

**2004 01 T 3711 CP
IN THE SUPREME COURT OF NEWFOUNDLAND AND LABRADOR
TRIAL DIVISION**

BETWEEN:	ARTHUR CLIFFORD SMITH	PLAINTIFF
AND:	MERCK FROSST CANADA LTD.	FIRST DEFENDANT
AND:	MERCK FROSST CANADA & CO.	SECOND DEFENDANT
AND:	MERCK & CO., INC.	THIRD DEFENDANT

BROUGHT UNDER *THE CLASS ACTIONS ACT*

Before the Honourable Mr. Justice Faour, Case Management Judge

AMENDED STATEMENT OF CLAIM

This pleading is an amendment to the original Statement of Claim issued on October 7, 2004. The amendments are designated in Appendix "A" to this Amended Statement of Claim.

The parties

1. The Plaintiff, Arthur Clifford Smith, is an Insurance Broker who resides at 5 Parsons Place, in the City of St. John's, in the Province of Newfoundland and Labrador.
2. The First Defendant, Merck Frosst Canada Ltd., is a corporation incorporated under the laws of Canada with its head office situate at 16711 Trans Canada Highway West, Kirkland, in the Province of Quebec. It is registered as an Extra-Provincial Corporation under the *Corporations Act*, RSNL 1990, c. C-36. The registered office of the First Defendant is at 11th Floor, Cabot Place, 100 New Gower Street, in the City of St. John's, in the Province of Newfoundland and Labrador.
3. The Second Defendant, Merck Frosst Canada & Co., is a corporation incorporated under the laws of Canada with its head office situate at 16711 Trans Canada Highway West, Kirkland, in the Province of Quebec.

4. The Third Defendant, Merck & Co., Inc., is a corporation incorporated under the laws of the State of New Jersey, United States of America, with its head office situate at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey 08889-0100 United States of America.
5. At all material times, the First Defendant was responsible for the sale, distribution and marketing of a wide range of Merck medications in Canada.
6. At all material times, the Second Defendant conducted research, development and manufacturing of Merck medications in Canada.
7. Both the First Defendant and the Second Defendant are affiliates of the Third Defendant. The Third Defendant is an international pharmaceutical company.
8. The Defendants acted collectively in developing, manufacturing, distributing, selling and marketing in Canada a prescription medication, rofecoxib, under the brand name “Vioxx”, for relief from pain and inflammation in the treatment of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, severe menstrual cycles, migraines and acute pain.
9. The Defendants are collectively referred to hereafter as the Defendants or “Merck.”

Facts

10. Vioxx was approved for the purposes stated in paragraph 5 by the United States Food and Drug Administration (“FDA”) in May, 1999. It was approved by Health Canada in October 1999.
11. Vioxx is a NonSteroidal Anti-Inflammatory Drug (“NSAID”). It was marketed on the basis that it provided more effective relief from pain and inflammation with fewer gastrointestinal side effects than did traditional NSAIDS such as aspirin, naproxen, ibuprofen and diclofenac. Unlike Vioxx, these other medications were low cost generic medications whose benefits, side effects, and risk factors were well-known.
12. NSAIDs reduce pain and inflammation by inhibiting the cyclooxygenase enzyme (COX). In the 1990s’ it was determined that this enzyme exists in two isoforms, cyclooxygenase-

1 (COX-1) and the cyclooxygenase-2 (COX-2). Traditional NSAIDs inhibit both COX-1 and COX-2.

13. The COX-2 enzyme is induced in inflammation. Through inhibiting the COX-2 enzyme, NSAIDs reduce pain and inflammation.
14. The COX-1 enzyme is a constitutive enzyme. It synthesizes prostaglandins that protect the gastro-intestinal tract. Inhibition of the COX-1 enzyme can cause adverse gastro-intestinal effects. For this reason, traditional NSAIDs (which inhibit COX-1 as well as COX-2) can cause adverse gastro-intestinal side effects.
15. Following the discovery of COX-1 and COX-2 as separate COX isoforms, pharmaceutical firms created a new class of medication that would target and inhibit the COX-2 enzyme. Selective inhibition of the COX-2 enzyme was intended to relieve pain and inflammation, while, at the same time, avoiding the gastro-intestinal side effects associated with traditional NSAIDs. This new class of drugs are known as selective NSAIDs or coxibs. Merck developed rofecoxib (Vioxx) as a selective NSAID.
16. Before and during the development, testing, marketing and distribution of Vioxx, Merck knew or ought to have known that there was a risk that Vioxx could have adverse effects upon the cardiovascular system. One such known potential effect was a reduction in prostacyclin, a prostaglandin which inhibits the aggregation of platelets and mediates vasodilation. Prostacyclin is produced by the COX-2 enzyme. A reduction in prostacyclin can increase the risk of thrombosis. Other known potential effects upon the cardiovascular system were the impairment of renal function and increased blood pressure. These potential effects of COX-2 inhibitors had been identified as early the mid-1990s.
17. Furthermore, the COX-1 enzyme affects the production of thromboxane. Thromboxane is a potent platelet activator and aggregator. Platelets are a component of blood. Excessive activation and aggregation of platelets can lead to the formation of blood clots. Inhibition of the COX-1 enzyme, insofar as it affects thromboxane, can reduce the risk of blood clots.
18. Vioxx, as stated above, was designed to inhibited the COX-2 enzyme without inhibiting the COX-1 enzyme; this created a potential cardiovascular risk.

19. During the period leading up to regulatory approval and distribution of Vioxx, Merck was aware that Vioxx could be associated with adverse cardiovascular effects. Merck did not, however, design or conduct clinical trials for the purpose of specifically or effectively assessing factors relevant to the cardiovascular effects of the drug or the cardiovascular risk itself.
20. Merck conducted a clinical trial of Vioxx known as VIGOR - Vioxx Gastrointestinal Outcomes Research. The results were published in 2000. The primary objective of the trial was to evaluate the gastrointestinal effects of Vioxx against those of a non-selective NSAID. The non-selective NSAID used as the comparator was naproxen. The participants in the trial who used Vioxx had twice as many serious cardiovascular events as those who used naproxen.
21. VIGOR was not designed to measure cardiovascular risk. Indeed, persons who took aspirin for cardiovascular reasons were excluded from the trial. This exclusion criteria substantially reduced the incidence of cardiovascular events in VIGOR: the persons most susceptible to adverse cardiovascular events were effectively kept out of the trial. (However, there were some participants in the study who were aspirin-indicated by reason of a prior cardiovascular conditions such as stroke, transient ischemic attack or heart attack. Among these participants, those who used Vioxx had a 4.89 times higher relative risk of a serious cardiovascular event than those who used naproxen.)
22. A separate trial was conducted by another pharmaceutical firm of a selective NSAID known as celecoxib (brand name, Celebrex). The Celecoxib Long-Term Arthritis Safety Study (CLASS) had the primary objective of evaluating the gastrointestinal effects of celecoxib against those of non-selective NSAIDs. In this trial, two non-selective NSAIDs were used, ibuprofen and diclofenac. There was no significant difference in serious cardiovascular events between participants who used celecoxib and those who used either ibuprofen or diclofenac.
23. Merck claimed that the higher incidence of cardiovascular events of Vioxx in the VIGOR trial was because naproxen had some cardioprotective effect. Whether naproxen did have a cardioprotective effect was not known at that time: it was conjecture, not fact. Naproxen did not affect blood pressure. Apart from any effect of naproxen, participants taking Vioxx in VIGOR did have a marked increase in blood pressure. Increased blood pressure itself places persons at a higher risk of adverse cardiovascular events.

24. An article entitled *Non-steroidal Anti-inflammatory Drugs and Risk of Serious Coronary Heart Disease: an Observational Cohort Study* was published in the January, 12, 2002 issue of *The Lancet* by Dr. Wayne Ray, et. al. This study - as well as others - indicated naproxen did not have a cardioprotective effect. Nevertheless, Merck continued to deny that the VIGOR results indicated a considerable potential cardiovascular risk with the use of Vioxx.
25. What was clear was that CLASS did not indicate a cardiovascular risk of Celebrex. Vioxx is a more selective COX-2 inhibitor than Celebrex. (Vioxx is more selective than Celebrex as it has more of an inhibiting effect on COX-2 relative to its inhibiting effect on COX-1.) This raised a real possibility - which was not acknowledged by Merck - that the risk associated with Vioxx was drug specific rather than class specific. The apparent cardiovascular safety of Celebrex did not shelter Merck from the cardiovascular risk of its coxib.
26. Merck marketed Vioxx as a more effective and safer drug than traditional NSAIDs for nearly all purposes. Vioxx was heavily promoted by Merck. It was widely used. VIGOR had indicated that the incidence of serious gastrointestinal events (perforation, hemorrhage, peptic ulcer) among those who used Vioxx, during the trial, was 54 percent lower than those who used naproxen during the trial. However, it did not mention the incidence of higher cardiovascular events during the marketing campaign. Merck did not limit the marketing of Vioxx to those with serious gastrointestinal illness; nor did it caution against the use of Vioxx by persons at risk for adverse cardiovascular events.
27. Based on the representations made by Merck to regulators, the medical profession, pharmacists and the public, the Representative Plaintiff and others first used Vioxx in 1999. The Representative Plaintiff continuously used Vioxx from 2000 to September 30, 2004.
28. Vioxx caused users to suffer adverse cardiovascular events including heart attack, stroke, transient ischemic attack, pulmonary embolism, heart failure, angina, blood clots, increased blood pressure, other injury and illness and increased risk factors for adverse cardiovascular events. These events are consistent with adverse effects of Vioxx including negative effects upon platelets, blood vessels, vasodilation, atherosclerosis, and kidneys.
29. Many class members had formerly taken aspirin-based NSAIDs. These NSAIDs, by inhibiting COX-1 (as well as COX-2), reduced the production of thromboxane. On

switching to Vioxx, those persons lost the potential benefit of COX-1 in moderating thromboxane.

30. The risks associated with Vioxx were raised in peer-reviewed academic articles in respected medical journals. Until Vioxx was withdrawn from the market, Merck denied there were cardiovascular concerns associated with its medication. Merck consistently stated that the studies were inaccurate, incomplete and flawed. Furthermore, Merck took active measures to suppress and counter the dissemination of unfavourable academic material.
31. Merck had the resources, knowledge and access to facilities to conduct proper clinical programs and monitoring after regulatory approval of Vioxx – at that point the medication was being used by doctors to treat the general population and for periods of time that extended beyond the regulatory approval phase. But Merck had concerns such an investigation would send a signal that there were cardiovascular risks associated with Vioxx. Vioxx had significant market share, was widely used, and was the source of significant revenue for Merck.
32. Given mounting concerns about the risk of Vioxx, the Defendants could have cautioned or warned patients and physicians that there was a potential significant cardiovascular risk of Vioxx. Merck could have conducted unbiased investigations and a clinical trial specifically designed to evaluate the cardiovascular safety of Vioxx. None of these measures were taken in a timely manner.
33. Notwithstanding the emerging evidence of the cardiovascular risks, Merck continued to indiscriminately promote the use of Vioxx. Because of the Defendants' conduct and its failure to issue appropriate cautions and warnings, there was little awareness in the medical community that the use of Vioxx created cardiovascular risks.
34. Physicians and patients rely upon pharmaceutical firms to provide correct advice about the safety and potential risks of drugs. Instead of providing such advice, Merck sought to discredit academic and scientific literature which identified the potential cardiovascular risks of Vioxx use.
35. By letter dated September 17, 2001, the FDA warned the Third Defendant that its Vioxx marketing campaign was deficient in warning consumers of the drug's potential to cause serious cardiovascular complications. In the letter, the FDA stated to the Third Defendant that:

You have engaged in a promotional campaign for Vioxx that minimizes potentially serious cardiovascular findings that were observed in the...VIGOR study, and thus, misrepresents the safety profile for Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients in Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients in the comparator non-steroidal anti-inflammatory drug (NSAID), Naproxen.

36. At all material times, long-term users of Vioxx, who were the highest at risk, were given little or no warning of the risk. Even the last (August 2004) Merck Patient Information Sheet on Vioxx indicated serious cardiovascular events have been “reported . . . but rare.”
37. As well, the last (also August 2004) Prescribing Information Circular issued by Merck for Vioxx stated:

[T]he following spontaneous events occurred in less than 0.1% to 1.9% of patients treated with VIOXX regardless of causality:

Cardiovascular System: angina pectoris, atrial fibrillation, bradycardia, hematoma, irregular heartbeat, palpitation, premature ventricular contraction, tachychardia, venus insufficiency

[T]he following serious adverse events have been reported rarely (estimated less than 0.1%) in patients taking VIOXX, regardless of causality. Cases reported only in the post-marketing experience are indicated in italics.

Cardiovascular: cerebrovascular accident, congestive heart failure, deep venous thrombosis, *hypertensive crisis*, myocardial infarction, *pulmonary edema*, pulmonary embolism, transient ischemic attack, unstable angina. [italics in original text]

38. The Third Defendant designed and undertook a clinical trial of 2,600 patients with colon polyps; the purpose of the trial was to have Vioxx approved as a therapy for rectal polyps; and, if so approved, expand the market for Vioxx. It was called the Adenomatous Polyp Prevention on Vioxx trial (“APPROVe”). APPROVe was intended to last three years.
39. In August 2004, APPROVe was terminated prematurely by the Data and Safety Monitoring Board of the United States National Institutes of Health. Participants in APPROVe who had been administered Vioxx were twice as likely to experience a

myocardial infarction as those individuals who administered a placebo. On September 30, 2004, the Defendants withdrew Vioxx from the global pharmaceutical market.

40. Neither members of the medical community nor the general public were informed of the nature or scale of the potential risk until September 30, 2004. The Prescribing Information Sheet and Patient Information Sheet of Merck did not indicate a significant and serious risk of heart attacks, strokes and other serious cardiovascular events.
41. Patients treated with Vioxx suffered adverse cardiovascular events and increased risk factors for such events which were caused by the negligence of Merck and the failure of Merck to warn physicians, pharmacists and other learned intermediaries and patients of the risks associated with Vioxx.

Facts relating to Representative Plaintiff

42. The Representative Plaintiff is a 63 year old self-employed insurance broker. At all material times, the Representative Plaintiff was within the Province of Newfoundland and Labrador.
43. The Representative Plaintiff suffers from osteoarthritis. For a number of years he has taken medication to control this condition. During the period leading up to 1999 the Representative Plaintiff took Arthrotec as prescribed by his family physician for this condition.
44. The Representative Plaintiff also has a long-standing gastro-intestinal problem manifested by ulcers. Arthrotec and other medication to control the osteoarthritis had aggravated his ulcers.
45. Since or before September 11, 2000, the family physician prescribed Vioxx for The Representative Plaintiff at a dosage of 25 mg daily. Since then, the Representative Plaintiff continued to take Vioxx at the prescribed dosage on a daily basis until the date of its recall on September 30, 2004.
46. The Representative Plaintiff was motivated to take Vioxx because it provided effective pain relief and reduced his gastro-intestinal problems. Until September 30, 2004, The Representative Plaintiff was unaware of the possibility let alone the severity of adverse cardiovascular events.

47. Prior to March 12, 2004, the Representative Plaintiff was in good health; his blood pressure and fat levels were normal. He had no known family history of adverse cardiovascular events.
48. On March 12, 2004 The Representative Plaintiff suffered a stroke in the nature of a transient ischemic attack which caused him to suffer temporary blindness. The Representative Plaintiff was in the City of St. John's at the onset of this condition.
49. The Representative Plaintiff was investigated by the emergency room physician, an ophthalmologist, a neurologist, a cardiologist, a hematologist and his family doctor. Each of these physicians was aware that the Representative Plaintiff had been prescribed and was taking Vioxx, as was the Representative Plaintiff's pharmacist. None of them was aware of the association between Vioxx and adverse cardiovascular events.
50. This lack of awareness on the part of all concerned was due to the continued promotion of Vioxx by Merck and its successful efforts to diminish public, academic and medical knowledge of the risks associated with Vioxx.
51. Having had a stroke, The Representative Plaintiff is at increased risk of having another stroke. Moreover, his long term exposure to Vioxx itself is an additional ongoing cardiovascular risk factor.
52. The Representative Plaintiff has been prescribed and must now take lipitor, a medication to reduce lipid fats. The Representative Plaintiff may have to take this medication for the remainder of his life. As well, the Representative Plaintiff has been advised to take and has been taking aspirin on a daily basis as a preventative measure against another stroke. Both of these medications have side effects which the Representative Plaintiff would not otherwise have had to experience.
53. The types of medications which would otherwise be available to treat The Representative Plaintiff for his condition of osteoarthritis, ulcers and other health conditions which may arise have been reduced by reason of The Representative Plaintiff suffering a stroke. He may not from time to time be able to avail of what would otherwise be the most effective medication.
54. The anticipated lifespan of The Representative Plaintiff has been reduced by reason of his suffering the stroke.

55. By reason of the various acts and omissions of the Defendants, outlined in this Amended Statement of Claim, and, in particular, the breaches by the Defendants outlined in paragraphs 57 to 72 below, the Representative Plaintiff has experienced - and will continue to experience - pain and suffering and serious mental distress. His ability to enjoy activities of daily living and recreation have been diminished. He has suffered loss of income and loss of income earning capacity; loss of past and future ability to perform domestic tasks. He has required past care and will require future care, including medical, hospital services, prescription, rehabilitation and other expenses.

Proposed Class

56. The Representative Plaintiff brings this action on his own behalf and on behalf of a proposed class of persons resident in Newfoundland and Labrador defined as follows:
- a. Persons who were treated with Vioxx and claim injury as a result;
 - b. Persons entitled to compensation under the *Fatal Accidents Act*, RSNL 1990, c. F-6, as amended, by reason of the death of a person who had been treated with Vioxx and died as a result; and
 - c. Persons who suffered loss of care, guidance and companionship by reason of the death of a person who had been treated with Vioxx and died as a result.

Causes of Action

57. Merck owed a duty of care towards persons using Vioxx. It breached this duty of care through various acts of negligence in the research, design, development, compounding, testing, manufacture, marketing, promotion, sales and monitoring of Vioxx. Particulars of the negligence include:
- a. Disregard of the actual and potential implications of its coxib upon relevant factors affecting cardiovascular illness;
 - b. Failure to properly design, conduct and assess the VIGOR or other trials;
 - c. Indiscriminate and aggressive marketing of Vioxx; and, in particular, marketing it without regard to cardiovascular risk factors;

- d. Failure to properly monitor the ongoing effects of Vioxx over time once Vioxx was in general use;
 - e. Failure to properly study, assess and follow up on the reports which indicated that Vioxx caused serious adverse cardiovascular effects;
 - f. Failure to conduct a proper clinical test of Vioxx once concerns about its risks were raised by respected academics and physicians;
 - g. Conducting biased, incomplete and inaccurate reports to contradict the studies that raised concerns about Vioxx;
 - h. Restricting its employees from participating in studies that indicated the risks associated with Vioxx;
 - i. Failure to withdraw Vioxx from the market on a timely basis;
 - j. Selling and advertising Vioxx in a manner that was false, misleading and deceptive or likely to create an erroneous impression as to its character, merit or safety contrary to section 9, *Food and Drug Act*, R.S.C., 1985, c. F-27 and failing to conform with the reporting and disclosure provisions under the said *Act*;
 - k. Misrepresenting Vioxx as a safe medication and as one which was more effective than other NSAIDs.
58. Merck knew and intended that the Representative Plaintiff and other class members suffering osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, severe menstrual cycles, migraines and acute pain would be the ultimate users of Vioxx. Merck owed a duty of care towards Vioxx users.
59. Merck marketed Vioxx to patients both directly through advertising and indirectly through its marketing and promotional activities directed towards physicians and pharmacists.
60. It is standard and mandatory industry practice to communicate the side effects of medication to patients, pharmacists and physicians and to emphasize those side effects according to levels of severity and frequency.

61. Merck did not advise, warn or caution the Representative Plaintiff, other class members, regulators, physicians or pharmacists of the existence, severity or frequency of the cardiovascular risks and other health risks associated with the use of Vioxx. Merck suppressed the information associated with such risks thereby making it more difficult for regulators and medical practitioners to learn that Vioxx might be an unacceptably dangerous medication.
62. The patient information pamphlet and the prescribing information provided to physicians and pharmacists in Canada did not warn adequately of serious cardiovascular risks associated with the use of Vioxx.
63. Merck owed a fiduciary duty to the class members. The facts giving rise to the existence of the fiduciary duty include:
 - a. Merck had the discretion and power to obtain and disclose information concerning the nature of Vioxx and the risks associated with it both to class members and to the health care intermediaries who prescribed and dispensed the drug. Merck developed, manufactured, distributed, sold and marketed the drug. Throughout, Merck was responsible for and represented that it had taken all reasonable measures to ensure the safety of the medication. There was a marked disparity between the means of knowledge and actual knowledge between Merck and class members and their health care intermediaries. Class members and their health care intermediaries relied upon Merck for information about Vioxx. The dependency and reliance of patients and health care intermediaries upon pharmaceutical firms for information about drugs is an essential characteristic of the pharmaceutical industry.
 - b. Merck had the power to disclose and admit to the regulatory authorities, health care intermediaries and class members the characteristics and cardiovascular risks that it suspected and knew were associated with the use of Vioxx.
 - c. Merck, as one of the leading pharmaceutical firms, was highly respected by health care intermediaries and class members. Health care intermediaries and class members were not in a position to suspect or learn of the potential cardiovascular risks. Merck represented that there was no material cardiovascular risk thereby increasing the dependence and vulnerability of class members.

- d. The exercise by Merck of its discretion and power in assessing and disclosing information concerning the drug had a material adverse effect on the well-being of class members. As indicated, the drug caused and contributed to cardiovascular illness in unsuspecting and unknowing class members.
64. The breaches by Merck of the fiduciary duty owed to class members include the acts of negligence outlined above in paragraph 57 relating to, in particular:
- a. Failure to disclose suspected cardiovascular risks to patients and health care providers;
 - b. Failure to properly assess the cardiovascular risks of Vioxx both before and after it was released into the market; and
 - c. Discrediting academic research which demonstrated such risks.
65. If Merck had warned the Representative Plaintiff, other class members, the regulators, physicians and pharmacists of the risks associated with Vioxx:
- a. Both Health Canada and the Food and Drug Administration would have ordered the product off the market;
 - b. Physicians would not have prescribed the product nor would pharmacists have dispensed it given the level of risk associated with it and the existence of viable alternate products;
 - c. The Representative Plaintiff and other class members would not have used Vioxx given the nature and magnitude of the risk and the alternatives of either using a different NSAID or not taking any such medication.
66. Merck represented and warranted that Vioxx was safe and fit for its intended purpose and of merchantable quality. The representations were made to the class members directly and through representations made by Merck to the class members' physicians and pharmacists. The form of the representations included:
- a. Product information sheets provided for patients and for physicians;

- b. General product information provided by Merck through marketing representatives and other means to physicians;
 - c. Product advertising to the general public.
67. The purpose of the representations made to physicians was to promote the sale of Vioxx among the broadest group of persons and without regard to the relative risks of Vioxx.
68. Merck represented that Vioxx was more effective and safer than NSAIDs. In particular, Merck represented that there was little or no risk of cardiovascular injury or illness associated with the use of Vioxx.
69. The Defendants breached the implied warranties in s. 16, *The Sale of Goods Act*, RSNL 1990, c. S-6 that Vioxx was fit for its purpose and of merchantable quality.
70. The Representative Plaintiff pleads the provisions of the *Trade Practices Act*, RSNL 1990, c. T-7. Merck was a "supplier" under section 2(g) who offered and advertised Vioxx to class members.
71. Merck committed an unfair trade practice contrary to section 5(1), *Trade Practices Act*, and in particular representations that, contrary subparagraphs (a) Vioxx had characteristics, uses or benefits that it did not; (b) Vioxx was of a particular standard or quality when it was not; and , (w) were exaggerated or ambiguous as to the safety of Vioxx. The Representative Plaintiff and other class members claim the relief available under s. 14 of the said *Act*.
72. Merck through its negligence, breach of the duty to warn, breach of fiduciary duty, breach of representation and warranty and breaches of the *Sales of Goods Act* and *Trades Practices Act* caused cardiovascular and other injury and harm to class members which has resulted in pain and suffering and serious mental distress. The ability of class members to enjoy activities of daily living and recreation have been diminished. Class members have suffered loss of income and loss of income earning capacity; loss of past and future ability to perform domestic tasks. Class members have required past care and will require future care, including medical, hospital services, prescription, rehabilitation and other expenses.

73. For those class members claiming compensation either under the *Fatal Accidents Act* or for loss of care, guidance and companionship, those same breaches by Merck have caused the losses suffered by them.
74. Merck's conduct in continuing to promote and market Vioxx without a proper warning or caution, while both knowing of the product's potential and actual danger and suppressing the proper study and dissemination of that knowledge, has been high-handed and oppressive. It has greatly increased the anxiety and worry of the Representative Plaintiff and other class members. The Defendants recklessly placed the health of the Representative Plaintiff and other class members in grave danger.
75. The conduct of Merck was deliberate, oppressive and high-handed in knowingly causing the Representative Plaintiff and other members of the class to suffer adverse cardiovascular events and other injury and increased risk of such injury.
76. Merck failed to investigate the dangers associated with its product. It went further and actively suppressed information about the risk of serious harm and injury until September 30, 2004. Merck did so because this medication represented a major source of revenue. A similar medication known under the brand name Celebrex was approved a few months before Vioxx had been approved. Merck was simply unwilling to do anything that would jeopardize the public perception of Vioxx. It put the risk to public health ahead of the risk to its revenues and market share.
77. Merck knew or ought to have known that the incidence of adverse cardiovascular events among class members was substantially increased by the use of Vioxx. It also knew that there were other risk factors and potential causes of adverse cardiovascular events. Merck knowingly or recklessly allowed class members to be exposed to such risks while believing it might be able to defend and avoid individual claims. This expectation and belief was based upon the anticipated burden and cost of proving the claims of class members on an individual basis and the deaths of individual class members.
78. A significant award of punitive damages and equitable compensation is required for the purpose of punishment and deterrence of Merck and others; and, to the extent class members are not compensated on an individual basis because of difficulties and cost of individual proof, to compensate class members for the increased risk and incidence of harm caused to class members by Merck.

Service outside of the jurisdiction

79. Rules 6.07(1)(h) and (j) of the *Rules of the Supreme Court of Newfoundland and Labrador* permit service of the within Statement of Claim outside of the jurisdiction upon the Second Defendant and the Third Defendant.
80. The Second Defendant and Third Defendant each committed the torts of negligence and the breach of the duty to warn as outlined above in paragraphs 57 to 62 within the Province of Newfoundland and Labrador. The Representative Plaintiff relies upon these facts and the other facts pleaded in this statement of claim to support the application of Rule 6.07(1)(h).
81. The Second Defendant was primarily responsible for the research, development and manufacturing of Merck and regulatory approval process for Merck products in Canada including Vioxx. The tort breaches by the Second Defendant which caused damage to the Representative Plaintiff and members of the class were committed throughout Canada as well as within the jurisdiction.
82. The Third Defendant was primarily responsible for developing, manufacturing and marketing Vioxx in the United States of America and in the global market including Canada. The Third Defendant obtained regulatory approval of Vioxx by the FDA in the United States of America. Obtaining and maintaining regulatory approval of Vioxx by the FDA was a critical factor in obtaining and maintaining regulatory approval in Canada and elsewhere.
83. The Defendants acted collectively in developing, manufacturing, distributing, selling and marketing Vioxx in the Province of Newfoundland and Labrador. They collectively committed the acts and are responsible for the omissions that give rise to the causes of action pleaded above.
84. The tort breaches by the Third Defendant which caused damage to the Representative Plaintiff and members of the class were committed by the Third Defendant throughout North America and the rest of the world market as well within the jurisdiction.
85. At all material times the Representative Plaintiff was within the jurisdiction when the acts of negligence and breach of the duty to warn occurred and when the Representative Plaintiff suffered the damages caused by the negligence and breach of the duty to warn committed by each of the three Defendants.

86. The within Statement of Claim is properly brought against the First Defendant. By reason of the facts stated in paragraphs 5 to 8, 58 to 78, 80 to 85 inclusive and the other facts alleged in this Statement of Claim, the Second Defendant and the Third Defendant are proper and necessary parties to this proceeding. The Representative Plaintiff relies upon these facts to support the application of Rule 6.07(1)(j).

Prayer for relief

87. The Representative Plaintiff on behalf of himself and the Class Members therefore claim against the Defendants jointly and severally:

- a. An order certifying this action as a class proceeding;
- b. General damages including damages for pain and suffering, mental distress, loss of life expectancy and loss of amenities;
- c. Loss of income and future earning capacity;
- d. Loss of past and future ability to perform domestic tasks and the requirement of paid or volunteer assistance in the performance of such tasks;
- e. Any and all damages as may be allowable under the *Fatal Accidents Act*, RSNL 1990, c. F-6
- f. Cost of past and future care including medical, hospital services, prescription and other medication and rehabilitation expenses;
- g. Equitable compensation;
- h. Costs, including the fees and expenses of expert witnesses in attending at discovery and trial;
- i. Such costs as may be allowed under the *Class Actions Act*, SNL2001, C - 18.1.
- j. Cost of providing notice to class members and administering this proposed class action for their benefit;

- k. Harmonized Sales Tax;
- l. Pre-judgment and Post-judgment interest pursuant to the *Judgment Interest Act*, R.S.N. 1990, c. J-2;
- m. Aggravated, exemplary and punitive damages;
- n. Such further relief as this Court may deem just and appropriate.

DATED AT the City of St. John's, Province of Newfoundland and Labrador, on February ____, 2005.

F. Geoffrey Aylward
Aylward, Chislett & Whitten
Solicitors for the Representative Plaintiff
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