Form 10
[Rule 3.25]

COURT FILE NUMBER	1301-00843
COURT	COURT OF QUEEN'S BENCH OF ALBERTA
JUDICIAL CENTRE	CALGARY
PLAINTIFF(S)	IRENE GLENDA EPP
DEFENDANT(S)	TAKEDA CANADA, ELI LILLY CANADA INC.., TAKEDA PHARMACEUTICAL COMPANY LTD., ELI LILLY AND COMPANY

CLERK OF THE COURT
Clerk's stamp
FILED
JAN 21 2013
JUDICIAL CENTRE OF CALGARY

Brought under the Class Proceedings Act

DOCUMENT **STATEMENT OF CLAIM**

ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT

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NOTICE TO THE DEFENDANT(S)

You are being sued. You are a defendant.

Go to the end of this document to see what you can do and when you must do it.

Statement of facts relied on:

The Parties

A. The Plaintiff

1. The Plaintiff, Irene Glenda Epp ("**Epp**"), is a resident of Calgary, Alberta.

B. The Class

2. Epp seeks certification of the following the class ("**the Class**"):

   a) All persons, their estates, administrators, or other legal representatives, throughout Canada, or, in the alternative, throughout Alberta, who were prescribed, purchased, used, or ingested the drug Actos®; and

   b) All persons who have a derivative claim on account of a family relationship with a person in (a) ("**the Family Class**").

C. The Defendants

3. Takeda Canada is a Canadian corporation, incorporated pursuant to the laws of Ontario. Its head office is located at 6750 Century Avenue, Suite 400, Missisauga, Ontario, L5N 2V8 ("**Takeda Canada**").

4. Takeda Pharmaceutical Company Limited is the parent company of Takeda Canada. It is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, 540-8645, Japan ("**Takeda Limited**").

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

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

PARTICULARS OF THE CLAIM

A. Defendants' Acts, Omissions, Knowledge, and Intent

7. Epp, as a representative of the Class, has 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'® unreasonably dangerous risks from Epp, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the risk of bladder cancer, bladder tumours, precancerous bladder conditions, and other grievous bladder-related health problems (inclusively, for brevity, "**Bladder Cancer**") associated with more than twelve months of Actos® ingestion.

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

9. 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.

10. 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. Insulin is necessary for the body to be able to use glucose for energy. Actos® is only used to treat type II diabetes and should not be used to treat type I diabetes.

11. Actos® was jointly launched by Takeda Limited and Eli Lilly and Company in 1999.

12. Actos® was approved by Health Canada as monotherapy to decrease insulin resistance and blood glucose levels in patients with Type II diabetes mellitus, in September 2000. Eli Lilly was responsible for distributing Actos® to the Canadian market until June 2009 when Takeda reacquired the Canadian commercial rights to Actos® from Eli Lilly Canada Inc.

13. Takeda Canada and Eli Lilly Canada Inc. are vicariously liable for the acts of Takeda Ltd. And Eli Lilly and Company respectively.

a) Each was affiliated with the other;

b) Both Takeda and Eli Lilly and Company's business was inextricably interwoven;

c) Both Takeda and Eli Lilly and Company intended that their businesses be operated as a global enterprise;

d) Each 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 Canadian company was the agent of its parent company;

f) Each acted in concert in designing, developing, and manufacturing Actos® and in distributing, marketing, and selling Actos® in Canada

14. Actos® is sold as a single ingredient product under the brand name Actos®.

15. Actos® is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

16. As a result of the defective nature of Actos® , persons who were prescribed and ingested Actos® for more than twelve months, including Epp, were at increased risk for developing Bladder Cancer, have suffered and may continue to suffer from Bladder Cancer.

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

18. Specifically, 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.

19. The Defendants negligently marketed and sold Actos® because they failed to review all information relevant to the safety of the prescription drug Actos® or otherwise 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.

20. The Defendants failed to meet the standard of care established at law, which was intended for the benefit of individual consumers such as Epp, making the Defendants liable under Alberta law.

21. As a result of Defendants' actions and inactions, Epp was injured due to her ingestion of Actos® , which caused and will continue to cause Epp and The Class various injuries and damages.

22. 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.

23. In 2005, the results of the PROactive (**PRO**spective Pioglit**A**zone **C**linical **T**rial **I**n Macro**V**ascular **E**vents) 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 MacroVascular Events): a Randomized Controlled Trial*, Lancet, 266: 1279-1289 (2005).

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

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

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

27. The Defendants willfully, 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.

28. 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.

29. On September 17, 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.

30. In a shocking spin on words, despite the FDA finding that Actos® is linked to a statistically significant increase in the risk for developing Bladder Cancer, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of Bladder Cancer or other cancers from Actos®.

31. 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.

32. 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 in 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).

33. 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.

34. On June 15, 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.

35. 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 in 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.

36. On July 12, 2011, Takeda Limited issued a recall on Actos® in France.

37. On June 17, 2011 Health Canada issued an advisory that it is reviewing the drug's status 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.

38. Following the recall in France, Takeda Limited 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.

39. As the manufacturers of Actos® , Takeda knew or should have known that Actos® use for longer than twelve months was associated with Bladder Cancer.

40. As marketers and distributers of Actos®, Eli Lilly knew or ought to have known that Actos® use for longer than twelve months was associated with Bladder Cancer.

41. 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.

42. 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/noncase 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.

43. Actos® is one of the Defendants' top selling drugs, sold by Eli Lilly in Canada from 2000 to 2009 and Takeda from June 2009 to present. Upon information and belief, in the last year, the medication had global sales of $4.8 billion and accounted for approximately 27% of Takeda's

revenue.

B. Plaintiff's Harms

44. Epp began using Actos® in 2005.

45. Epp had been diagnosed with type II diabetes in the fall of 1996. Prior to that she had been taking Metformin® alone between 1997 and April of 2005 to control her diabetes, on a dose of 500mg twice a day.

46. In April of 2005, Epp had her medication changed to Glucanorm (generic name: Repaglinide) in a 2mg dose twice daily, along with Actos® in a dose of 1 tablet of 30mg per day. She was told that Actos® would have better performance than Metformin® in aiding her body to absorb insulin and to manage her blood glucose levels.

47. Shortly after taking Actos®, Epp started experiencing recurring bladder infections the until current date of this very day. Doctors were sought and a variety of antibiotics were prescribed for the continual infections, but to no avail, with excruciating pain and continual urination occurring daily.

48. At all times, she was not informed by any doctor or pharmacist of any issue with Actos®. Epp was never informed of these bladder-related risks developing through the use of Actos®. There were no warnings given to her by the pharmacist or in the labeling of the drug.

49. Epp continued on the aforementioned dose until February of 2012 when she became aware of the connection between her multiple bladder problems with subsequent deteriorating health and her use of Actos®; this occurred as she became aware in February of 2012 of litigation proceeding in the United States through a US newspaper ad against the Defendants relating to the link between

long-term use of Actos® and developing Bladder Cancer.

50. Epp then discontinued using Actos® to manage her diabetes. She now takes 800 mg twice a day of Sulfatrim DS®, two 2 mg Repaglinide up to three times per day to control blood sugar levels, and has been able to successfully manage her diabetes without using Actos®, but the grievous damages caused by Actos® persist. Epp currently awaits an appointment with a urologist to confirm her suspected bladder cancer diagnosis.

51. Had Epp been aware of the demonstrated risk of Bladder Cancer developing through long-term use of Actos®, she would not have taken it.

52. Epp began taking Actos® on the recommendation of her family physician. Had her physician and the larger medical community been aware of the risk of Bladder Cancer developing in their patients through the use of Actos® they would have sought safer alternatives. Clearly in Epp's case, the benefits of using Actos® to control her type II diabetes have been far outweighed by the detrimental impact of developing Bladder Cancer.

53. She experiences extreme pain, blood in the urine, abdominal and lower back pains, and frustration daily. In addition, she has difficulty controlling her bladder and experiences an almost constant urge to urinate, sometimes up to six times nightly.

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

C. Damages

55. Epp requires and will in the future require ongoing medical care and treatment. Epp, as a direct and proximate result of long-term Actos® use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, and living related

expenses due to her new lifestyle.

56. The Defendants knew, or should have known, that consumers such as Epp would foreseeably suffer injuries as a result of the Defendants' failure to exercise ordinary care, as described above.

57. The Defendants' actions constitute knowing omission, suppression, and concealment of material facts, made with the intent that others, including Epps, relied upon such omissions, suppressions, and concealment in connection with the marketing of Actos®. Such deliberate omissions, suppressions, and concealment, were done with the intent to mislead.

58. The Defendants' negligence and tortious conduct was the proximate cause of the increased risk of harm suffered by Epp and members of the class.

59. The conduct of the Defendants as aforesaid constitutes unlawful and wrongful conduct, negligence, false pretense, and misrepresentation.

60. The Defendants manufactured, marketed, and distributed Actos®, and made misrepresentations, as previously set forth herein, to Epp, her physicians and the general public, including but not limited to the misrepresentation that Actos® was safe, fit, and effective for the treatment of type II diabetes. At all material times, the Defendants conducted a sales and marketing campaign to promote the sale of Actos® and deceived Epp, the medical community and the general public as to the health and risks and consequences of the use of Actos®.

61. The Defendants made the foregoing misrepresentations without any reasonable grounds for believing them to be true. These misrepresentations were made directly by the Defendants, by sales representatives and other authorized agents of the Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase, and use of Actos®.

62. The foregoing representations by the Defendants were in fact misrepresentations, in that Actos® was not safe, fit, and effective for human consumption. The use of Actos® is hazardous to health. Actos® has a serious propensity to cause serious injuries or death to users, including but not limited to the injuries suffered by Epp.

63. At the time the Defendants marketed, sold, and distributed the drug Actos®, for use by Epp and members of the class, the Defendants knew of the use for which Actos® was intended and expressly or impliedly warranted the product to be of merchantable quality and safe and fit for such use.

64. Epp and Epp's physicians reasonably relied upon the skill and judgment of the Defendants as to whether Actos® was of merchantable quality and safe and fit for its intended use.

65. The Defendants breached the implied warranty of merchantability because Actos® was not of merchantable quality, and was not safe or fit for its intended use because the product was and is reasonably dangerous and unfit for the ordinary purpose for which it was intended.

66. As a direct and proximate result of the Defendants' breach of the implied warranty of merchantability, Epp suffered harm, and is entitled to damages.

67. The Defendants expressly warranted that Actos® was safe and well tolerated by patients studied.

68. Epp purchased Actos® for the purpose of ingesting it and obtaining health benefits therefrom.

69. Epp and Epp's physicians reasonably relied upon the skill and judgment of the Defendants as to whether Actos® was of merchantable quality and safe and fit for its intended use.

70. Actos® did not conform to the Defendants' express representations because Actos® is not safe and has serious side effects, including life-threatening side effects.

71. As a result of the conduct of the Defendants as aforesaid and the consequent injuries suffered by Epp, the Class, and the Family Class have and continue to suffer damages. The Family Class have provided and will continue to provide nursing, housekeeping, and other services to the other members of the Class. The Family Class have and will continue to incur expenses for the benefit of the other members of the Class. The Family Class have lost the guidance, care and companionship they might have expected to receive from the Class, had their injuries not occurred.

D. Aggravated, Punitive, and Exemplary Damages

72. The Defendants acted recklessly, intentionally and maliciously and with callous disregard for the rights and safety of Epp, as aforesaid, entitling Epp to punitive damages in an amount appropriate to punish the Defendants.

73. Takeda is Asia's largest pharmaceutical company, and Takeda Canada, along with Eli Lilly and Company, are some of Canada's largest and most respected pharmaceutical corporations. Their financial capacity to seek advice from in-house and out-of-office advice on issues of law and compliance with Canadian law, is not doubted.

74. Either the Defendants decided, for reasons which will be determined in discoveries, that it would deliberately not address the issues mentioned in this Claim, or the were astoundingly noncompliant with Canadian law which is astounding given the legal resources available to the Defendants.

75. The third arm of governance, the judicial arm, should, on behalf of Canadians, make clear that the conduct of the Defendants, based on deliberate wrongdoing or woeful and unexplainable ignorance of the law, will not be tolerated. Only through a sizeable award of exemplary and punitive damages will a meaningful message be given to the Defendants and other pharmaceutical companies

who may have or may be currently committing the same types of wrongdoings. Only an award in the tens of millions will have impact and communicate society's message to the Defendants and others like it: be candid and honest about scientific research and the side effects of the drugs you manufacture or serious financial consequences will result.

F. Consumer Protection and Business Practices

76. The Defendants also breached provincial consumer protection and business practices legislation including the *Business Practices and Consumer Protection Act,* S.B.C. 2004, c.2, as am.; s. 13 of the *Fair Trading Act*, R.S.A. 2000, c. F-2, as am.; s. 14 and Part III of *The Consumer Protection Act*, S.S. 1996, c. C-30.1; *The Business Practices Act*, S.M. 1990-91, c. 6, as am.; s. 8 of the *Consumer Protection Act*, 2002, S.O. 2002, c. 30, Sched. A, as am.; and s. 10 of the *Consumer Protection and Business Practices Act*, S.N.L. 2009, c C-31.1. In particular, because the Defendants failed to accurately disclose the risk of Bladder Cancer, the Defendants are liable thereunder, and:

(a) the Plaintiff claims all available statutory relief arising therefrom for any subclasses that may be entitled to such relief, and

(b) the Plaintiff relies on independent breaches thereof as supporting their claim for punitive damages for the class.

F. Waiver of Tort, Unjust Enrichment, and Subrogation

77. The Plaintiff paid for and consumed (ingested) Actos®.

78. The Defendants accepted payment by the Plaintiff for the purchase of Actos®.

79. The Plaintiff did not receive a safe and effective drug for which she paid.

80. Given the wrongful conduct of the Defendants, it would be inequitable for the Defendants to keep the money paid by the Plaintiff and the Class to receive a safe and efficacious drug. The Plaintiffs and Class are entitled to elect at the end of the trial of the common issues, to waive the tort and require the Defendants to account for all the revenue they received from the sale of Actos® in

Canada.

81. Such election is appropriate for the following reasons among others:

(i) such revenue was acquired in such circumstances that the defendants cannot in good conscience retain it;

(ii) the integrity of the pharmaceutical regulations, guidelines, and marketplace would be undermined if the court did not require an accounting;

(iii) Actos® could not have been marketed, and the Defendants would not have received any revenues from its sales in Canada but for the Defendants' tortious conduct;

(iv) the Defendants engaged in wrongful conduct by marketing a drug which caused or had the potential for serious adverse events when they knew, prior to selling Actos®, that Actos® was not safe, and intentionally failed to warn stakeholders of such serious adverse events.

82. The Government of Alberta's Department of Health provides coverage for healthcare services to Alberta residents through Alberta Health Services ("**AHS**"). Similar programs are available in other provinces, such as the Ontario Ministry of Health and Long-Term Care, which provides coverage for healthcare services to Ontario residents through Ontario Health Insurance Plan.

83. The Plaintiff and other Class Members required many medical resources and medical services ("**services**") as a result of the conduct of the Defendants as aforesaid. These medical services were paid for partially by AHS and other provincial health insurers. AHS and other provincial health insurers will continue to provide treatment in the future to the Plaintiff and other Class Members.

84. The subrogated interest of AHS and all other provincial health insurers includes the cost of all past and future insured services for the benefits of the Plaintiff and all other Class Members.

85. Class Members who paid for their own Actos® seek a full indemnification of the purchase

price. Provincial and territorial third party payors have a subrogated interest in their expenditures for Actos® on behalf of the Plaintiff and other individuals of the Class and they seek a full indemnification of the purchase price.

86. The claims herein include claims in respect of a set of torts committed in Alberta and throughout Canada and in respect of damage sustained in Alberta and throughout Canada arising from that set of torts, therefore, a real and substantial connection exists between Alberta and the facts on which the Claim is based.

87. Pursuant to Rule 11.25(1)(b) of the *Alberta Rules of Court*, service of this Statement of Claim outside Alberta is permissible.

88. The Plaintiff and the Class Members, therefore, submit that judgment be granted for the relief sought herein.

Remedy sought

89. As a result of Defendants' actions and inaction, Plaintiff and the Class were injured due to their ingestion of Actos®, which caused and will continue to cause Plaintiff's and the Class' injuries and damages. The Plaintiff and the Class accordingly seek damages associated with these injuries. WHEREFORE THE PLAINTIFF ON BEHALF OF HERSELF AND THE PUTATIVE CLASS, CLAIM FOR THE FOLLOWING RELIEF, ON A RATIONAL BASIS TO BE DETERMINED BY THIS HONOURABLE COURT:

(a) an order certifying the herein action as a class proceeding pursuant to the *Class Proceedings Act,* S.A. 2003, c C-16.5;

(b) compensatory and general damages;

(c) restitution of revenues that Takeda and Eli Lilly directly or indirectly received from the sale of Actos® ® to treat type II diabetes;

(d) exemplary, aggravated and punitive damages;

(e) pre-judgment and post-judgment interest pursuant to the *Judgment Interest Act*,

R.S.A. 2000, c. J-1;

(f) costs on a substantial indemnity basis;

(g) other relief as counsel may advise;

(h) such further and other relief as this Honourable Court deems just.

NOTICE TO THE DEFENDANT(S)

You only have a short time to do something to defend yourself against this claim:

20 days if you are served in Alberta

1 month if you are served outside Alberta but in Canada

2 months if you are served outside Canada.

You can respond by filing a statement of defence or a demand for notice in the office of the clerk of the Court of Queen's Bench at CALGARY, Alberta, AND serving your statement of defence or a demand for notice on the plaintiff's(s') address for service.

WARNING

If you do not file and serve a statement of defence or a demand for notice within your time period, you risk losing the law suit automatically. If you do not file, or do not serve, or are late in doing either of these things, a court may give a judgment to the plaintiff(s) against you.