File No: CI 04-01- 39784

THE QUEEN'S BENCH
Winnipeg Centre

BETWEEN:

PHILIP ROGERS, DEBORAH MAY and STANLEY HRABARCHUK,

plaintiffs,

-and-

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

defendants.

Proceeding under *The Class Proceedings Act*, C.C.S.M. c C130

STATEMENT OF CLAIM

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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 a Manitoba lawyer acting for you must prepare a Statement of Defence in Form 18A prescribed by the Queen's Bench Rules, serve it on the plaintiffs' lawyer or where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it in this court office, WITHIN TWENTY DAYS after this Statement of Claim is served on you, if you are in Manitoba.

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.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

DATE: October 22-, 2004

Issued By: ALICIA E. ABANIEL
DEPUTY REGISTRAR
COURT OF QUEEN'S BENCH FOR MANITOBA

DEPUTY REGISTRAR
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TO: Merck Frosst Canada Ltd.
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AND TO: Merck Frosst Canada Ltd.
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AND TO: Merck Frosst Canada & Co.
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AND TO: Merck Frosst Canada & Co.
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AND TO: Merck & Co., Inc.
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Whitehouse Station, New Jersey 08889-0100
U.S.A.

CLAIM

1 The plaintiffs claim on behalf of themselves, and other persons entitled to benefit under The Fatal Accidents Act of Manitoba C.C.S.M. c.F50 in respect to the death of BRUNO DUDAR, deceased, and on behalf of the members of the proposed class as follows:

a) An Order certifying this proceeding as a Class Proceeding, in accordance with the provisions of The Class Proceedings Act, C.C.S.M. c.C130 and amendments thereto and Regulations thereunder ("the Act");

b) General damages in an amount to be determined by this Honourable Court;

c) An award on account of the loss of opportunity to invest non-pecuniary damages at the rate of 3% per annum, pursuant to Part XIV of The

Queen's Bench Act, C.C.S.M. Cap C280, and the amendments, rules and regulations thereto;

d) Special damages including medical costs, costs for past and future care, loss of income, and any other special damages, past, present and future to be proved at the trial of this action;

e) Punitive, Exemplary and/or Aggravated damages in a sum to be assessed at the trial of this action by this Honourable Court;

f) Prejudgment and Postjudgment Interest pursuant to Part XIV of The Queen's Bench Act, C.C.S.M. Cap C280, and the amendments, rules and regulations thereto;

g) An award sufficient to satisfy any obligation to pay Goods and Services Tax (GST) on any amounts awarded pursuant to the Excise Tax Act, R.S.C. 1985, c.E-5, and amendments thereto;

h) The cost of providing appropriate notice to Class members and administering this proposed class proceeding for their benefit in accordance with the provisions of the Act;

i) Costs on a solicitor/client basis; and

j) Such further and other interim and permanent relief as the nature of this case may require, and this Honourable Court deems just.

2. The plaintiff, Philip Rogers ("Rogers") is a television production editor and resides in the City of Winnipeg, in the Province of Manitoba

3. The plaintiff, Deborah May ("May"), is a school teacher who resides in Winnipeg, Manitoba and is the daughter of the late Bruno Dudar ("Dudar"). May brings this action under and by virtue of The Fatal Accidents Act of Manitoba C.C.S.M. c.F50

and The Trustee Act of Manitoba C.C.S.M. T160 for the benefit of the following individuals who are Winnipeg residents:

Elsie Jonasina Dudar, born October 12, 1932 (wife)

Raymond Dennis Dudar, born July 19, 1955 (son)

Deborah Susan May, born November 9, 1959 (daughter)

Riley David Dudar, born April 1, 1985 (grandchild)

Chelsea Patricia Dudar, born October 16, 1986 (grandchild)

Andrea Rae Dudar, born March 5, 1991 (grandchild)

Brett Daniel Dudar, born May 27, 1993 (grandchild)

Jacob (Jake) Robert Dudar, born May 12, 1996 (grandchild)

4. The plaintiff, Stanley Hrabarchuk ("Hrabarchuk") is a retired Federal Civil Servant and resides in St. Andrews, Manitoba.

5. The plaintiffs further bring this action on their own behalf, and on behalf of a proposed class of similarly situated residents of Manitoba to be further defined in the plaintiffs' application for class certification

6. The defendant, Merck Frosst Canada & Co. ("Merck & Co.") is a corporation duly incorporated pursuant to the laws of Canada with its headquarters in Halifax, Nova Scotia, and maintains a principal place of business in Mississauga Ontario. At all times material, Merck & Co. was involved in and/or was responsible for the research, development, manufacture and distribution to Canadian physicians and consumers of the drug, VIOXX, known generically as Rofecoxib, and was an affiliate of the co-defendant, Merck & Co., Inc.

7. The defendant, Merck Frosst Canada Ltd. ("Merck Ltd.") is a corporation duly incorporated pursuant to the laws of Canada, with its registered head office in Kirkland, Quebec, and maintains a principal place of business in Mississauga, Ontario At all times material, Merck Ltd. carried on business in Manitoba in the area of pharmaceutical manufacturing, supplies and sales, was involved in and/or was responsible for the sales, distribution and marketing of VIOXX in Canada to Canadian physicians and consumers, and was an affiliate of the co-defendant, Merck & Co., Inc

8. The defendant, Merck & Co., Inc. ("Merck USA") is a corporation duly 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 sales, distribution and marketing of VIOXX in Canada for Canadian physicians and consumers, including the Province of Manitoba, manufactured, marketed, sold and/or distributed VIOXX in Canada directly or indirectly through an agent, affiliate, or subsidiary, and has as it affiliates, Merck & Co and Merck Ltd

9. At all times material, Merck & Co., Merck Ltd. and Merck USA carried on business as, *inter alia,* the manufacturers and distributors of VIOXX in Canada, including Manitoba. As such, the defendants are referred to collectively herein as "Merck".

10. The plaintiffs say that Merck is liable in damages to each of them and to the class members and that each Merck company is responsible for the acts and omissions of the others for the following reasons:

(a) Each was the agent of the other;

(b) Each company's business was operated so that it was inextricably interwoven with the business of the others;

(c) Each company entered into a common advertising and business plan and shared the common purpose of developing, manufacturing, distributing, marketing and selling VIOXX in Canada and Manitoba for profit;

(d) Each company shared the common purpose of concealing the adverse effects from Canadian regulatory authorities including Health Canada, the medical community and class members;

(e) Each company owed a duty to the other and to each class member by virtue of the common business plan to manufacture, distribute and sell VIOXX; and

(f) Each company intended that its business be run as one global business organization.

BACKGROUND

11. VIOXX is a non-steroidal, anti-inflammatory drug prescribed to relieve pain and swelling and is used in the treatment of symptoms of osteoarthritis and rheumatoid arthritis. VIOXX is a member of a class of painkilling drugs known as COX-2 inhibitors.

12. VIOXX was approved for marketing and sale in Canada on or about October 25, 1999. The plaintiffs claim that the defendants heavily marketed VIOXX to

physicians and patients as being less likely to cause gastric bleeding and therefore superior to other arthritic drugs on the Canadian market.

13. 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 and death.

14. The defendants knew, or ought to have known, of the significant risk of adverse cardiac complications from ingesting VIOXX as early as 2000. A page published in the New England Journal of Medicine in 2000 illustrated a clear link between taking VIOXX and an increased risk of heart disease and death. Despite these findings, the defendants failed to inform either the physicians practicing in Manitoba or the Manitoba public of those risks.

15. In or about August 2001, a study published in the Journal of the American Medical Association concluded that VIOXX presented a potential heart attack risk and death. The defendants failed to notify or inform physicians in Manitoba or the Manitoba public of those risks.

16. On April 19, 2002, Health Canada issued an advisory which included preliminary information about the increased risk of cardiovascular events related to the ingestion of VIOXX. The advisory indicated to patients having a medical history of hypertension, eschemic heart disease or heart failure to discuss their medical conditions with their physician before ingesting VIOXX. The advisory was issued with a letter

provided by Merck to healthcare professionals reminding them of the above-mentioned information. However, neither the advisory nor the letter specifically alerted patients or physicians of the increased risk of cardiovascular complications associated with VIOXX

17. Neither the Patient Information Pamphlet nor the prescribing information provided to physicians and pharmacists in Canada warned the public 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

18. On September 30, 2004, Merck announced a voluntary world-wide withdrawal of VIOXX, having based its decision on a trial study known as APPROVe [Adenomatus Polyp Prevention on VIOXX]. In a Health Canada notice of the VIOXX withdrawal, dated October 1, 2004, it was noted in the APPROVe study that "there was an increased relative risk for confirmed cardiovascular (CV) events such as heart attack and stroke and death, beginning after 18 months of treatment in those patients taking VIOXX compared to those taking Placebo".

19. 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 and death. The defendants therefore ought not to have proceeded to manufacture, sell and market VIOXX in Manitoba, particularly given the presence of other safer drugs available in the marketplace

PLAINTIFFS:

I. Rogers

20. On or about May 3, 2000, Rogers began ingesting VIOXX at a dose of 25mg per day for pain in his knee. On or about January 9, 2002, Rogers underwent knee replacement surgery.

21 Rogers used VIOXX in accordance with the package label and consumer information provided to him and used VIOXX as it was intended to be used

22. Rogers continued to take VIOXX until on or about September 30, 2004.

23. On or about May 9, 2002, Rogers began to suffer severe chest pain and was taken to the Emergency Ward of the Salvation Army Grace General Hospital in Winnipeg where he was diagnosed as having suffered a heart attack. Rogers underwent an angiogram, and an angioplasty whereupon a stent was inserted

As a result of Rogers' ingestion of VIOXX and subsequent heart attack, Rogers will require medical follow-up and monitoring in relation to his heart condition for the rest of his life as well as other forms of medical treatment. Additionally, Rogers has received and will continue to receive medication for his heart condition, and will incur these expenses for the duration of his life

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

26. Prior to ingesting VIOXX, Rogers was physically active, in good health and worked on a full-time basis as a television production editor. Rogers was active in his employment and leisure time including as a volunteer soccer coach for children.

As a result of ingesting VIOXX pursuant to the defendants' recommended and allowable dosages, Rogers 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.

II. May

May, as representative plaintiff for the claimants under Paragraph 9(b) of this Claim brings this action pursuant to The Fatal Accidents Act of Manitoba C.C.S.M. c.F50 and The Trustee Act of Manitoba C.C.S.M. T160, for damages, including but not limited to, awards for loss of care, guidance and companionship, including the Claim under these Acts for the Estate of her father, Bruno Dudar, born May 10, 1931, and who died on March 22, 2004, in Winnipeg.

29. In consequence to suffering osteoarthritis, Dudar was prescribed 25mg per day of VIOXX in or about January 2002 by his family physician and continued to take VIOXX daily as prescribed until on or about March 22, 2004 or thereabout.

30. On March 22, 2004, Dudar suffered a massive stroke and was rushed to St. Boniface General Hospital in Winnipeg, Manitoba, where he was pronounced dead that day at the age of 72 years.

31. At no time did Dudar receive any warning from the defendants about the risk of cardiovascular complications associated with the ingestion of VIOXX.

32. Prior to ingesting VIOXX, Dudar was physically active, in good health and worked on a full-time basis as a hairdresser, operating his own hairdressing business Dudar was active in his employment and leisure time, supported his wife, children and grandchildren and looked forward to enjoying a long healthy life.

33. As a result of ingesting VIOXX, Dudar suffered a sudden stroke on March 22, 2004, never recovered and died.

34. Had Dudar been advised of the serious adverse cardiovascular complications associated with VIOXX, May claims that Dudar would not have ingested the drug and furthermore, would not have suffered the stroke.

III. Hrabarchuk

35. For his arthritis, Hrabarchuk was prescribed a daily dose of 25 mg of VIOXX by his family physician in or about 2000 and continued ingesting VIOXX on a daily basis as prescribed until May 27, 2004 or thereabout.

36. On or about May 28, 2004, while in Ottawa, Ontario, Hrabarchuk felt pain radiating in the back of his arms and suffered chest pain. Consequently, he attended Ottawa General Hospital's Cardiac Arrest Unit and was diagnosed as having suffered a heart attack.

37. On or about June 1, 2004, Hrabarchuk was transferred to the University of Ottawa Heart Institute whereupon he underwent an angioplasty and insertion of a stent. He was discharged the following day and returned to Manitoba.

38. During the period in which Hrabarchuk consumed VIOXX, he received no warnings from Merck about the risks of adverse cardiovascular complications associated with VIOXX ingestion. Had Hrabarchuk been made aware of the above mentioned complications and threats to his health interests, he would have declined VIOXX

39. Prior to ingesting VIOXX, Hrabarchuk was physically active, worked on a volunteer basis as a representative of the Federal Superannuants National Association for Manitoba and Northwestern Ontario Region, was active in his volunteer work and leisure time. As a result of Hrabarchuk's ingestion of VIOXX, his enjoyment of life has been degraded.

DUTY OF CARE

40. At all times material, Merck owed the plaintiffs a duty of care to do the following:

Ensure that VIOXX was fit for its intended purpose;

Conduct appropriate testing to ensure that VIOXX was safe for public ingestion before releasing VIOXX onto the Manitoba market;

(c) Conduct ongoing clinical trials and tests as to the safety and efficacy of VIOXX after releasing VIOXX to the Manitoba market;

(d) Adequately monitor and investigate reports of adverse reactions to VIOXX in Manitoba and Canada, as well as to adequately monitor studies investigating the efficacy and safety of VIOXX, and to act promptly to protect the Canadian public in view of raising public controversy surrounding a link between VIOXX and adverse reactions and questions concerning VIOXX's safety;

Warn the plaintiffs, Manitoba consumers, physicians and the Canadian public 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.

41 The plaintiffs claim that Merck owed each of them and the other class members a duty of care not to create a risk of harm to their safety and health interests. The plaintiffs further state that Merck breached their duty of care and breached the requisite standard of conduct expected of them in the circumstances, and in so doing, caused or materially contributed to the injuries and subsequent losses sustained by each plaintiff and the class members, which were foreseeable

PARTICULARS OF NEGLIGENCE

42. The plaintiffs claim that Merck, their servants and agents were negligent in the design, development, testing, licensing, distribution, monitoring, marketing and sale of VIOXX, particulars of which, *inter alia*, include the following:

In 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;

In marketing VIOXX, having conducted inadequate studies and tests to establish its safety;

(c) In failing to appreciate data from clinical trials in patients who ingested VIOXX which revealed an increased risk of cardiovascular and heart disease, heart attack and stroke;

In ignoring data from clinical trials in patients who ingested VIOXX which revealed an increased risk of cardiovascular and heart disease, heart attack and stroke;

(e) In becoming aware of the serious and adverse effects of VIOXX including a risk of heart attack and stroke, and failing to warn or to adequately warn in a timely fashion, class members and their physicians, pharmacists and health care providers of these serious and adverse effects;

(f) In wrongfully and intentionally accepting the known risk and adverse effects of injury to a class member as a result of the ingestion of VIOXX;

(g) In knowing that the incidents of heart disease increased when the dosage level of VIOXX was increased, and failing to adequately warn the class members and their physicians, pharmacists and health care professionals of these adverse effects;

In failing to include a warning that described the serious, adverse effects in the promotional literature for VIOXX;

(i) In failing to instruct their employees to properly evaluate, record and advise on complaints of side effects of VIOXX;

(j) In failing to accurately, candidly, and promptly disclose consumer complaints and the serious side effects of the ingestion of VIOXX to Health Canada in a timely manner, or at all;

In failing to initiate timely review, evaluation and investigation of the side effects of VIOXX following complaints of injury, death and/or hazard to safety;

(l) In failing to properly assess and investigate complaints of VIOXX adequately upon receiving them;

In refraining to report, in a timely manner, the serious side effects of VIOXX to regulators, doctors, the public and class members in order to maximize profits and retain market value;

(n) In failing to conform to acceptable disclosure and reporting requirements under the *Food and Drugs Act* of Canada;

(o) In hiring incompetent personnel and appointing incompetent officers and directors;

(p) In failing to instruct their servants, agents, and officers to act ethically and responsibly

(q) In failing to properly supervise their employees, their subsidiaries, and their affiliating corporations;

(r) In encouraging their employees to increase sales volumes while neglecting to inform consumers, retailers, hospitals, physicians and pharmacists of the side effects of VIOXX;

In failing to recall VIOXX in a timely manner;

(t) In failing to take appropriate steps to protect patient safety;

(u) In introducing VIOXX onto the marketplace when they knew, or ought to have known that there were other drugs in the marketplace which were safer;

In failing to provide warnings of the potential hazards of ingesting VIOXX on package labels;

In failing to warn the plaintiffs, class members, and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of serious cardiovascular complications arising from the use of VIOXX;

(x) In representing to the public that VIOXX was safe and fit for its intended purpose and was of merchantable quality when they knew or ought to have known that these representations were false;

In encouraging and participating in the aggressive marketing and sale of VIOXX to the public, including the providing of free samples of VIOXX to patients, when they knew or ought to have known of the serious adverse cardiovascular complications caused by the ingestion of VIOXX.

DAMAGES

43. The risks of serious adverse cardiovascular complications associated with VIOXX ingestion, including but not limited to, heart attack and stroke and death, were in the exclusive knowledge and control of the defendants. The plaintiffs were prescribed VIOXX by their respective medical doctors and each plaintiff filled his/her prescription at

the licensed pharmacy of choice, followed the instructions for consumption and ingested VIOXX. The plaintiffs followed the VIOXX refill regime and repeatedly ingested VIOXX prior to its recall and removal from the Canadian marketplace.

44. The plaintiffs and class members state that their 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 plaintiffs and to their physicians and health care providers

45 As a result of ingesting VIOXX in accordance with Merck's recommended and allowable dosage, personal injury with pain and suffering, loss of enjoyment of life and amenities including but not limited to, adverse cardiovascular complications, stroke, heart attack and death were sustained by plaintiffs and class members. The plaintiffs 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 and amenities

46. As a further result of their taking VIOXX, each plaintiff continues to suffer serious personal injuries, pain and suffering which have impaired and interfered with their enjoyment of life and regular daily activities, and ability to earn income

47 Particulars of the past and ongoing loss or damage suffered by each plaintiff and the class members include, *inter alia,* the following

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

(b) Past loss of income

(c) Diminishment of earning capacity resulting in a loss of future income;

Past and ongoing costs of care;

Medical and other expenses, including the costs of diagnosis and treatment of VIOXX side effects; and

(f) Out-of-pocket expenses incurred by class members or on behalf of class members for their benefit, including the claim of Manitoba Health

48 At no time prior to the withdrawal of VIOXX from the Canadian marketplace on September 30, 2004 did Merck provide any warning in Canada or Manitoba that they had received post marketing reports:

of increased incidents of heart disease, including fatalities of patients who ingested VIOXX;

demonstrating an increased reporting rate of adverse cardiovascular events in patients who ingested VIOXX, relative to other drugs; and/or

(c) that showed an increased rate of risk of heart disease, heart attacks, and/or strokes and death in patients who ingested 50mg per day dose levels of VIOXX.

The plaintiffs claim that Merck intentionally attempted to withhold this information during periods of risk of harm to the plaintiffs and class members, and did maintain secrecy for a considerable period of time to build profit and protect their other financial interests.

49. Merck's conduct in bringing VIOXX to Canadian and Manitoba pharmacies for distribution to, and consumption by the plaintiffs and the class members, and their failure to recall VIOXX in a timely fashion was high-handed, arrogant, deplete of care and of disregard for the class members' safety and health interests. Furthermore, the defendants' conduct was indifferent to the consequences and motivated by economic considerations to build cash flow, capture market control and earn profit. For such disreputable and deliberately injurious conduct, the plaintiffs claim on behalf of themselves and the class members, punitive, exemplary and/or aggravated damages, in amounts to be determined at the trial of this action by this Honourable Court.

50. In addition, the plaintiffs and class members seek recovery of any medical expenses and hospital costs required to be paid on their behalf or on behalf of the class members, including the account of Manitoba Health, pursuant to the provisions under The Health Services Insurance Act of Manitoba C.C.S.M. c H35, upon which the plaintiffs plead and rely.

51 The plaintiffs plead and rely upon The Business Practices Act of Manitoba C.C.S.M. c B120, ("BPA").

52. The defendants are "suppliers" within the meaning of the BPA The defendants' sales of Vioxx to consumers in this province are "consumer transactions" within the meaning of the BPA.

53. In the defendants' sale brochures, advertisements and other forms of representations to the public regarding Vioxx, the defendants made statements that had

the potential or effect of deceiving or misleading consumers which conduct constituted deceptive, misleading and false acts and representations, and constituted unfair business practices, contrary to section 2 of the BPA. In particular, the defendants failed to disclose material facts concerning the risks of Vioxx contrary to s. 2(3)(p) of the BPA.

54. As a result of the defendants' breaches of the BPA, the plaintiffs and class members have suffered damage and injury and are entitled to statutory remedies provided by s.23 of the BPA.

As a result of the defendants' actions, Dudar died on March 22, 2004. During his lifetime, Dudar was a healthy, normal, gainfully employed individual of 72 years and was a contributing member to society and the community at large, including his family. Dudar assisted other family members, and, in consequence to his death, the plaintiffs have been deprived of Dudar's services, maintenance, support, guidance, care and companionship. Numerous expenses have been incurred by Dudar's estate, for which the plaintiffs claim damages under The Fatal Accidents Act of Manitoba C.C.S.M. c.F50 and The Trustee Act of Manitoba C.C.S.M. T160.

The plaintiffs and class members further seek an award on account of loss of opportunity to invest non-pecuniary damages and an award of interest on all sums awarded to them as pecuniary damages pursuant to Part XIV *of The Queen's Bench Act* of Manitoba, and the amendments, rules and regulations thereto, upon which statute the plaintiffs plead and rely.

57. The plaintiffs further seek an award of costs against the defendants on a solicitor/client basis.

58. This action is served on defendants outside of Manitoba without leave pursuant to Rule 17.02(g)(h) and (l) of the Court of Queen's Bench Rules.

October 22, 2004

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