

ONTARIO
SUPERIOR COURT OF JUSTICE



BETWEEN

ROBERT TIBONI

Plaintiff

MERCK FROSST CANADA LTD., MERCK FROSST CANADA & CO.
AND MERCK & CO., INC.

Defendants

Brought under the *Class Proceedings Act*, S.O. 1992, c. 6

STATEMENT OF CLAIM

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. 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 the 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 of 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 \$500.00 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 is excessive, you may pay the Plaintiff's claim and \$400.00 for costs and have the costs assessed by the court.

Issue Date: November 23, 2004

Issued by:

Sean Roden
Registrar

Address of Court Office:
10th Floor, 393 University Avenue
Toronto, Ontario M5G 1E6

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

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

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

CLAIM

1. The plaintiff, Robert Tiboni, claims on behalf of himself, and others similarly situated in Ontario:
 - (a) an order certifying this action as a class proceeding and appointing him as representative plaintiff under the *Class Proceedings Act*, S.O. 1992, c. 6;
 - (b) general damages;
 - (c) special damages;
 - (d) punitive damages;
 - (e) interest;
 - (f) costs; and
 - (g) such further and other relief as this Honourable Court may deem just.

2. The plaintiff brings this action on his own behalf, and on behalf of a proposed class of similarly situated residents of Ontario to be further defined in the plaintiff's notice of motion for class certification.

3. The defendant, Merck Frosst Canada & Co. ("Merck Canada & Co.") is a corporation incorporated pursuant to the laws of Canada with its headquarters in Halifax, Nova Scotia, and maintains a place of business in Mississauga, Ontario. At all times material, Merck Canada & Co. was involved in and/or was responsible for the research, development, testing, manufacture, marketing, distribution and sale of the drug, VIOXX, (generic name: Rofecoxib), in Canada and in particular in Ontario. At all material times, Merck Canada & Co. was an affiliate of the defendant, Merck & Co., Inc.

4. The defendant, Merck Frosst Canada Ltd. ("Merck Canada Ltd.") is a corporation incorporated pursuant to the laws of Canada, with its registered head office in Kirkland, Quebec, and maintains a place of business in Mississauga, Ontario. At all times material, Merck Canada Ltd. was involved in and/or was responsible for the research, development, testing, manufacture, marketing, distribution and sale of the drug, VIOXX, in Canada and in particular in Ontario. At all material times, Merck Canada Ltd. was an affiliate of the defendant, Merck & Co., Inc.

5. The defendant, Merck & Co., Inc. ("Merck USA") is a corporation incorporated pursuant to the law of the United States of America, with its corporate headquarters at Whitehouse Station, New Jersey, USA. At all material times, Merck USA was involved in and/or was responsible for the research, development, testing, manufacture, marketing, distribution and sale of VIOXX in Canada and in particular in Ontario. Merck USA researched, developed, tested, manufactured, marketed, distributed and/or sold VIOXX in Ontario directly or indirectly through an agent, affiliate, or subsidiary, and has as its affiliates, Merck Canada & Co. and Merck Canada Ltd.

6. At all times material, Merck Canada & Co., Merck Canada Ltd. and Merck USA carried on the research, development, testing, manufacture, marketing, distribution and sale of VIOXX in Canada, including Ontario, as a joint enterprise for their mutual benefit and profit. As such, the defendants are referred to collectively herein as "Merck".

7. With respect to claims asserted herein, each defendant is responsible 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 with respect to the research, development, testing, manufacturing, marketing, distribution and sale of VIOXX was operated so that it was inextricably interwoven with the business of the others;
- (c) The defendants entered into a common business plan for the shared purpose of researching, developing, testing, manufacturing, marketing, distributing, and selling VIOXX in Canada and Ontario for profit;
- (d) The defendants shared the common purpose of concealing the adverse effects of VIOXX from Canadian regulatory authorities including Health Canada, the medical community and class members;

8. VIOXX is a non-steroidal, anti-inflammatory drug prescribed to relieve pain and swelling. VIOXX is a member of a class of painkilling drugs known as COX-2 inhibitors.

9. VIOXX was approved for sale in Canada on or about October 25, 1999. The defendants promoted VIOXX as being less likely to cause gastric bleeding and therefore superior to other arthritis and pain control drugs on the Canadian market.

10. VIOXX has been associated with an increased risk of serious adverse reactions including, but not limited to, cardiovascular complications such as heart attack, stroke, unstable angina, pulmonary embolism, palpitations, irregular heartbeat and congestive heart failure.

11. The defendants knew, or ought to have known, of the significant risk of adverse cardiovascular complications from ingesting VIOXX. The defendants failed to inform or adequately inform the Ontario health care community and the Ontario public of those risks.

12. Neither the patient information pamphlet nor the prescribing information provided to physicians and pharmacists in Canada warned of the adverse cardiovascular risks associated with taking VIOXX. However, the patient information pamphlet available to consumers in the United States contained a warning that heart attacks and other serious cardiovascular conditions such as blood clots, had been reported by patients taking VIOXX.

13. On September 30, 2004, Merck announced a voluntary worldwide withdrawal of VIOXX due to the increased risk of cardiovascular events such as heart attack and stroke.

14. The defendants knew, or ought to have known that VIOXX caused or materially contributed to an increased risk of harm to consumers' cardiovascular health, particularly heart attack and stroke. The defendants ought not to have proceeded to manufacture,

market, distribute or sell VIOXX in Ontario, particularly given the presence of other safer drugs available in the marketplace.

15. On or about September 4 2001, the plaintiff was first prescribed VIOXX by his family physician at a dose of 25mg per day for back pain and arthritis. The plaintiff consumed VIOXX daily as directed and in accordance with the package label and consumer information provided to him.

16. On or about July 2002, the plaintiff began to suffer severe chest pain and was taken to hospital where he was diagnosed as having suffered a heart attack. The plaintiff requires an angioplasty and a stent as a result of his heart attack.

17. As a result of the plaintiff's ingestion of VIOXX and subsequent heart attack, the plaintiff has received and will continue to receive medical treatment and medications for his heart condition for the rest of his life. Additionally, the plaintiff will require medical follow-up, testing and monitoring in relation to his heart condition for the rest of his life.

18. The plaintiff received no warning from the defendants prior to his ingesting VIOXX as to the risk of adverse cardiovascular complications. Had the plaintiff been warned of those risks, he would have declined VIOXX.

19. Prior to ingesting VIOXX, the plaintiff was physically active and in good health. As a result of ingesting VIOXX pursuant to the defendants' recommended and allowable

dosages, the plaintiff has experienced, and will continue to experience weakness, pain, and fatigue, which have impaired and interfered with his enjoyment of life and regular daily activities.

20. At all material time, Merck owed the plaintiff and class members a duty of care to:

- (a) Ensure that VIOXX was fit for its intended purpose;
- (b) Conduct appropriate testing to ensure that VIOXX was safe for human ingestion before releasing VIOXX onto the Ontario market;
- (c) Conduct ongoing clinical trials and tests as to the safety and efficacy of VIOXX after releasing VIOXX to the Ontario market;
- (d) Adequately monitor and investigate reports of adverse reactions to VIOXX in Ontario, in Canada, and throughout the world, as well as to adequately monitor studies investigating the efficacy and safety of VIOXX, and to act promptly to protect the Ontario public in view of rising controversy regarding adverse reactions to VIOXX and questions concerning VIOXX's safety;
- (e) Warn the plaintiff, Ontario consumers, physicians and the health care community as to the serious health risks caused by ingesting VIOXX including, but not limited to, an increased risk of serious cardiovascular complications such as heart attack and stroke.

21. Merck breached the above duties of care and failed to meet the standards of care expected of them in the circumstances. In so doing, Merck caused or materially contributed to the injuries and subsequent losses sustained by the plaintiff and class members. Those injuries and losses were reasonably foreseeable.

22. Merck, their servants and agents, were negligent in the design, development, testing, licensing, distribution, monitoring, marketing and sale of VIOXX, particulars of which, include the following:

- (a) Placing VIOXX on the market, when they knew, or ought to have known, that the drug was unsafe, unfit for human consumption and defective, and that it caused serious and potentially life threatening side effects including, but not limited to, heart attack and stroke;
- (b) Failing to conduct adequate studies and tests on the safety of VIOXX;
- (c) Failing to adequately appreciate the significance of data from clinical trials in patients who ingested VIOXX which revealed an increased risk of cardiovascular complications including heart attack and stroke;
- (d) Ignoring data from clinical trials in patients who ingested VIOXX which revealed an increased risk of cardiovascular complications including heart attack and stroke;
- (e) Failing to warn or to adequately warn in a timely fashion, class members and their physicians, pharmacists and health care providers of the risk of serious adverse effects of VIOXX, including heart attack and stroke, after they became aware of those serious adverse effects;

- (f) Failing to warn or adequately warn in a timely fashion, the class members and their physicians, pharmacists and health care professionals of these adverse effects of VIOXX, including heart attack and stroke that are associated with increased dosage levels of VIOXX;
- (g) Failing to instruct their employees, servants and agents to properly evaluate, record and advise on complaints of side effects of VIOXX;
- (h) Failing to accurately and candidly disclose consumer complaints and the serious side effects of the ingestion of VIOXX to Health Canada in a timely manner, or at all;
- (i) Failing to initiate timely review, evaluation and investigation of the side effects of VIOXX following complaints of injury, death and/or hazard to safety;
- (j) Failing to properly assess and investigate complaints of VIOXX adequately upon receiving them;
- (k) Refraining from reporting, in a timely manner, the serious side effects of VIOXX to regulators, doctors, health care providers, the public and class members in order to retain market value and maximize profits;
- (l) Failing to conform with acceptable disclosure and reporting requirements under the *Food and Drugs Act* of Canada;
- (m) Employing incompetent personnel;
- (n) Failing to instruct their servants, agents, and officers to act ethically and responsibly;

- (o) Failing to properly supervise their employees, and their subsidiaries and affiliating corporations;
- (p) Encouraging their employees to increase sales volumes while neglecting to inform consumers, retailers, hospitals, physicians and pharmacists of the side effects of VIOXX;
- (q) Failing to recall VIOXX in a timely manner;
- (r) Introducing VIOXX onto the marketplace when they knew, or ought to have known that there were other drugs in the marketplace which were safer;
- (s) Failing to provide warnings of the potential hazards of ingesting VIOXX on package inserts and package labels;
- (t) Failing to warn the plaintiff, class members, their physicians and their health care providers about the need for comprehensive regular medical monitoring to ensure early discovery of serious cardiovascular complications arising from the use of VIOXX; and
- (u) Encouraging and participating in the aggressive marketing and promotion of VIOXX, including the providing of free samples of VIOXX to physicians to give to their patients, when they knew or ought to have known of the serious adverse cardiovascular complications caused by the ingestion of VIOXX.

23. The risks of serious adverse cardiovascular complication associated with VIOXX ingestion, including but not limited to, heart attack and stroke, were in the exclusive

knowledge and control of the defendants. The plaintiff was prescribed VIOXX by his doctor, filled his prescription at a licensed pharmacy, and followed the instructions for consumption. The plaintiff followed the VIOXX refill regime and repeatedly ingested VIOXX prior to its recall and removal from the Canadian marketplace.

24. The plaintiff's injuries would not have occurred but for the negligence of the defendants in failing to ensure that VIOXX was safe for use or, alternatively, in providing an adequate warning of the risks to the plaintiff, his physician and his pharmacist.

25. As a result of ingesting VIOXX in accordance with Merck's recommended and allowable dosage, the plaintiff and class members have sustained personal injury with pain and suffering, and loss of enjoyment of life including but not limited to, adverse cardiovascular complications, stroke, heart attack and death. The plaintiff and class members who remain alive will continue to experience the effects of their VIOXX ingestion with associated pain, suffering, loss of enjoyment of life. As a result of ingesting VIOXX, the plaintiff and other class members will continue to have pain and suffering which will impair and interfere with their enjoyment of life and regular daily activities.

26. Particulars of the past and ongoing loss or damage suffered by the plaintiff and class members includes

- (a) Pain, suffering, loss of quality and enjoyment of life, and reduction of life expectancy;

- (b) Past loss of income;
- (c) Diminishment of earning capacity resulting in a loss of future income;
- (d) Past and future costs of care;
- (e) Past and future medical and other expenses, including the costs of diagnosis and treatment of VIOXX side effects; and
- (f) Out-of-pocket expenses.

27. Merck intentionally withheld information about the serious health risks of using VIOXX during periods of risk of harm to the plaintiff and class members, and maintained secrecy for a considerable period of time to build profit and protect their financial interests.

28. Merck's conduct in bringing VIOXX to Canadian and Ontario pharmacies for distribution to, and consumption by the plaintiff and the class members, and their failure to recall VIOXX in a timely fashion was high-handed, arrogant, devoid of care and a wanton disregard for the class members' health and safety. Furthermore, the defendants' conduct was indifferent to the consequences and motivated by economic considerations to capture market control, build cash flow, and earn profit. For such disreputable and deliberately injurious conduct, the plaintiff claims on behalf of himself and the class members, punitive damages, in amounts to be determined at the trial of this action by this Honourable Court.

29. In addition, the plaintiff seeks recovery of any medical expenses and hospital costs paid or required to be paid on his behalf or on behalf of class members.

30. To the extent that any of the defendants are resident outside of Ontario, the plaintiff pleads Rules 17(g)(h)(o) and (p) of the *Rules of Civil Procedure* allowing service *ex juris* on foreign defendants without leave of the court.

31. The plaintiff proposes that this action be tried in Toronto, Ontario.

Date: November 22, 2004

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Tiboni v. Merck Frosst Canada Ltd. et al
Plaintiff Defendant

Court File No. 04 CV 279434 CP

**ONTARIO
SUPERIOR COURT OF JUSTICE**
Proceedings Commenced at Toronto

STATEMENT OF CLAIM

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