QC H1N 2G4

AND TO: JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
United States

**AND TO: JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT,
L.L.C., f/k/a R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE**
920 Route 202 South
P.O. Box 300
Mail Stop 2628
Raritan, NJ 08869
United States

AND TO: ORTHO-McNEIL PHARMACEUTICAL, INC.
1000 Route 202 South
P.O. Box 300
Raritan, NJ 08869
United States

CLAIM

1. The Plaintiffs, Maria Fodor and Leslie Fodor, claim on behalf of themselves and others similarly situated in Canada:
 - (a) an order certifying this proceeding and appointing them as representative Plaintiffs for the class and any appropriate sub-class
 - (b) general damages in the amount of \$400,000 for each person prescribed Ortho Evra;
 - (c) special damages for, *inter alia*, refund of the portion of the purchase price of Ortho Evra purchases which exceeded the maximum non-excessive price, as well as medical and other expenses related to testing, treatment and monitoring in an amount to be determined;
 - (d) in the alternative to the claim for damages, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from their sales of Ortho Evra generally and specifically from their sales of Ortho Evra at prices exceeding the maximum non-excessive price;
 - (e) damages pursuant to the *Family Law Act*, R.S.O. 1990, c F.3 s.61 and similar legislation in other provinces as listed in Schedule "A", where applicable, in the amount of \$100,000 for each such plaintiff;
 - (f) punitive, aggravated, and exemplary damages in the amount of \$20,000,000;
 - (g) the costs of distributing all monies received to class members;
 - (h) prejudgement interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;

- (i) costs on a substantial indemnity basis, including G.S.T.; and
 - (j) such further and other relief as this Honourable Court may deem just.
- 2. The Plaintiffs Maria Fodor and Leslie Fodor are individuals residing in Toronto, Ontario.
- 3. Leslie Fodor is the spouse of Maria Fodor and is pursuing his claim in that capacity.
- 4. Johnson & Johnson is a New Jersey corporation which has its principal place of business in New Brunswick, New Jersey. At all material times, Johnson & Johnson was engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling Ortho Evra in Canada directly or indirectly through an agent, affiliate or subsidiary.
- 5. Johnson & Johnson Inc. is a federal corporation with its headquarters in Montreal, Quebec. Johnson & Johnson Inc. is a member of the Johnson & Johnson's Family of Companies.
- 6. Johnson & Johnson Pharmaceutical Research & Development, L.L.C., f/k/a R.W. Johnson Pharmaceutical Research Institute is a limited liability company organized under the laws of New Jersey and is a part of the Johnson & Johnson's Family of Companies. Johnson & Johnson Pharmaceutical Research & Development, L.L.C. was formed by a 2001 merger of the Janssen Research Foundation and the R.W. Johnson Pharmaceutical Research Institute.
- 7. Ortho-McNeil Pharmaceutical, Inc. is a Delaware corporation which has its principal place of business in New Jersey and is a wholly owned subsidiary of Johnson & Johnson.
- 8. Janssen-Ortho Inc. is an Ontario corporation with its headquarters in Don Mills, Ontario. Ortho Products began operations in Canada in 1941. McNeil products were first offered

in Canada in 1948 through a distributor. Some ten years later, Johnson & Johnson acquired McNeil Laboratories. In 1991, McNeil merged with Ortho to form Ortho-McNeil Inc. Janssen and Ortho-McNeil Inc. merged in 1985 to form Janssen-Ortho Inc.

9. The business of each of Janssen-Ortho Inc., Johnson & Johnson Inc., Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., f/k/a R.W. Johnson Pharmaceutical Research Institute, and Ortho-McNeil Pharmaceutical, Inc. (collectively the "Defendants") is inextricably interwoven with that of the other and each is the agent of the other for the purposes of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling Ortho Evra in Canada.
10. In bringing this action on behalf of a class of people in Canada who were prescribed Ortho Evra, to be further defined in the motion for certification, the Plaintiffs plead and rely upon the provisions of the *Class Proceedings Act, 1992*, S.O. 1992, c.6 and the *Negligence Act*, R.S.O. 1990, c. N-1, as amended, and regulations thereunder, and the *Food and Drugs Act*, R.S.C. 1985, c. F.27 and regulations thereunder.

THE DRUG

11. Ortho Evra is a transdermal contraceptive patch designed to prevent pregnancy. Ortho Evra was the first skin patch approved for birth control and received a Notice of Compliance from Health Canada on August 20, 2002. The Defendants began selling Ortho Evra in Canada, as "Evra", on October 23, 2002.
12. At or about the time of introducing Ortho Evra to the marketplace, the Defendants' patent for its best-selling oral contraceptive, Ortho Tri-Cyclen, was about to expire.

13. The brand of Ortho Evra marketed in Canada contains a lower amount of estrogen (0.6 mg EE) than the brand of Ortho Evra marketed in the United States (0.75 mg EE), but both products are nevertheless considered bioequivalent.
14. Despite the differing brand names between the U.S. and Canadian versions of the drug, and slight changes in the Canadian pharmacokinetics (i.e. lower levels of estrogen/EE), Evra and Ortho Evra are bioequivalent. Therefore, wherever Ortho Evra is expressly referred to, Evra is implied.
15. Although Ortho Evra and most oral contraceptives are loaded with the same amount of estrogen, hormones from the Ortho Evra patch go directly into the bloodstream, while oral contraceptives are digested first, reducing much of the estrogen that eventually enters the blood.
16. The Defendants did not provide adequate safety data to Health Canada with respect to Ortho Evra. The Defendants knew or should have known that Ortho Evra was unsafe, defective, unreasonably dangerous, and not fit for its intended purposes.

THE RISKS

17. The risk of developing and/or dying from a blood clot is substantially higher among women who use Ortho Evra compared to women who use traditional oral contraceptive pills.
18. Following Health Canada's approval of Ortho Evra, the Defendants aggressively marketed the product without properly disclosing the safety hazards associated with Ortho Evra.
19. The packaging insert accompanying Ortho Evra stated that the contraceptive patch is expected to be associated with similar risks to that of other hormonal contraceptives,

including birth control pills. The same package insert, however, stated that the safety information provided to consumers is derived primarily from studies of birth control pills.

20. The package insert for Ortho Evra is misleading and in direct conflict with the risks associated with using Ortho Evra.
21. The Defendants have been analyzing adverse event reports with respect to use of Ortho Evra and have been creating their own charts that document a higher rate of blood clots and deaths in association with use of Ortho Evra than with ~~the~~ oral contraceptives.
22. Over seven times as many adverse event reports have been associated with use of Ortho-Evra as opposed to use of ~~the~~ oral contraceptives.
23. In 2000, doctors reviewing Ortho Evra clinical trials submitted by the Defendants warned that blood clots could be a problem if the patch was approved. Despite the expressed concern of the reviewer that the label should clearly reflect the safety concern, there was no requirement for follow-up studies other than routine reviews of voluntary reports called in by doctors, consumers, and the Defendants.
24. The Defendants' own records show that they received some 500 reports of serious problems associated with use of Ortho Evra between April 2002 and December 2004, while only 61 reports were received on all types of oral contraceptives during that time.
25. Notwithstanding the well documented safety hazards associated with using Ortho Evra, the Defendants failed to conduct any meaningful post-market surveillance.
26. The various sales messages sent to healthcare providers failed to warn that use of Ortho Evra carried a higher risk of blood clots than oral contraceptives and actually implied that Ortho Evra carried the same risks as oral contraceptives.

27. At all material times, the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Plaintiff and putative class members, that the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis from using Ortho Evra is significantly higher than the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis while using oral contraceptives.
28. At all materials times, the Defendants knew or should have known that the risks of using Ortho Evra included severe and life threatening complications and side effects.
29. At all material times, the Defendants, through their servants and agents, negligently, recklessly and/or carelessly marketed, distributed and/or sold Ortho Evra without adequate instructions or warnings of the product's serious side effects and unreasonably dangerous risks.

EXCESSIVE PRICING

30. The results of a Therapeutic Class Comparison test done by the Board Staff of the Patented Medicine Prices Review Board pursuant to their guidelines indicated that the introductory price of Ortho Evra in Canada (\$8.3333 per patch) exceeded the maximum non-excessive price of \$4.2133 per patch by more than 90% in 2002.
31. By letter dated March 23, 2004, the Board Staff advised the Defendants of the commencement of an investigation into the introductory price of Ortho Evra.
32. By letter dated April 28, 2004, the Defendants replied to the Board Staff's investigation letter maintaining its position that the price of Ortho Evra was not excessive.
33. Following its review of the Defendants' submission, the Board Staff advised the Defendants by letter dated November 5, 2004 that it had completed its investigation and that the price of Ortho Evra continued to be excessive. It was the position of the Board

Staff that the Defendants had engaged in a policy of selling Ortho Evra at an excessive price. The Defendants had been selling Ortho Evra since its introduction in Canada in October 2002 at a price per patch which the Defendants knew or ought to have known exceeded the maximum non-excessive price calculated in accordance with the Patented Medicine Prices Review Board's Guidelines.

34. On February 21, 2005, the Board Staff accepted a Voluntary Compliance Undertaking from the Defendants which resulted in the price of Ortho Evra in Canada being lowered by approximately 45% to \$4.47 per patch effective January 1, 2005.

THE PLAINTIFFS' EXPERIENCE

35. The Plaintiff, Maria Fodor, was prescribed by her physician and commenced using ~~Ortho~~ Ortho Evra in or about October 2004. In or about January 2005, Mrs. Fodor began suffering from intense pain in her lower rib cage and left shoulder. On January 21, 2005, Mrs. Fodor was treated in the emergency department of the Toronto East General Hospital. Mrs. Fodor was diagnosed by doctors as having suffered from a bilateral pulmonary embolism. Mrs. Fodor immediately ceased using Ortho Evra. Ms. Fodor's damages are a direct result of her use of Ortho Evra and the Defendant's negligence.
36. Mrs. Fodor used Ortho Evra in accordance with the package label and consumer information pamphlet, and in the manner it was intended to be used.
37. Mrs. Fodor does not smoke or consume alcohol and has no family history of blood clotting or heart disorders. Mrs. Fodor was in excellent health prior to commencing use of Ortho Evra.
38. In the time period before and during Mrs. Fodor's use of Ortho Evra, she received no warnings about the increased risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis from using Ortho Evra.

39. Had Mrs. Fodor been aware of the potential risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis from using Ortho Evra, she would never have used it. Ms. Fodor's damages are a result of her use of Ortho Evra and the Defendants' negligence in respect therewith.

40. Leslie Fodor and other class members, have suffered and continue to suffer damages including loss of income due to work absences required to attend to, care for and provide services to class members, loss of care, guidance and companionship as well as expenses and special damages.

THE SAFETY UPDATES

41. On November 10, 2005, the U.S. Food and Drug Administration announced new prescribing information for the brand of Ortho Evra patch marketed in the United States. The U.S. prescribing information was revised to include a new, bolded warning alerting health care providers that the amount of estrogen delivered through the skin produces a higher estrogen exposure than when taking the typical birth control pill and that greater exposure to estrogen may increase the risk of blood clots.

42. On November 28, 2005, Health Canada issued a warning advising consumers that it is in the process of reviewing whether any product labelling changes are required for the Canadian version of Ortho Evra. Health Canada is continuing to monitor the safety of Ortho Evra through its post-marketing surveillance program.

43. On March 30, 2006, Health Canada issued an advisory that it is currently reviewing the results of two studies looking at the risk of serious side effects when using Ortho Evra and continuing to monitor the safety of using Ortho Evra.

CAUSES OF ACTION

44. The Defendants at all material times owed a duty of care to the Plaintiffs to:

- (a) ensure that Ortho Evra was fit for its intended or reasonably foreseeable use;
 - (b) conduct appropriate testing to determine whether and to what extent use of Ortho Evra posed serious health risks, including the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis;
 - (c) adequately warn the Plaintiffs and their physicians that use of Ortho Evra carries the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis;
 - (d) ensure that prescribing physicians were kept fully and completely informed of all risks associated with Ortho Evra;
 - (e) monitor, investigate, evaluate and follow up on adverse reactions to the use of Ortho Evra;
 - (f) properly inform Health Canada and other regulatory agencies of the risks of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis, associated with the use of Ortho Evra; and
 - (g) sell Ortho Evra at a price not exceeding the maximum non-excessive price as determined by the Patented Medicine Prices Review Board Guidelines.
45. The Defendants negligently breached their duty of care.
46. The Plaintiffs state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following:
- (a) the Defendants failed to ensure that Ortho Evra was not dangerous to recipients during the course of its use and that the drug was fit for its intended purpose and of merchantable quality;

- (b) the Defendants failed to adequately test Ortho Evra in a manner that would fully disclose the magnitude of the risks associated with its use, including but not limited to the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis;
- (c) the Defendants failed to give Health Canada complete and accurate information as it became available from time to time;
- (d) the Defendants failed to conduct any or any adequate follow-up studies on the efficacy and safety of Ortho Evra;
- (e) the Defendants failed to conduct any or any adequate long-term studies of the risks of continued use of Ortho-Evra;
- (f) the Defendants failed to provide the Plaintiffs and their physicians with any adequate warning of the risks associated with use of Ortho Evra, including but not limited to the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis;
- (g) the Defendants failed to provide the Plaintiffs and their physicians with any or any adequate information and warnings respecting the correct usage of Ortho Evra;
- (h) the Defendants failed to warn the Plaintiffs and their physicians about the need for comprehensive regular medical monitoring to ensure the early discovery of side effects related to using Ortho Evra;
- (i) the Defendants failed to adequately monitor, evaluate and act upon reports of adverse reactions to Ortho Evra in Canada and elsewhere;

- (j) the Defendants failed to provide any or any adequate updated and current information to the Plaintiffs and their physicians respecting the risks and efficacy of Ortho Evra as it came available from time to time;
- (k) the Defendants failed to provide adequate warnings of the potential hazards of Ortho Evra on package labels;
- (l) The Defendants failed to provide adequate warnings of the risks associated with Ortho Evra, including the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis in all persons receiving Ortho Evra, on the customer information pamphlets in Canada;
- (m) the Defendants, after noticing problems with Ortho Evra, failed to issue adequate warnings, timely recall the drug, publicize the problem and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiffs and their physicians of the drugs' inherent dangers, including but not limited to the danger of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis in all persons receiving Ortho Evra;
- (n) the Defendants failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the correct usage of Ortho Evra and the risks associated with the drug;
- (o) the Defendants represented that Ortho Evra was safe and fit for its intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;
- (p) the Defendants misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Ortho Evra and its associated

risks, including the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis in all persons receiving Ortho Evra;

- (q) the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known to the Defendants;
- (r) the Defendants failed to timely cease the manufacture, marketing and/or distribution of Ortho Evra when they knew or ought to have known that this drug caused or could cause developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis;
- (s) the Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;
- (t) the Defendants failed to properly supervise their employees, their subsidiaries and their affiliated corporations;
- (u) the Defendants actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Ortho Evra;
- (v) the Defendants breached other duties of care to the Plaintiffs and the putative class of Plaintiffs, details of which breaches are known only to the Defendants;
and
- (w) the Defendants sold Ortho Evra at a price which exceeded the maximum non-excessive price by over 90% from October 23, 2002 until January 1, 2005.

47. The risks associated with use of Ortho Evra, including the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis in all persons using Ortho Evra, were in the exclusive knowledge and control of the Defendants. The extent of the risks was not known and could not have been known to the Plaintiffs. The

Plaintiffs' injuries would not have occurred but for the negligence of the Defendants in failing to ensure that Ortho Evra was safe for use or, in the alternative, for providing an adequate warning of the risks associated with using Ortho Evra to the Plaintiffs and to the Plaintiffs' physicians.

DAMAGES

48. The Plaintiffs' and other putative class members' injuries and damages were caused by the negligence of the Defendants, their servants and agents.
49. As a result of the Defendants' negligence, the Plaintiffs have suffered and continue to suffer serious personal injuries and pain and suffering.
50. As a result of the conduct of the Defendants, the Plaintiffs and other class members suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.
51. Some of the expenses related to the medical treatment that the Plaintiffs and class members have undergone, and will continue to undergo, have been borne by the various provincial health insurers including the Ontario Health Insurance Plan ("OHIP"). As a result of the negligence of the Defendants, the various provincial health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect of all past and future insured services. These subrogated interests are asserted by the Plaintiffs and the putative class members pleading and relying upon the statutes listed in Schedule "B".
52. Some of the cost of purchasing Ortho Evra between October 23, 2002 and January 1, 2005, when Ortho Evra was being sold at a price exceeding the maximum non-excessive amount, by Ms. Fodor and the putative class members was covered, in whole, or in part, by third parties, including health insurers, and drug benefit plans. To the

extent that such third parties have a subrogated interest in these expenditures for Ortho Evra, those claims are asserted by the Plaintiffs and the putative class members.

53. The Plaintiffs claim punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendants.
54. In the alternative to damages, the Plaintiffs plead they are entitled to claim "waiver of tort" and elect to claim an accounting or other such restitutionary remedy to disgorge the revenues generated by the Defendants as a result of the sale of Ortho Evra. Revenues which were generated in large part due to the Defendants' breach of the Patented Medicine Price Review Board guidelines, but also due to their failure and refusal to properly bring the risks associated with Ortho Evra to the attention of the Plaintiffs.

SERVICE OUTSIDE OF ONTARIO

55. The Plaintiffs plead and rely on section 17 (g), (h), (o) and (p) of the Rules of Civil Procedure, allowing for service *ex juris* of the foreign defendants. Specifically, this originating process may be served without court order outside Ontario in that the claim is:
- (a) in respect of a tort committed in Ontario (rule 17.02(g));
 - (b) in respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed (rule 17.02(h));
 - (c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and
 - (d) against a person carrying on business in Ontario (rule 17.02(p)).

PLACE OF TRIAL

56. The Plaintiffs propose that this action be tried in London, Ontario.

July 28, 2006

SISKIND, CROMARTY, IVEY & DOWLER ^{LLP}
Barristers & Solicitors
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