COURT FILE NUMBER QBG 3011

COURT OF QUEEN'S BENCH FOR SASKATCHEWAN

JUDICIAL CENTRE OF REGINA

PLAINTIFF LANNY ROSS WEILER

DEFENDANTS TAKEDA CANADA INC.,
TAKEDA PHARMACEUTICALS AMERICA INC.,
TAKEDA PHARMACEUTICALS U.S.A., INC.,
ELI LILLY CANADA INC., and
ELI LILLY AND COMPANY

Brought under *The Class Actions Act*

NOTICE TO DEFENDANTS

1. The plaintiff may enter judgment in accordance with this Statement of Claim or such judgment as may be granted pursuant to the Rules of Court unless, in accordance with paragraph 2, you:

(a) serve a Statement of Defence on the plaintiff; and

(b) file a copy of it in the office of the local registrar of the Court for the judicial centre named above.

2. The Statement of Defence must be served and filed within the following period of days after you are served with the Statement of Claim (excluding the day of service):

- within 20 days if you were served in Saskatchewan;
- within 30 days if you were served elsewhere in Canada or in the United States of America;
- within 40 days if you were served outside Canada and the United States of America

3. In many cases a defendant may have the trial of the action held at a judicial centre other than the one at which the Statement of Claim is issued. Every defendant should consult his lawyer as to his rights.

4. This Statement of Claim is to be served within six months from the date on which it is issued.

5. This Statement of Claim is issued at the above-named judicial centre on the 24 day of November, 2017.

D. MILLARD
DY. LOCAL REGISTRAR

Local Registrar

Court Seal

SEAL

STATEMENT OF CLAIM

I. THE PARTIES

PLAINTIFF

1. The Plaintiff, Lanny Ross Weiler, is a resident of Saskatoon, Saskatchewan, and a member of the proposed Class.

DEFENDANTS

2. The Defendant, Takeda Canada Inc., is a corporation incorporated pursuant to the laws of Canada. Its head office is located at 435 North Service Road West, Suite 101, Oakville, Ontario, L6M 4X8 ("**Takeda Canada**").

3. The Defendant, Takeda Pharmaceuticals America Inc., is a related Takeda company. It is a foreign corporation with its head office located at One Takeda Parkway, Deerfield, Illinois, USA, 60015.

4. The Defendant, Takeda Pharmaceuticals U.S.A., Inc. (formerly known as: Takeda Pharmaceuticals North America, Inc.), is a related Takeda company. It is a foreign corporation with its head office located at One Takeda Parkway, Deerfield, Illinois, USA, 60015.

5. Takeda Canada, Takeda Pharmaceuticals America Inc., Takeda Pharmaceuticals U.S.A., Inc., are all inter-related companies with the same parent company, being Takeda Limited, and are parts of a worldwide corporate pharmaceutical operation.

6. The Defendant, Eli Lilly Canada Inc., is a corporation incorporated pursuant to the laws of Canada. Its head office is located at 3650 Danforth Avenue, Scarborough, Ontario, M1N 2E8 ("**Eli Lilly Canada**").

7. The Defendant, Eli Lilly and Company, is the parent company of Eli Lilly Canada Inc. It is a foreign corporation with its head office located in Indiana at Lilly Corporate Center, 839 South Delaware Street, Indianapolis, Indiana, USA, 46225 ("**Eli Lilly**").

8. Takeda Canada, Takeda Pharmaceuticals America Inc., Takeda Pharmaceuticals U.S.A., Inc., Eli Lilly Canada, and Eli Lilly (hereinafter, collectively referred to as the "**Defendants**") acted in concert with the others, regarding Actos®. Each Defendant is liable, vicariously liable, and joint and severely liable, for the actions of the others, regarding Actos®. Each were part of their worldwide corporate entities' plans regarding Actos®, acting together and in common ways with each other and their parent companies.

Proposed Class

9. The Defendants have, by their acts or omissions, caused harm, economic loss, mental distress, and other losses to the Plaintiff and other similarly situated persons. The Plaintiff brings this action on his own behalf and on behalf of the following Class:

> Persons (including their estates) who were prescribed and ingested Actos® in Canada; and persons who, on account of a relationship with such individuals, may make a claim under Dependants' Statutes (the "**Class**" or "**Class Members**")
>
> "**Dependants' Statutes**" include the *Fatal Accidents Act*, RSY 2002, c 86, ss 2-3; *Family Compensation Act*, RSBC 1996, c 126, ss 2 and 3(8)-(9); *Fatal Accidents Act*, RSNWT 1988, c F-3, ss 2-3; *Fatal Accidents Act*, RSA 2000, c F-8, ss 1, 2, and 3(1); *The Fatal Accidents Act,* RSS 1978, c F-11, ss 2, 3(1), and 4(1)-(3); *Fatal Accidents Act*, SNu 2010, c14, s6, ss 2-3; *The Fatal Accidents Act*, CCSM c F50, ss 2-3; *Family Law Act*, RSO 1990, c F 3, ss 61(1)-(2); *Fatal Accidents Act*, RSNL 1990, c F-6, ss 2-4; *Fatal Accidents Act*, SNB 2012, c 104, ss 3, 4, 7; *Fatal Injuries Act*, RSNS 1989, c 163, ss 2-3 and 5; *Fatal Accidents Act*, RSPEI 1988, c F-5, ss 1-2, 6.

II. PARTICULARS OF THE CLAIM

10. The Plaintiff, and other members of the proposed Class, have suffered injury, economic loss, and damages as a result of the Defendants' acts, omissions, wrong doings, and breaches of legal duties and obligations since 2005. The Defendants concealed and continue to conceal their knowledge of Actos®'s dangerous risks from the Plaintiff, Class Members, and the medical community.

11. Specifically, the Defendants failed to adequately inform the Plaintiff, Class Members, and the medical community about the risk of bladder cancer, bladder tumours and precancerous bladder conditions (inclusively, for brevity "**Bladder Cancer**") associated with more than twelve months of Actos® ingestion.

12. The Defendants, directly or through their agents, including servants or employees designed, manufactured, tested, marketed, advertised, distributed, promoted and sold Actos® known generically as pioglitazone, for the treatment of type II diabetes mellitus.

13. Actos® is exclusively marketed, produced, and sold by the Defendants. It is still currently under patent and accordingly has not been developed in generic form by any other company.

14. According to the Canadian Diabetes Association, type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or does not efficiently use the insulin that it does produce. Type I diabetes occurs when the body does not produce any insulin at all. Actos® is only used to treat type II diabetes and should not be used to treat type I diabetes.

15. Actos® was jointly launched by the Defendants and Takeda Limited in Canada in 1999.

16. Actos ® was approved by Health Canada as a monotherapy to decrease insulin resistance and blood glucose levels in patients with Type II diabetes mellitus, in September 2000.

17. Eli Lilly Canada was responsible for distributing Actos ® to the Canadian market until June 2009, when Takeda Canada working with Takeda Limited reacquired the Canadian commercial rights to sell Actos® in Canada, from Eli Lilly Canada.

18. The Defendants are vicariously liable for the acts of each other, given that:
    (a) Each was affiliated with the others;
    (b) The business interests of the Defendants were inextricably interwoven;

(c) The Defendants intended that their businesses be operated as part of a global enterprise;

(d) The Defendants created and executed a common business plan to make and sell Actos® in Canada, and throughout the world;

(e) For the purposes of designing, developing, manufacturing, distributing, marketing, and selling Actos® in Canada, each Defendant was the agent of its parent company; and/or

(f) Each of the Defendants acted in concert in designing, developing, and manufacturing Actos® and in distributing, marketing, and selling Actos® in Canada.

19. Pioglitazone is sold as a single active ingredient product under the brand name Actos®.

20. Pioglitazone is also sold in combination with metformin (Actoplus Met, Actoplus Met XR, Competact) and in combination with glimepiride (Duetact).

21. As a result of the inadequate acts by the Defendants, intentionally or not, regarding the risks of using Actos®, persons who were prescribed and ingested Actos® for more than twelve months, including the Plaintiff and Class Members, were at increased risk for developing Bladder Cancer, and have suffered and continue to suffer from Bladder Cancer.

22. The Defendants concealed and continue to conceal their knowledge that Actos® can cause Bladder Cancer from the Plaintiff, the Class, and the medical community.

23. The Defendants have yet to adequately inform consumers and the prescribing medical community about the risks of Bladder Cancer with use of Actos® for more than twelve months.

24. The Defendants negligently marketed and sold Actos® because they failed to review all information received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities relevant to the safety of the prescription drug Actos®.

25. The Defendants failed to meet the standard of care established at law, which was intended for the benefit of individual consumers such as the Plaintiff and Class Members, making the Defendants liable under Saskatchewan law.

26. As a result of the Defendants' actions and inactions, the Plaintiff and Class Members were injured due to their ingestion of Actos®, which caused and will continue to cause the Plaintiff and Class Members various injuries and damages.

27. Prior to Actos® being approved by the United States Food and Drug Administration ("**FDA**") and Health Canada, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos® that produced blood drug levels equivalent to those resulting from a clinical dose.

28. In 2005, the results of the PROactive (PROspective, PioglitAzone Clinical Trial In Macto Vascular Events) three-year study were published. PROactive looked at the impact in total mortality and macrovascular morbidity using Actos®. Dormandy J.A. et al. *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective, Pioglitazone Clinical Trial In Macro Vascular Events*): a Randomized Controlled Trial, Lancet, 266: 1279-1289 (2005).

29. The PROactive study was looking at cardiovascular events and outcomes.

30. During the course of monitoring the study, the researchers and Defendants became aware that there was a statistically significant number of Bladder Cancer cases in patients receiving Actos® versus comparators.

31. Neither during the study, nor in the actual final Dormandy paper, did the researchers or the Defendants publish these statistically significant increased rates of Bladder Cancer.

32. The Defendants wilfully, wantonly, and recklessly withheld the knowledge of increased risk of cancer in users of Actos® to prevent any chances of its products registration being delayed or rejected by the FDA and regulatory agencies in other countries, including Canada.

33. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of Bladder Cancer cases in patients receiving Actos® versus comparators.

34. On September 17th, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos® and Bladder Cancer. The planned five-year interim analysis demonstrated that the risk of Bladder Cancer increases with increasing dose and duration of Actos® use, reaching statistical significance after 24 months.

35. Despite the FDA finding that Actos® is linked to a statistically significant increase in the risk for developing Bladder Cancer, Robert Spanheimer on behalf of the Defendants claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of Bladder Cancer or other cancers from Actos®.

36. On June 9, 2011, the European Medicines Agency ("**EMA**") announced that it had been informed by the French Medicines Agency of its decision to suspend the use of pioglitazone-containing medicines (Actos®, Competact®) in France while awaiting the outcome of the ongoing European review.

37. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan, which demonstrated a statistically significant increase to the risk for Bladder Cancer in males exposed to Actos® for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

38. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos® after Germany's Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, "**BfArM**") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

39. On June 15th, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication Actos® (pioglitazone) for more than one year may be associated with an increased risk of Bladder Cancer." The FDA ordered information about this risk to be added to the Warnings and Precautions section of the label for pioglitazone-containing medicines.

40. The FDA reported that the risk of Bladder Cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposed to pioglitazone therapy for longer than 12 months was associated with a 40% increase to risk. Based on this data, the FDA calculated that therapy with Actos® for longer than 12 months was associated with 27.5 excess cases of Bladder Cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

41. On July 12, 2011, Takeda Limited, the parent corporation of Takeda Canada, issued a recall on Actos® in France.

42. On June 17, 2011 Health Canada issued an advisory that it is reviewing the status of Actos® due to concerns about an increased incidence of Bladder Cancer associated with long term use of Actos® that was suggested in various published scientific studies. Its review was also supported by actions taken by other regulatory agencies in response to this documented increased risk of Bladder Cancer.

43. Following the recall in France, the Defendants refused to issue a recall of Actos® in Canada thereby continuing to subject Canadian citizens to the significant risk of developing Bladder Cancer while ensuring the users in France and Germany were no longer subject to this risk.

44. A medical study by Piccinni et al. analyzed the association between antidiabetic drugs and Bladder Cancer by reviewing reports from the FDA Adverse Event Reporting System ("**AERS**") between 2004 and 2009. The association was analyzed by the case/non-case methodology. There were 31 recorded reports of Bladder Cancer in patients using pioglitazone. Piccinni's results indicated that the reporting odds ratio for pioglitazone was indicative of a "definite risk". *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccini, et al. Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

45. Actos® ought not to have been put on the market and marketed by the Defendants. Actos® ought not to have been maintained on the market by the Defendants. From the time of introduction to market, it became more apparent that Actos® was dangerous, and the benefits, if any, were not worth the risk of use. Actos® ought to have been removed from the market by the Defendants. If the Defendants did not know sufficiently of the risks of Actos® at their respective times of introducing Actos® and maintaining Actos® on the market, they came to know of the risks and should have removed Actos® from the market.

46. The Defendants notwithstanding enhanced knowledge by 2011 of the dangers of Actos® continued the sale and marketing of Actos® rather than withdrawing Actos® from the market, and failed to adequately warn the Plaintiff, Class, the medical community, and the public of the risks known to the Defendants (or of risks that should have been known to the Defendants).

47. As the manufacturers of Actos®, the Defendants knew or should have known that Actos® use for longer than twelve months was associated with a statistically significant increased risk of Bladder Cancer.

48. As marketers and distributors of Actos®, the Defendants knew or ought to have known that Actos® use for longer than twelve months was associated with Bladder Cancer.

49. With the knowledge of the true relationship between long-term use of Actos® and developing Bladder Cancer, rather than take steps to pull the drug off the market, Defendants promoted Actos as a safe and effective treatment for type II diabetes and they falsely defended its use notwithstanding the then knowledge of the dangers of Actos® use.

50. Actos® is one of the Defendants' top selling drugs.

Plaintiff's Harms

51. In or around September 2009, the Plaintiff was prescribed Actos® for the treatment of type II diabetes mellitus.

52. Sometime in 2014, the Plaintiff stopped taking Actos® because the drug was ineffective at managing his type II diabetes mellitus symptoms.

53. In or around August 2017, the Plaintiff was undergoing a bladder examination, when he was diagnosed with Bladder Cancer.

54. Shortly thereafter, the Plaintiff underwent surgery to have the Bladder Cancer removed.

55. As a direct result of being prescribed and ingesting Actos® for many years, the Plaintiff has been permanently and severely injured, having suffered serious consequences from long-term Actos® use.

III. CAUSES OF ACTION

Negligence

56. In discharging their duties of care, the Defendants breached the standards of care expected of them. As designers, developers, testers, manufacturers, distributors and marketers of pharmaceutical drugs, including Actos®, the Defendants owed Class Members duties:

(a) to ensure that Actos® was fit for its marketed use, intended use, and other reasonably foreseeable uses including but not limited to being reasonably safe;

(b) to conduct proper design, development and testing of Actos® to determine potential side effects;

(c) to continue to keep physicians up to date on all risks associated with Actos®, and keep them abreast of new data becoming available about the efficacy and safety of Actos® and other pioglitazone containing products;

(d) not to market an unreasonably dangerous drug;

(e) to warn of the risks of serious side effects, including communicating clear, complete and current warnings to Plaintiff, Class Members, and physicians that using Actos® for longer than twelve months is associated with a statistically significant increased risk of Bladder Cancer; and

(f) to remove Actos® from the market when mounting evidence of risk mandated that removal.

57. The relationship proximity is a relationship where it was reasonably foreseeable that negligent design, testing and development of Actos® would result in personal injury and resulting harms to the Plaintiff and other Class Members.

58. The Defendants' drug Actos® is not reasonably safe. The failure to provide a reasonably safe product was the proximate cause of Plaintiff's and Class Members' injuries and damages.

59. The Defendants' product has caused the Plaintiff and Class Member's significant pain, and may cause consequences of future surgeries as a result of Defendant not providing Plaintiff with a reasonably safe product.

60. The Defendants were aware or ought to have been aware of the problems with Actos® through reports from users as well as reports published by independent researchers and other regulators similar to Health Canada and the FDA.

61. A responsible pharmaceutical provider would have removed the product from the market.

62. Even though Actos® was withdrawn from the markets in Germany and France due to high incidence of Bladder Cancer, Actos® continues to be sold in Canada.

63. The Defendants failed to ensure that Actos® was not dangerous to patients during the course of its use.

64. The Defendants failed to ensure that Actos® were fit for the intended, marketed purpose and of merchantable quality.

65. The Defendants did not adequately test Actos® in a manner that would bring to light the full magnitude of risks associated with use of the product.

66. The Defendants designed Actos® in an unreasonable, careless, and negligent manner.

67. The Defendants failed to adequately test Actos® in a manner that would fully disclose the magnitude of risk associated with its use, including the risk of Bladder Cancer.

68. The Defendants failed to conduct proper development and testing of both short and long term effects of Actos®, including whether Actos® caused, contributed to, increased the risk of Bladder Cancer.

69. The Defendants did not adequately communicate to the Plaintiff, Class Members or the medical community that using Actos® use for more than 12 months is associated with a statistically increased risk of Bladder Cancer.

70. The Defendants did not provide any, or did not adequately update information to the Plaintiff, Class Members, the medical community, and Health Canada respecting the association between Bladder Cancer and Actos® use, once such information became available.

71. The Defendants did not provide adequate or accurate warnings of the risks associated with Actos® in any product monograph or product insert.

72. When the problems with Actos® first came to be known, the Defendants failed to issue adequate warnings, issue a timely recall, publicize the problems, and otherwise act properly and in a timely manner to alert the Plaintiff, Class, the medical community, and the public of the risk of Bladder Cancer.

73. The Defendants failed to establish adequate procedures to inform their sales representatives and Canadian physicians and others in the medical community regarding the risks of Bladder Cancer associated with Actos®.

74. The Defendants claimed, stated, and represented that Actos® was safe and fit for its intended purpose and of merchantable quality when they were aware or should have been aware that these claims, statements, and representations were false.

75. The Defendants misrepresented that Actos® was safe and fit for its intended purpose and of merchantable quality when they were aware or ought to have been aware that these representations were false.

76. The Defendants misrepresented the state of research, opinion, and medical literature pertaining to the claimed benefits of Actos® and its associated risks, including the risk of Bladder Cancer.

77. The misrepresentations made by the Defendants were unreasonable in the context of the risks that were known or should have been known by the Defendants.

78. The Defendants failed to cease the manufacture, marketing, and distribution of Actos® in a timely and effective manner when they were aware or should have been aware that Actos® was associated with an increased risk of Bladder Cancer.

79. The Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and associated regulations.

80. The Defendants failed to properly supervise their employees, subsidiaries, and affiliated corporations.

81. The Defendants breached other duties of care to the Plaintiff and other Class Members, details of which are known only to the Defendants.

82. The Defendants were callous and reckless in there disregard for the health and safety of the Plaintiff and other Class Members.

83. The Defendants' breach of duty of care resulted in injury and loss to the Plaintiff and the Class Members.

84. Actos® is defective. Actos® is dangerous to an unreasonable degree, and to a degree that could not have been reasonably contemplated or assumed by the Plaintiff, Class Members, or the medical community. Actos® benefits as they may be proven, do not outweigh the serious and undisclosed risks of using Actos® when used as the Defendants intended and advertised. No individuals can be said to have benefited from Actos® to a greater extent than they lost, as there are multiple alternative products and

procedures that are at least as effective as Actos® and carry less risk or less serious risks.

85. The Defendants had the exclusive knowledge and control of the risks of Actos®. The Plaintiff and Class Members could not have known about the extent and seriousness of the risk. The Plaintiff and Class Members' injuries and damages would not have occurred but for the negligence of the Defendants in failing to ensure that Actos® was safe for use or, in the alternative, for failing to provide an adequate warning of the risks of Bladder Cancer associated with Actos® to the Plaintiff, Class Members, and their physicians and others in the medical community.

Negligent Design, Development, and Testing

86. At all material times the Defendants owed a duty of care to Plaintiff and Class Members to ensure safety of their pharmaceutical drugs for their intended use. Breach of this duty of care on the part of the Defendants constitutes negligence.

87. Prior to releasing Actos® into the Canadian market, the Defendants failed to conduct appropriate and sufficient premarket research, development, design, and testing, or alternatively are liable for relying upon the negligent pre-market research, development, design, and testing of others.

88. By marketing Actos® as a pharmaceutical drug for the treatment of a medical condition, the Defendants created a relationship of proximity where it was reasonably foreseeable that negligent design, testing, or development of Actos® would result in personal injury and resulting harms to the Plaintiff and Class Members. Particulars of this negligence are as follows:

(a) the Defendants failed to adequately design, develop, or test Actos® to ensure that Actos® was safe for its intended use prior to selling and distributing it;

(b) the Defendants failed to ensure that Actos® was not unreasonably dangerous to those who ingested it and that Actos® was fit for its intended purpose, and of merchantable quality;

(c) the Defendants failed to adequately test Actos® in a manner that would fully disclose the magnitude of the risks associated with its use, including but not limited to Bladder Cancer;

(d) the Defendants' failure to conduct proper development and testing of Actos® caused, contributed, or increased the magnitude of the risks associated with its use, including but not limited to Bladder Cancer; and

(e) the Defendants breach of their duties of care resulted in injury and loss to the Plaintiff and Class Members.

Negligent Distributing, Marketing, and Selling

89. At all material times the Defendants owed a duty of care to the Plaintiff and the Class not to distribute, market, or sell unsafe, defective pharmaceutical drugs, or alternatively, provide a clear, current, and complete warning with respect to any potential side effects associated with the its pharmaceutical drugs. Breach of this duty of care on the part of the Defendants constitutes negligence.

90. By marketing Actos® as a pharmaceutical drug for the treatment of a medical condition, the Defendants created a relationship of proximity where it was reasonably foreseeable that negligent marketing, distribution, and sale of Actos® would result in personal injury and resulting harms to the Plaintiff and Class Members. Particulars of this negligence are as follows:

(a) the Defendants failed to adequately design, develop, or test Actos® to ensure that Actos® is safe for its intended uses, prior to selling and distributing it;

(b) by marketing Actos® in Canada at all and by failing to withdraw Actos® from markets in Canada because Actos® is defective, unreasonably dangerous, or unfit for its intended uses because Actos® can cause Bladder Cancer, the Defendants breached a duty not to market an unsafe, defective pharmaceutical drug;

(c) the Defendants did not provide adequate safety data to Health Canada with respect to Actos®;

(d) the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Plaintiff and Class Members, of the risk of serious side effects caused by Actos®;

(e) despite the Defendants' knowledge of potential side effects caused by Actos®, the Defendants have, and continue to, manufacture, market, and sell Actos®, without adequately warning, labeling, instructing, and disseminating information with respect to these risks, either prior to or after the marketing and sale of Actos®;

(f) by failing to adequately warn physicians and consumers, and failing to include a clear, complete, and current warning in any Actos® product monographs, that Actos® can cause, contribute to, or increase the risk of Bladder Cancer, the Defendants breached a duty to warn; and

(g) the Defendants breached duty of care resulted in injury and loss to the Plaintiff and Class Members.

Breach of Express Warranty

91. The Defendants expressly warranted that Actos® was a safe and effective form of treatment for type II diabetes mellitus.

92. Actos® manufactured, promoted, and sold by the Defendants did not conform to these express representations because it caused serious injury to consumers who used the products.

93. As a direct and proximate result of the Defendants' breach of warranty, the Plaintiff and other Class Members suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

Breach of Implied Warranty

94. The Defendants manufactured, marketed, promoted, sold, and distributed Actos®, and made an impliedly warranted that Actos® was of merchantable quality, fitness, and safe for such use.

95. The Plaintiff, other Class Members, and their health care providers, reasonably relied upon the skill and judgment of the Defendants as to whether Actos® was of merchantable quality and safe for its intended use, and relied upon the Defendants' express and implied warranty as to such matters.

96. Contrary to the implied warranty, the Actos® was not of merchantable quality or safe for their intended use because Actos® use is associated with an increased risk of Bladder Cancer.

97. As a direct and proximate result of the Defendants' breach of warranty, the Plaintiff and other Class Members suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

Violations of the Food and Drugs Act

98. Sections 19 and 20 of the *Food and Drugs Act,* R.S.C., 1985, c. F-27, prohibit the use of any false pretense, misrepresentation, or deception in the conduct of any trade or commerce with respect to pharmaceutical drugs and declares such acts or practices as unlawful.

99. At material times, the Defendants violated sections 19 and 20 of the *Food and Drugs Act* by the use of false and misleading representations or omissions of material fact in connection with the marketing, promotion, and sale of the Actos®

100. As a result of violating the *Food and Drugs Act*, the Defendants caused the Plaintiff and Class Members to have, purchase, and ingest Actos®, thereby causing severe injuries and damages, as previously described herein.

Consumer Protection Act

101. The Defendants engaged in: unfair practices; deceptive acts or practices; unconscionable acts or practices; unfair business practices; unfair consumer practices; prohibited practices; false, misleading or deceptive representations; unfair trade practices; knowingly or recklessly making a representation to the public that is false or misleading in a material respect; and breached statutory, express, or implied conditions or warranties by marketing Actos® in Canada and failing to include an adequate warning in any of the Actos® product monographs about the risks of Bladder Cancer.

102. The Defendants deliberately withheld information from the public and Health Canada about the risk of Bladder Cancer associated with the use of Actos®.

103. Actos® is not of acceptable quality, state, or condition; particular standard, quality, grade, style, model, origin, or method of manufacture; or merchantable quality. The serious and life-threatening side effects of Actos® outweigh its benefits, and safer alternatives are available.

104. On behalf of Class Members, the Plaintiff pleads the consumer protection and trade practice legislation in Saskatchewan, and other provinces, including:

(a) *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2, as am., including ss. 4-5 & 8-10;

(b) *Fair Trading Act*, R.S.A. 2000, c. F-2, as am., including ss. 6, 7 & 13;

(c) *The Consumer Protection Act*, S.S. 1996, c. C-30.1, as am., including ss. 5- 8, 14, 16, 48, 64 & 65;

(d) *The Business Practices Act*, S.M. 1990-91, c. 6, as am., including ss. 2 & 23;

(e) *Consumer Protection Act*, 2002, S.O. 2002, c. 30, Sched. A, as am., including ss. 8, 11 & 14;

(f) *Consumer Protection Act*, R.S.Q. c. P-40.1, as am., including ss. 219 & 272;

(g) *Consumer Product Warranty and Liability Act*, S.N.B. 1978, c. C-18.1, including ss. 4, 10, 12, 15-18, 23 & 27;

(h) *Consumer Protection Act*, R.S.N.S. 1989, c. 92, including ss. 26 & 28A;

(i) *Business Practices Act*, R.S.P.E.I. 1988, c. B-7, as am., including ss. 2-4;

(j) *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1, including ss. 7, 8 & 10; and

(k) *The Competition Act*, R.S.C. 1985, c. C-34, including ss. 36, 52 and 74.01.

Subrogated Medical Claims

105. The Plaintiff claims on behalf of the:

(a) Minister of Health of Saskatchewan, for the cost of health services received by Class Members under *The Department of Health Act*, SS 1978, c D-17, s. 19(5);

(b) Minister of Health of British Columbia, for the cost of health services received by Class Members pursuant to s. 2 of the *Health Care Costs Recovery Act*, S.B.C. 2008, c. 27, including necessary operating and care room facilities, diagnostic or therapeutic X-ray and laboratory procedures, anesthetics, prescriptions and drugs;

(c) Minister of Health of Alberta, for the cost of health services received by class members pursuant to Part 5, Division 1, of the *Hospital Act,* R.S.A. 2000, c. H-12, as am., including in-patient and out-patient services, transportation services, public health services, mental health services and drug services;

(d) Minister of Health of Manitoba, for the cost of health services received by Class Members under s. 106(1) of *The Health Services Insurance Act*, C.C.S.M. c. H35.

(e) Ontario Health Insurance Plan, for the cost of insured services received by class Members pursuant to *Health Insurance Ac*t, R.S.O. 1990, c. H.6, as am., s. 31(1), including, prescribed services of hospitals and health facilities, prescribed medically necessary services rendered by physicians, and prescribed health care services rendered by prescribed practitioners;

(f) Minister of Health and Social Services of Quebec, for the cost of all insures services furnished or to be furnished pursuant to the *Hospital Insurance Act*, R.S.Q. c. A-28, s. 10;

(g) Her Majesty the Queen in right of New Brunswick, for the cost of entitled services received by Class Members pursuant to *Health Services Act*, R.S.N.B. 1973, c. H-9, as am., s.10, including accommodation and meals, nursing services, laboratory, radiological and other diagnostic procedures, drugs, use of operating rooms, case rooms and anaesthetic facilities, and routine surgical supplies;

(h) Her Majesty the Queen in right of Nova Scotia, for the cost of insured hospital services received by Class Members pursuant to the *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197, as am., s. 18, including benefits under the Insured Prescription Drug Plan, ambulance services, and insured professional services; and

(i) Minister of Health of Newfoundland and Labrador, for the cost of insured services received by Class Members pursuant to s. 5 of the *Hospital Insurance Agreement Act*, R.S.N. 1990, c. H-7, s. 5, as am.

Estates and Derivative Claims

106. On behalf of the estates and families of Class Members, the Plaintiff pleads:

(a) *Survival of Actions Act*, R.S.A. 2000, c. S-27, ss. 2, 5(1), 5(2); *The Survival of Actions Act,* S.S. 1990, c. S-66.1, ss. 3 and 6(1)-(3); *Trustee Act,* R.S.O. 1990, c. T.23, s. 38(1); *Survival of Actions Act*, R.S.N.S. 1989, c. 453, ss. 2(1)-(2) and 5; *Survival of Actions Act*, R.S.N.B. 2011, c. 227, ss. 3(1)-(2) and 6(1)-(2); *Survival of Actions Act*, R.S.P.E.I. 1988, c. S-11, ss. 2 and 5; *Survival of Actions Act*, R.S.N.L. 1990, c. S-32, ss. 2 and 4.

(b) *Family Compensation Act*, R.S.B.C. 1996, c. 126, ss. 2 and 3(8)-(9); ss. 1, 2, and 3(1) of the *Fatal Accidents Act*, R.S.A. 2000, c. F-8; *The Fatal Accidents Act*, R.S.S. 1978, c. F-11, ss. 2, 3(1), and 4(1)-(3); *Family Law Act*, R.S.O. 1990, c. F. 3, ss. 61(1)-(2); *Fatal Accidents Act,* S.N.B. 2012, c. 104, ss. 3, 4, 7; *Fatal Injuries Act*, R.S.N.S. 1989, c. 163, ss. 2-3 and 5; *Fatal Accidents Act*, R.S.P.E.I. 1988, c. F-5, ss. 1-2, 6; *Fatal Accidents Act*, R.S.N.L. 1990, c. F-6, ss. 2-4.

Waiver of Tort

107. The Defendants deliberately withheld information about the risks of Bladder Cancer associated with Actos®.

108. The Defendants intended to and did profit through their withholding of information. If the Defendants had not committed the wrongs set out above, they would not have obtained the revenues that they did through the commission of those wrongs.

109. The Plaintiff and Class therefore seek a disgorgement of all of the revenues which the Defendants received from to sale of Actos® in Canada.

IV. DAMAGES

Losses and Damages

110. As a result of the Defendants' acts and omissions particularized above, the Plaintiff and the Class have suffered and will continue to suffer loss and damage, and such loss and damage was foreseeable by the Defendants. Particulars of the loss and damage suffered by the Plaintiff and the Class which were caused by the acts and omissions of the Defendants include, *inter alia*:

(a) Personal injuries, emotional distress, pain, suffering, loss of quality and enjoyment of life, and loss of life expectancy;

(b) Special damages for medical expenses and out of pocket expenses;

(c) Loss of both past and prospective income and earning capacity; and,

(d) Damages for past and future cost of care.

111. The Family Class has suffered loss and damage that was foreseeable by the Defendants and includes loss of guidance, care, consortium, and companionship, loss of income, and loss of value of services as a result of the injury to the primary claimant, and expenses incurred as a result of the injury to the injured Class Members.

112. The Family Class relies on common law and legislation in Saskatchewan and comparable legislation in other jurisdictions, including: *Family Law Act*, R.S.O. 1990, c. F. 3, ss. 61; *Family Compensation Act*, R.S.B.C. 1996, c. 126, ss. 2, 3; *Fatal Accidents Act,* R.S.A. 2000, c. F-8, ss. 2, 3; *The Fatal Accidents Act*, R.S.S. 1978, c. F-11, ss. 3-4; *The Fatal Accidents Act,* C.C.S.M. c F-50, s. 3; *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7, ss. 2-3; *Fatal Injuries Act*, R.S.N.S. 1989, c. 163, ss. 3, 5; *Fatal Accidents Act,* R.S.P.E.I. 1988, c. F-5, ss. 2, 6; and, *Fatal Accidents Act*, R.S.N.L. 1990, c. F-6, ss. 3-4.

Disgorgement of revenue

113. The Plaintiff and the Class are entitled to elect to waive the tort and require the Defendants to account for and disgorge the revenues they received from the sale of Actos® to Plaintiff and Class Members.

114. The Defendants tortiously introduced and maintained the marketing, and distribution of Actos® in the Canadian market.

115. But for the Defendants' negligent and intentional acts, and statutory breaches, they would have sold less Actos® and the Defendants would not have received any or part of the revenues they received.

116. As a result of the Defendants' breaches of duty and intentional wrongdoing, they have generated substantial revenues that they should not in good conscience retain.

Punitive and Exemplary Damages

117. The Defendants' conduct through actions and omissions, the awareness of the Defendants of the serious risks of Actos®, and the failure by the Defendants to provide a clear, complete, and current warning, and publicize the dangers of Actos®, should result in this Honourable Court awarding aggravated, punitive, and exemplary damages to the Plaintiff and Class Members.

118. In addition to their failure to provide a clear, complete, and current warning concerning the dangers associated with Actos®, particularly the statistically significant increased risk of Bladder Cancer associated with Actos® use, the Defendants, rather than discharging their duty to the ultimate public by fully informing the learned intermediaries who would communicate directly to the public the risks inherent in the use of Actos®, willfully, deliberately, flagrantly, and wantonly took steps to withhold and manipulate information that it knew or ought to have known about the adverse effects of using Actos®.

119. As a direct and proximate result of the conduct of the Defendants, and the imminent hazard posed to Class Members, as well as the accompanying emotional distress, there should be awarded, in addition to special and compensatory damages, exemplary and punitive damages of a sufficient size to emblazon in the collective minds of these Defendants and others in similar circumstances, the seriousness of the wrongful conduct of the Defendants and the opprobrium with which the judicial arm of governance in Saskatchewan and Canada views such conduct.

120. At all material times, the acts and omissions of the Defendants as set forth above:

(a) Were reprehensible towards the public and the Class, and the Defendants have conducted themselves in a wilful, wanton, and reckless manner with regards to the Class Members' health and safety;

(b) Demonstrated a cavalier and arbitrary approach with respect to their obligations to the Class and put their profits ahead of public safety; and

(c) Pursued conduct which constitutes unfair business practices with the Class and the public.

121. The Plaintiff and the Class Members relied on the Defendants to fully and accurately inform them of the safety and efficacy of Actos® and had no way to determine the efficacy and safety of Actos® on their own.

122. Unless the third arm of governance in Canada acts to award significant exemplary and punitive damages in a case of this nature or orders disgorgement of revenues, corporations like the Defendants will continue to put profits ahead of safety.

123. The economic reality of product development impacts corporate decision making. The design of a stove, an automobile, Actos®, or any product is expensive. The establishment of production mechanisms is expensive. For many products, obtaining regulatory approval is expensive. This is particularly true in the pharmaceutical industry. Regulatory approval for drugs takes many years. The losses on failed or unsafe drugs is massive and is considered in pricing drugs like Actos® that reach the market.

124. The production of a pill may cost $2 but the *cost* of that pill to the producer, taking into account sunk costs in research and development, may be $12 or $22 for a large volume production. If the market for the drug is small, expected sales will probably not be large in number, and spreading the sunk costs over expected sales, that pill may have to be sold for $222 or $2,222.

125. The economics of sunk costs results in the marketing of dangerous products and, as here, the flagrant continuation of marketing. The true test of pharmaceuticals is by the actual users. Other than for elective drugs like birth control, pleasure drugs like Viagra, vanity drugs like Rogaine to grow hair or Latisse for longer eyelashes, drugs treat sick people. Clinical trials do not test like the actual marketplace.

126. When, as with Actos®, pharmaceutical providers learn that the risks of a drug outweigh the benefits, these providers will often nonetheless continue to sell the drug because of sunk costs economics. Manufacturing a $2 pill, plus legal costs to delay judgment, plus the almost invariably inadequate settlements negotiated with class counsel where the providers pay by settlemetn only a small percentage of the real value of the harm, and almost nothing for pain and suffering including nothing at all for the deceased, means that it is profitable for the pharmaceutical industry to continue to sell dangerous drugs like Actos® long after the Defendants should have removed the drugs from the Canadian market.

127. The judiciary, the third arm of governance in Canada, must make it uneconomical for the pharmaceutical industry to put profits and the recovery of sunk costs ahead of safety and the health of Canadians.

128. The Attorneys General of the United States and many American states are active in extracting fines and penalties from corporations selling dangerous products. They use investigative powers not available to plaintiffs in private litigation. Some European governments are similarly active in these same *policing* activities.

129. Provincial and Territorial Attorneys General in Canada do not have these policing powers and Canada chooses not to exercise these kinds of powers.

130. The third arm of governance in Canada must fill this policing void to make it uneconomical for the pharmaceutical industry to put profits and the recovery of sunk costs ahead of safety and the health of Canadians.

131. The conduct of the Defendants requires an award of punitive or exemplary damages.

V. RELIEF SOUGHT

132. The Plaintiff therefore claims on his own behalf and on behalf of all members of the Class:

(a) general damages in an amount to be determined;

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

(c) an accounting and disgorgement of all revenues earned by the Defendants from the sale of Actos®;

(d) punitive and exemplary damages in an amount to be fixed by the court;

(e) costs of investigation and prosecution of this proceeding pursuant to section 36 of the *Competition Act*;

(f) pre-judgment interest, pursuant to *The Pre-Judgment Interest Act* (and equivalent legislation in other provinces);

(g) costs of this action; and,

(h) such further and other relief as the Court may deem just in the circumstances.

DATED AT Regina, Saskatchewan this 24th day of November, 2017.

MERCHANT LAW GROUP LLP

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