

AMENDED THIS / MODIFIÉ CE Nov 6/08 PURSUANT TO / CONFORMÉMENT À
 RULE/LA RÉGLE 26.02
 THE ORDER OF / L'ORDONNANCE DU Justice Cullity
DATED / FAIT LE July 28/08
REGISTRAR / GREFFIER
SUPERIOR COURT OF JUSTICE / COUR SUPÉRIEURE DE JUSTICE **ONTARIO**

Court File No. | 04-CV-045435 CP

S. Chandradat
Registrar

SUPERIOR COURT OF JUSTICE

BETWEEN:

BENNY MIGNACCA
and ELAINE MIGNACCA

Plaintiffs

and

MERCK FROSSI CANADA LTD., MERCK FROSST CANADA & CO.
and MERCK & CO., INC.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

SIXTH AMENDED FRESH 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 plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, 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.

IF YOU PAY THE PLAINTIFF'S CLAIM, and \$10,000.00 for costs, within the time for serving and filing your statement of defence, you may move to have this proceeding dismissed by the court. If you believe the amount claimed for costs is excessive, you may pay the plaintiff's claim and \$400.00 for costs and have the costs assessed by the court.

Date: October 1, 2004

Issued
by:

R. Baker
Registrar

Address of Court Office:
London Court House
Civil, Landlord/Tenant Section
Group Floor, Unit A
80 Dundas Street
London, ON N6A 1E7

TO: Merck Frosst Canada Ltd.
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Kirkland, QC H9H 3L1

AND TO: Merck Frosst Canada Ltd.
2250 Argentia Road
Mississauga, ON L5N 6A5

AND TO: Merck Frosst Canada & Co.
1959 Upper Water Street
P.O. Box 997
Halifax, NS B3J 2X2

AND TO: Merck Frosst Canada & Co.
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Mississauga, ON L5N 6A5

AND TO: Merck & Co., Inc.
P.O. Box 100
1 Merck Drive
Whitehouse Station, NJ 08889-0100
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CLAIM

DEFINITIONS

- I. The following definitions apply for the purposes of this statement of claim:
- (a) "APPROVe" means the Adenomatous Polyp Prevention on Vioxx trial, a multi-centre, randomized, placebo-controlled double-blind study to determine the effect of long-term treatment with Vioxx on the recurrence of adenomatous polyps of the large bowel in patients with a history of colorectal adenomas;
 - (b) "Benny" means Benny Mignacca;
 - (c) "Class" or "Class Members" means a person in Canada, including their estates, other than residents of Quebec and Saskatchewan, who were prescribed and ingested Vioxx;
 - (d) "Classes" means the Class, and the Family Class;
 - (e) "Cox-2" means cyclooxygenase-2;
 - (f) "Dependants Statutes" means *Family Law Act*, R.S.O. 1990, c. F.3; *Family Compensation Act*, R.S.B.C. 1996, c. 126; *Fatal Accidents Act*, R.S.A. 2000, c. F-8; *Tort-feasors Act*, R.S.A. 2000 c. T-5; *Fatal Accidents Act*, C.C.S.M. c. F50; *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7; *Fatal Accident Act*, R.S.N.L. 1990, c. F-6; *Fatal Injuries Act*, R.S.N.S. 1989, c. 163; *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3; *Fatal Accidents Act*, R.S.P.E.I. 1988 c. F-5; and *Fatal Accidents Act*, R.S.Y. 2002, c. 86.
 - (g) "Elaine" means Elaine Mignacca;
 - (h) "Family Class" means all persons who by reason of his or her relationship to a member of the Class are entitled to make claims under any of the **Dependants Statutes** as a result of the death or personal injury of member of the Class;
 - (i) "FDA" means the U.S. Food and Drug Administration;
 - (j) "Formulary" means the list of drugs that "third party payors" such as a government drug plan, insurance company, self insured corporation, union or health benefit trust have approved and are therefore responsible for paying in whole or in part based upon the individual insurance plan;

- (k) "JAMA" means the Journal of the American Medical Association;
- (l) "Merck" means Merck Canada, Merck Ltd. and Merck USA;
- (m) "Merck Canada" means Merck Frosst Canada & Co.;
- (n) "Merck Ltd." means Merck Frosst Canada Ltd.;
- (o) "Merck USA" means Merck & Co. Inc.;
- (p) "NSAIDs" means non-steroidal anti-inflammatory drugs;
- (q) "OHIP" means the Ontario Health Insurance Plan;
- (r) "VIGOR" means the Vioxx Gastrointestinal Outcomes Research trial, a prospective randomized double-blind controlled trial which aimed to assess the gastrointestinal effects of Vioxx in 8076 patients with rheumatoid arthritis;
- (s) "Vioxx" means rofecoxib, a non-steroidal, anti-inflammatory drug designed to act as a selective inhibitor of cyclooxygenase-2; and

2. Benny and Elaine claim on their own behalf and on behalf of all members of the Classes:

- (a) an order certifying this action as a class proceeding and appointing: Benny as the representative plaintiff of the Class; and Elaine as the representative plaintiff of the Family Class;
- (b) a declaration that the defendants were negligent in the development, testing, design, manufacturing, licensing, distribution, marketing and sale of Vioxx and are liable to the Classes for damages;
- (c) a declaration that the defendants are vicariously liable to the Classes for the acts and omissions of their officers, directors, agents, employees and representatives;
- (d) general damages in the amount of \$500,000,000.00 or such other sum as this Honourable Court deems just;
- (e) special damages in the amount of \$750,000,000.00 or such other sum as this Honourable Court deems just;
- (f) alternatively, an accounting and order requiring disgorgement of all revenue received by the defendants from the sale of Vioxx in Canada;

- (g) punitive and exemplary damages in the amount of \$50,000,000.00 or such other sum as this Honourable Court deems just;
- (h) the costs of distributing all monies received to the Classes;
- (i) pre-judgment and post-judgment interest pursuant to sections 128 and 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43;
- (j) the costs of this action on a substantial indemnity basis, together with G.S.T. and other applicable taxes thereon; and
- (k) such further and other relief as this Honourable Court deems just.

THE PLAINTIFFS

3. Benny is 53 years old and resides in the Town of Elora, in the province of Ontario.

4. Benny started taking Vioxx on or about July 10, 2000 for treatment of arthritis. As a result of consuming Vioxx, on or about November 4, 2000, Benny suffered a stroke for which he was hospitalized. Since his stroke, Benny requires ongoing medical treatment.

5. Benny discontinued his Vioxx use on November 4, 2000.

6. Elaine is 54 years old and is married to Benny. She and Benny have two children, aged 26 and 25

7. OHIP and other provincial health insurance plans in other provinces have and will continue to incur the costs of health care benefits required by Class Members as a result of their use of Vioxx, including, but not limited to, the cost of prescription drugs

used to treat conditions associated with adverse reactions to Vioxx. These health care costs are asserted in this action as subrogated claims by the Class Members.

THE CLASSES

8. This action is brought on behalf of the Classes.

THE DEFENDANTS

9. Merck Canada is a Nova Scotia corporation with headquarters in Halifax, Nova Scotia. It carries on business in Mississauga, Ontario and in Kirkland, Quebec. At all material times, Merck Canada was involved in and/or responsible for the research and development which led to the discovery and manufacturing of Vioxx. At all material times, Merck Canada was an affiliate of Merck USA.

10. Merck Ltd. is a federal corporation, with its registered head office in Kirkland, Quebec. Merck Ltd. maintains a principal place of business in Mississauga, Ontario. At all material times, Merck Ltd. was involved in and/or responsible for the sales, distribution and marketing of Vioxx in Canada. At all material times, Merck Ltd. was an affiliate of Merck USA.

11. Merck USA is a US publicly traded pharmaceutical company with its headquarters in Whitehouse Station, New Jersey. At all material times, Merck USA was involved in Canada in development, manufacturing, sales, distribution and/or marketing of Vioxx. At all material times, Merck USA manufactured, marketed, sold and/or

distributed Vioxx in Canada directly or indirectly through an agent, affiliate or subsidiary.

12. The business of each of Merck Canada, Merck Ltd. and Merck USA is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the development, manufacture, marketing, sale and/or distribution of Vioxx in Canada.

DEVELOPMENT OF VIOXX

13. Vioxx is a Cox-2 specific inhibitor in the class of drugs known as NSAIDs. Cox-2 is an enzyme considered to be responsible for pain associated with the inflammation caused by osteoarthritis, among other conditions. NSAIDs that selectively inhibit the Cox-2 enzyme were believed to be capable of providing relief from pain and inflammation without inducing various gastrointestinal complications associated with many traditional NSAIDs.

14. Merck isolated the compound that was to become Vioxx in 1992 at the Merck Frosst Centre for Therapeutic Research in Montreal. According to the Merck website, "*the race was on to find a selective inhibitor of Cox-2*".

15. Merck was intent on developing a Cox-2 inhibitor before any competitor could do so. By its own admission, Merck accelerated the timelines normally associated with the development and testing of drugs. On or about May 20, 1999, Vioxx was approved by the FDA in the United States after just seven years of development and testing

16. On or about October 25, 1999, Vioxx was approved for sale in Canada to treat acute and chronic osteoarthritis, pain in adults and severe menstrual pain.

17. In or about April 2000, Vioxx was listed on the Ontario Drug Benefit Formulary. Once listed on the Formulary, the price was set at or about \$1.35 for both the 12.5 mg and 25 mg single daily doses.

18. All Vioxx distributed in Canada was developed, manufactured and distributed by the defendants acting in concert.

THE DEFENDANTS' PRE-MARKET KNOWLEDGE OF CARDIOVASCULAR RISKS

19. From the pre-market development stages of Vioxx, Merck knew or ought to have known of the cardiovascular risks associated with Vioxx. Indeed, Merck's scientists recognized the potential for such risks as early as November 1996, long before the first Canadian consumer ever ingested Vioxx.

20. In addition to the results from various clinical studies, Merck was advised by its Board of Scientific Advisors in 1998 that Vioxx's mechanism of action could potentially cause cardiovascular events. As a result of these concerns, the Board of Scientific Advisors recommended that specific studies be conducted in order to resolve the issue. No such study was ever conducted by Merck

21 By 1999, the results of several small Vioxx trials conducted by Merck had showed that thromboembolic events, such as heart attack and stroke, were three times as frequent in patients receiving Vioxx compared to placebo.

22. Despite the Board of Scientific Advisors' concern about a mechanism-based increase in cardiovascular risk with Vioxx and various study results supporting that likelihood, Vioxx was launched onto the Canadian market on October 25, 1999, with a label that contained no warning of cardiovascular risks.

VIOXX IN THE MARKETPLACE

23. In the thirteen months following the introduction of Vioxx into the Canadian market, Health Canada's Canadian Adverse Drug Reaction Monitoring Program received 151 reports describing 417 suspected adverse reactions to Vioxx. Five of those adverse reactions were fatalities and twenty-five reports involved suspected cardiovascular reactions, including heart failure. In addition, Merck was receiving further information on an on-going basis which indicated the troubling cardiovascular risk profile of Vioxx.

24. For example, in March, 2000, the results from VIGOR were released. This study demonstrated a significantly increased risk of cardiovascular event rates with the use of Vioxx. Indeed, patients treated with Vioxx in the VIGOR study were found to have a 5-fold greater risk for heart attack than patients treated with the comparator drug naproxen.

25. Nonetheless, Merck issued a press release in April, 2000 entitled "Merck confirms favorable cardiovascular safety profile of Vioxx" in which it stated that the data from VIGOR and other on-going clinical trials showed no difference in the incidence of cardiovascular events, including heart attack, among patients taking Vioxx.

26. Further, Merck did not conduct a study focusing on Vioxx's cardiovascular risks. Instead, Merck officials decided to monitor ongoing and planned clinical trials designed to test Vioxx for other uses.

27. In December 2000, health policy analysts at George Washington University reviewed Merck's sponsored clinical trials of Vioxx and concluded that the trials showed Vioxx provided roughly the same amount of pain relief for arthritis sufferers that a consumer would get with aspirin, ibuprofen or other NSAIDs which were far cheaper than Vioxx.

28. Nonetheless, at all material times, Merck marketed Vioxx as being superior to other pain relievers and worth the vastly increased cost. Indeed, Vioxx was the most heavily advertised drug in the year 2000.

29. In 2003, Merck reported worldwide sales of Vioxx of U.S.\$2.5 billion. Vioxx was among Canada's top ten prescribed medications in the years 2001, 2002 and 2003.

30. In August 2001, an article by noted cardiologists at the Department of Cardiovascular Medicine, The Cleveland Clinic Foundation, was published in JAMA and raised concerns over the possible impact of Vioxx on cardiovascular health. The authors recommended that Merck launch new studies to assess possible cardiovascular risks of Vioxx. In response, Merck publicly dismissed the study's results, continued to downplay the cardiovascular risks of Vioxx and denied the need for further study regarding the risk of cardiovascular events with Vioxx.

31. In September 2001, the American Heart Association, the National Stroke Association and the Arthritis Foundation all asked Merck to test whether Vioxx increased the risk of heart attack and stroke. Merck refused to conduct or commission such a study

32. In September 2001, the FDA sent Merck a warning letter concerning its marketing practices as they related to the cardiovascular risks of Vioxx. The letter required Merck to cease certain promotional activities for Vioxx. The FDA asserted that Merck had misled doctors about potential cardiovascular side effects and had downplayed the risks of stroke and heart attack. In addition, the FDA stated that a press release issued by Merck in May, 2001, which was similar to the release from April, 2000, and which asserted that Vioxx had a favourable safety profile, was "simply incomprehensible" and amounted to false and misleading advertising.

33. In January 2002, an Advisory Committee on Pharmacovigilance of Health Canada met to discuss the results of the VIGOR study and to consider revising

the relevant product monographs to issue warnings. At the conference, the Committee agreed that physicians and all patients contemplating Cox-2 inhibitor therapy should be warned of potential negative cardiovascular effects of these drugs. The Committee recommended that a "Dear Health Care Professional" letter from Health Canada be issued regarding the potential problems with Vioxx.

34. Notwithstanding the important cardiovascular findings in numerous studies and other data and information that was being collected worldwide by Merck and their affiliates and subsidiaries on an on-going basis, Merck concealed and continued to downplay the cardiovascular risks of Vioxx.

35. In addition, despite the publicity surrounding reports by third parties, Merck continued to market and distribute Vioxx as being safe and effective, without undertaking its own cardiovascular studies in order to either confirm or dispute the findings reported by others.

36. On April 19, 2002, some 25 months after Merck received the results of the VIGOR study, the recommended "Dear Health Care Professional" letter was issued in Canada. Thereafter, arrangements were made to revise Vioxx's product monograph. However, the amended monograph provided only a vague precaution about cardiovascular risk and stated that the significance of the cardiovascular findings from VIGOR and two other placebo-controlled studies was "unknown".

37. On September 30, 2004, Merck issued a voluntary worldwide withdrawal of Vioxx effective immediately, due to the increased risk of cardiovascular events. The company's decision was reported to be based on data from a new three-year prospective, randomized, placebo-controlled clinical trial known as APPROVe. The trial began enrolment in 2000 and was designed to determine the effect of three years of treatment with Vioxx on the recurrence of polyps of the large bowel. The trial was halted prematurely after results showed an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke.

38. Merck organized its work force in a manner that was set up to preserve and expand the market for Vioxx in an effort to maximize its profits. For Merck's business plan to work effectively, it was necessary to have Vioxx listed on the provincial Formularies. Merck pursued this business plan by inaccurately promoting the alleged safety and efficacy benefits of Vioxx, while downplaying the known cardiovascular risks of the drug.

39. In addition to misrepresenting the safety profile of Vioxx to achieve Formulary approval, Merck employed a similar strategy of misinformation to encourage dramatically increased prescriptions of the drug.

NEGLIGENCE

40. Prior to Vioxx ever being sold in Canada, Merck was privy to early and alarming information, data and analyses which reflected the high risks to cardiovascular health posed by Vioxx. From that time until September 2004, Merck downplayed and/or

concealed the relevant information and data from physicians, the public and from regulatory authorities. But for Merck's alleged misconduct, Vioxx would never have achieved regulatory approval.

41. Merck's worldwide withdrawal of Vioxx constitutes an admission by it that the drug was and is dangerously defective and not fit for its intended use.

42. Merck owed to Benny and to the members of the Classes a duty of care, which Merck has breached, causing injury and damage to them and the members of the Classes. Particulars of Merck's negligence are as follows:

- (a) they failed to ensure that Vioxx was not dangerous to consumers and that the drug was fit for its intended purpose and of merchantable quality;
- (b) they failed to conduct appropriate testing to determine whether and to what extent the ingestion of Vioxx poses serious health risks, including adverse cardiovascular events;
- (c) they failed to adequately test Vioxx in a manner that would fully disclose the various side effects and the magnitude of the risks associated with its use;
- (d) they failed to conduct any or adequate follow-up studies on the efficacy and safety of Vioxx;
- (e) they failed to provide the Class members and their physicians with any or adequate warnings of inherent risks associated with Vioxx;
- (f) they failed to provide the Class members and their physicians with any or adequate information and warnings respecting the correct usage of Vioxx;
- (g) they failed to provide any or adequate updated and current information to the Class members and their physicians respecting the risks and efficacy of Vioxx as such information became available;
- (h) they failed to provide prompt warnings of potential hazards of Vioxx in the product monograph and in the product labelling;

- (i) they failed to warn the Class members and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of potentially fatal cardiovascular events,
- (j) after receiving actual or constructive notice of problems with Vioxx, they failed to issue adequate warnings, withdraw or recall the drug, publicize the problem and otherwise act properly and in a timely manner to alert the public, the Class members and their physicians, of the drug's inherent dangers;
- (k) they failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the correct usage of Vioxx and the risks associated with the drug;
- (l) they falsely stated and/or implied that Vioxx was safe and fit for its intended purpose when they knew or ought to have known that these representations were false;
- (m) they misstated the state of research, opinion and medical literature pertaining to the purported benefits of Vioxx and its associated risks;
- (n) they failed to cease the manufacture and/or distribution of Vioxx when they knew or ought to have known that this drug caused or could cause significant injury;
- (o) they marketed Vioxx at dosage levels which it knew or ought to have known to be unsafe;
- (p) they disregarded reports of symptoms of adverse cardiovascular events among patients who participated in clinical trials of Vioxx;
- (q) they failed to instruct their employees to properly evaluate, record and advise on complaints of adverse cardiovascular effects of Vioxx;
- (r) they failed to accurately and promptly disclose to Health Canada information relating to increased cardiovascular risks associated with Vioxx and to modify Vioxx's product monograph and product labelling accordingly in a timely manner or at all;
- (s) they failed to monitor and to initiate a timely review, evaluation and investigation of reports of adverse cardiovascular events associated with Vioxx in Canada and around the world;
- (t) they marketed Vioxx when they knew or ought to have known of the risks of adverse cardiovascular events;
- (u) they failed to provide any or adequate warnings to the health profession and/or to Class members;

- (v) they failed to properly investigate cases of adverse cardiovascular events caused by Vioxx;
- (w) they failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and the regulations thereunder;
- (x) they hired incompetent personnel and appointed incompetent officers and directors;
- (y) they failed to instruct their servants, agents, officers and directors to act ethically and responsibly;
- (z) they failed to properly supervise their employees, their subsidiaries and their affiliated corporations;
- (aa) they encouraged their employees to increase sales volumes while neglecting to inform consumers, retailers, hospitals, physicians and pharmacists of the increased cardiovascular risks associated with Vioxx;
- (bb) they failed to withdraw or recall Vioxx in a timely manner because of the cost and the negative publicity and their overriding concern for lost profits;
- (cc) they falsely understated the cardiovascular risks of Vioxx, while at the same time falsely overstating the safety and efficacy of the drug; and
- (dd) as it relates to OHIP and various other provincial health insurance plans, they knew or ought to have known that had their representatives been honest and forthright about the true cardiovascular risks associated with Vioxx, the drug would not have been placed on their Formularies

43. The plaintiffs plead that, by virtue of the acts described herein, Merck is liable to them in damages. Each of the defendants is vicariously liable for the acts and omissions of the others for the following reasons:

- (a) each was the agent of the other;
- (b) each defendant's business was operated so that it was inextricably interwoven with the business of the other;
- (c) each defendant entered into a common advertising and business plan with the other to distribute and sell Vioxx;

- (d) each defendant operated pursuant to a common business plan to distribute and sell Vioxx; and
- (e) each defendant intended that the businesses be run as one global business organization.

WAIVER OF TORT

44. The plaintiffs and Class Members are entitled to elect, at the end of the trial of the common issues, to waive the tort and require the defendants to account for all or part of the revenue they received from the sale of Vioxx in Canada.

45. The plaintiffs plead that such an election may be appropriate for the following reasons, among others:

- (a) such revenue was acquired in such circumstances that the defendants may not in good conscience retain it;
- (b) the integrity of the pharmaceutical regulations and marketplace would be undermined if the court did not require an accounting;
- (c) Vioxx could not have been marketed, and the defendants would not have received any or part of the revenue from its sale in Canada, absent the defendants' tortious conduct; and
- (d) the defendants engaged in wrongful conduct by putting into the marketplace a pharmaceutical product which causes or has the potential to cause serious risks of cardiovascular injury.

DAMAGES AND OTHER SUBROGATED CLAIMS

46 The Ontario Ministry of Health and Long-Term Care provides coverage for health care services to Ontario residents through OHIP. Similar programs are available in other provinces.

47. Benny and other Class Members required hospitalization and other medical services as a result of the negligence of the defendants as particularized in the paragraphs above. These services were paid for by OHIP and other provincial insurers.

48. OHIP and other provincial insurers, will continue to provide treatment in the future to Benny and other Class Members.

49. The subrogated interests of OHIP and all other provincial insurers, for all past and future insured services are asserted for the plaintiffs and all other members of the Class.

50. Some of the cost of the purchase of Vioxx by Class Members was covered, in whole, or in part, by third parties, including health insurers, and drug benefit plans. OHIP, for example, paid for Vioxx for Class Members while they were in hospital.

51. Such third parties have a subrogated interest in these expenditures for Vioxx which is asserted for the plaintiffs and for all other members of the Class.

52. Benny pleads that he and the other members of the Class would not have used Vioxx if the defendants had acted reasonably and responsibly.

53. The plaintiffs and the other members of the Class are entitled to recover from the defendants as special damages the incremental cost of Vioxx, being the

difference in the cost of Vioxx as compared with other, lower cost, prescription or over-the-counter NSAIDS. But for the defendants' wrongdoing as particularized above, the plaintiffs and other Class Members would not have incurred the expense of purchasing Vioxx, but would have sought out other, less expensive and safer treatments.

54. As a result of the defendants' negligence, Benny and the other members of the Class have suffered and will continue to suffer damages and loss, including:

- (a) personal injury;
- (b) out-of-pocket expenses incurred, including those connected with hospital stays, medical treatment, medication and the cost of Vioxx or, alternatively, the incremental cost of Vioxx as paid for by Class Members and/or by OHIP and other provincial health insurers;
- (c) costs of future care and future services; and
- (d) loss of income and loss of future income.

55. As a result of the defendants' negligence and the resulting injuries to Benny and the other members of the Class, Elaine and the other members of the Family Class have suffered loss and damage. They have incurred out-of-pocket expenses for the benefit of the Class. They have suffered and will continue to suffer loss of income. They have paid for or provided nursing, housekeeping and other services. They have suffered a loss of support, guidance, care and companionship that they might reasonably have expected to receive if the injuries had not occurred. Elaine and the members of the Family Class plead and rely upon the various Dependents Statutes, as applicable.

PUNITIVE DAMAGES

56. The plaintiffs plead that the defendants' conduct, as particularized above, in the design, development, testing, manufacturing, licensing, distribution, marketing,

sale and promotion of Vioxx and the delayed withdrawal or recall and/or the failure to withdraw or recall was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, willful, in intentional disregard of the rights and safety of Benny and the rights and safety of the members of the Class, indifferent to the consequences and motivated by economic considerations, such as the maintaining of profits and market share. Such conduct renders the defendants liable to pay punitive damages to the members of the Classes.

STATUTES

57. The Plaintiffs plead and rely upon, *inter alia*:

- *Alberta Health Care Insurance Act*, R.S.A. 2000, c. A-20;
- *Class Proceedings Act, 1992*, S.O. 1992, c. 6;
- *Courts of Justice Act*, R.S.O. 1990, c. C.43;
- *Family Law Act*, R.S.O. 1990, c. F.3;
- *Family Compensation Act*, R.S.B.C. 1996, c. 126
- *Fatal Accident Act*, R.S.N.L. 1990, c. F-6;
- *Fatal Accidents Act*, C.C.S.M. c. F50;
- *Fatal Accidents Act*, R.S.A. 2000, c. F-8;
- *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7;
- *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3;
- *Fatal Accidents Act*, R.S.P.E.I. 1988 c. F-5;
- *Fatal Accidents Act*, R.S.Y. 2002, c. 86;
- *Fatal Injuries Act*, R.S.N.S. 1989, c. 163;
- *Health Insurance Act*, R.S.O. 1990, c. H 6;

- *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197;
- *Health Services Insurance Act*, C.C.S.M., c. H35;
- *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988 c. H-8;
- *Hospital Insurance Agreement Act*, R.S.N.L. 1990 c. H-7;
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3;
- *Hospital Insurance Services Act*, R.S.Y. 2002, c.112;
- *Hospital Services Act*, R.S.N.B. 1973, c. H-9;
- *Hospitals Act*, R.S.A. 2000, c. H-12;
- *Negligence Act*, R.S.O. 1990, c. N.1;
- *Tort-feasors Act*, R.S.A., 2000 c T-5;
- *Trustee Act*, C.C.S.M. c. T160;
- *Trustee Act*, R.S.N.W.T. 1988, c. T-8; and
- *Trustee Act*, R.S.O. 1990, c. T.23.

all as amended and the regulations made thereunder.

THE REAL AND SUBSTANTIAL CONNECTION BETWEEN THE SUBJECT MATTER OF THIS ACTION AND ONTARIO

58. There is a real and substantial connection between the subject matter of this action and the Province of Ontario, among others, for the following reasons:

- (a) Merck Canada, Merck Ltd. and Merck USA carry on business in Ontario;
- (b) Merck Ltd. has its principal place of business in Mississauga, Ontario;
and
- (c) the regulatory approval in Canada for Vioxx was granted in Ottawa, Ontario.

SERVICE OUTSIDE OF ONTARIO

59. 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) in respect of property in Ontario (rule 17.02(a));
- (d) against a person outside Ontario who is a necessary or proper party to a proceeding properly brought against another person served in Ontario (rule 17.02(o)); and
- (e) against a person carrying on business in Ontario (rule 17.02(p)).

60. The plaintiffs propose that this action be tried in the City of Toronto.

October 1, 2004

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04-CV-045435P

Court File No:

**ONTARIO
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at LONDON
Consolidated and Transferred to Toronto

Proceeding under *The Class Proceedings Act, 1992*

**SIXTH AMENDED
FRESH STATEMENT OF CLAIM**

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