AMENDED THIS / MODIFIÉE Jan 7/15 PURSUANT TO / CONFORMÉMENT À

☐ RULE/LA RÈGLE 26.02 ( )

☑ THE ORDER OF / L'ORDONNANCE DU Justice Belobaba

DATED / FAIT LE Dec 16/14

REGISTRAR SUPERIOR COURT OF JUSTICE / GREFFIER COUR SUPÉRIEURE DE JUSTICE

Court File No.: CV-13-491534-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

~~JEAN ROBERT, ANNE ROBERT and~~ RANDOLPH CARRIER, PETER NELSON and SHARON NELSON

Plaintiffs

-and-

APOTEX INC., ~~SANDOZ INTERNATIONAL GMBH~~, and SANDOZ CANADA INCORPORATED

Defendants

Proceeding under the *Class Proceedings Act, 1992*

AMENDED 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 an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the *Rules of Civil Procedure*, serve it on the plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period 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.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the *Rules of Civil Procedure*. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date: ~~October 25, 2013~~
~~October XX, 2014~~ - R
Oct 25/13

Issued by: "Y. Grant"
Local Registrar

Address of court office:

393 University Avenue
10th Floor
Toronto, Ontario
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TO: APOTEX INC.
150 Signet Drive
Toronto, ON M9L 1T9

~~AND TO: SANDOZ INTERNATIONAL GMBH~~
~~Industriestrasse 25~~
~~83607 Holzkirchen~~
~~Germany~~

AND TO: SANDOZ CANADA INCORPORATED
145 Jules-Léger Street
Boucherville, QUE J4B 7K8

CLAIM

1. The plaintiffs, ~~Jean Robert ("Jean"), Anne Robert ("Anne"), and~~ Randolph Carrier ("Randolph"), Peter Nelson ("Peter") and Sharon Nelson ("Sharon") on their own behalf and on behalf of all members of the classes of persons described in paragraphs 10 ~~23~~ and 11 ~~24~~ ("the Class" or "Class Members" and "the Family Class" or "Family Class Members") *infra*:

a) an order certifying this action as a class proceeding and appointing Peter ~~Jean~~ and Randolph, as the representative plaintiffs of the Class and Sharon ~~Anne~~ as the representative plaintiff of the Family Class, all pursuant to the *Class Proceedings Act, 1992* ("CPA");

b) a declaration that the defendants owed a duty of care to the Class Members;

c) a declaration that the defendants were negligent in the development, testing, design, manufacturing, licensing, distribution, marketing and sale of PIO as defined *infra.* at para 2 and are liable to the Classes for resulting damages;

d) a declaration that the defendants breached their duty to warn the plaintiffs and other Class Members of the health risks associated with PIO;

e) a declaration that the defendants breached their implied warranties relating to the safety and efficacy of PIO;

f) a declaration that the defendants made representations related to the safety and efficacy of PIO to the plaintiffs and other Class Members that were false, misleading, deceptive and unconscionable and amounted to unfair practices;

g) a declaration that the defendants are vicariously liable to the Classes for the acts and omissions of their officers, directors, agents, employees and representatives;

h) general damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;

i) special damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;

j) punitive damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;

k) alternatively, a declaration that the plaintiffs and other Class Members are entitled to recover under restitutionary principles and an accounting and an order requiring disgorgement of all revenue received by the defendants from the sale of PIO in Canada;

l) the costs of notice and administering the plan of distribution of the recovery in this action plus applicable taxes pursuant to s.26(9) of the CPA;

m) an order directing a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

n) pre-judgment and post-judgment interest pursuant to sections 128 and 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;

o) the costs of this action on a substantial indemnity basis, together with all applicable taxes thereon; and

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

NATURE OF THE ACTION

2. This action relates to the pain and suffering and resulting damages suffered by the plaintiffs herein and other members of the Classes as a result of the defendants' negligent research and development, design, testing, manufacture, licensing, marketing, distribution and sale of pioglitazone hydrochloride ("PIO") in Canada.

3. Peter ~~Jean~~ and Randolph were prescribed PIO for the treatment of their diabetes and used the drug in accordance with the prescribing information provided by the defendants and in accordance with her treating physician's instructions.

4. Peter ~~Jean~~ and Randolph were both later diagnosed with bladder cancer.

5. The plaintiffs allege that PIO is defective and inherently dangerous in that it causes, materially contributes to, and materially increases the risks of bladder cancer and bone fractures. The plaintiffs further allege that the defendants have known about these defects

but have failed to disclose these defects and the resulting risks to the health and life of the plaintiffs, Class Members, their treating physicians and regulatory authorities in Canada and have failed to recall PIO in Canada.

THE PARTIES

6. Peter is 73 years old and resides in Sudbury, in the province of Ontario, with his wife Sharon. ~~Jean is 77 years old and resides in Val Caron, in the province of Ontario, with his wife Anne.~~

7. Randolph is 52 years old and resides in Lorne, in the province of New Brunswick.

8. The defendant, Apotex Inc. ("Apotex"), is a Canadian corporation with its registered office located in Toronto, Ontario. At all times, its activities included the development, manufacture, marketing and distribution of generic PIO, APO-Pioglitazone.

~~9. The defendant, Sandoz International GMBH ("Sandoz International"), is a German corporation, with its headquarters in Holzkirchen, Germany and at all times material to this action engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling generic PIO, Sandoz® Pioglitazone, to Canadian consumers.~~

~~10.~~ 9. The defendant, Sandoz Canada Incorporated ("Sandoz Canada") is a Canadian corporation, incorporated under the *Canada Business Corporations Act*, with its principal place of business in Boucherville, Quebec and is a wholly owned subsidiary of Sandoz

International. Sandoz Canada was engaged in the business of licensing, marketing, labeling, manufacturing, promoting, packaging, advertising and/or selling generic PIO, Sandoz® Pioglitazone, to Canadian consumers.

THE CLASSES

~~11.~~ 10. Peter ~~Jean~~ and Randolph bring this action on behalf of the members of the Class defined as follows:

> "All persons resident in Canada who purchased and/or used PIO, in the generic form APO-Pioglitazone or Sandoz® Pioglitazone and their estates, administrators or other legal representatives, heirs or beneficiaries ("the Class" or "Class Members")"

~~12.~~ 11. Sharon ~~Anne~~ brings this action on her own behalf and on behalf of the members of the Family Class defined as follows:

> "All persons who on account of a personal relationship to a Class Member are entitled to assert a derivative claims for damages pursuant to section 61(1) of the *Family Law Act*, R.S.O. 1990, c.F.3, as amended and comparable provincial and territorial legislation ("the Family Class" or "Family Class Members")"

PLAINTIFFS' CIRCUMSTANCES

Peter's ~~Jean's~~ Circumstances

12. Peter was diagnosed with non-insulin dependent Type-II diabetes in or around 1993.

13. He was first prescribed a generic form of PIO (specifically, CO-Pioglitazone) for the management of his diabetes in or about February 2008 and continued using it until in or around July, 2009, at which time he began using APO-Pioglitazone, which he used until in or around May 2010, when he was again prescribed CO-Pioglitazone. Thereafter, he was again prescribed APO-Pioglitazone in May 2011 and continued to use it until in or around March, 2012, at which point he stopped taking any form of PIO.

14. At all material times, Peter took the APO-Pioglitazone as advised by his family doctor and in accordance with the information provided by the defendant Apotex.

15. In or around January, 2013, Peter experienced gross hematuria and was subsequently diagnosed with bladder cancer in or around February 2013.

16. Sharon is Peter's wife and brings her claim in that capacity. Sharon has been her husband's primary caregiver throughout his illness and has found the experience terrifying and exhausting. She has expended and will continue to expend significant emotional and financial resources in caring for her husband, and brings her claim on behalf of all members of the Family Class.

~~13. Jean was diagnosed with non-insulin dependent Type 11 diabetes in or around 2006.~~

~~14. He was first prescribed ACTOS for the management of his non-insulin dependant Type II diabetes, specifically for management of her blood glucose levels, in July 2006~~

~~remaining on it to May 2008 at which time he began taking generic PIO, APO-pioglitazone. He continued to take APO-pioglitazone for three years until in or around May 2011. From May 2011 until December 2011 he took generic PIO from Mylan Pharmaceuticals. At all times, Jean took the medication as prescribed by his family doctor and in accordance with the dosing information provided by the defendants.~~

~~15. Jean was diagnosed with bladder cancer in or around January 2010 while on APO-pioglitazone after three cancerous tumours were discovered and, that same month, he underwent surgery for the these malignant tumours.~~

Randolph's Circumstances

17. Randolph was diagnosed with non-insulin dependent Type-II diabetes in or around January 2000.

18. He was first prescribed PIO for the management of his non-insulin dependant Type-II diabetes, specifically for management of hi~~ser~~ blood-glucose levels, in or around October 2004, remaining on it until in or around April 2007. He did not take any form of PIO again until December 2009, when he was prescribed Sandoz® Pioglitazone. He continued to take Sandoz® Pioglitazone until November 2011. At all times, he took the medication as prescribed by his family doctor and in accordance with the dosing information provided by the defendants.

19. In or about March 2012, he developed gross hematuria followed by the passage of a blood clot. He underwent related investigations at Campbellton Regional Hospital.

As a result of these investigations, on or about March 6, 2012, he was diagnosed with transitional cell carcinoma in his bladder.

20. Randolph subsequently underwent surgery for removal of the tumour in his bladder and subsequently underwent a six-week session of chemotherapy. However, the cancer subsequently returned and he had to undergo a second six-week round of chemotherapy treatment.

FACTS

History of PIO and Mechanism of Action

21. PIO, under the brand name ACTOS, manufactured by Takeda, was approved for sale in Canada in August, 2000 to control blood sugar levels in people with Type 2 (non insulin-dependant) diabetes. The original New Drug Submission ("NDS") for ACTOS was made by Eli Lilly Canada Inc. ("Lilly"), which was granted a Notice of Compliance by Health Canada on August 17, 2000. Lilly had acquired the Canadian commercial rights to ACTOS from Takeda as part of a worldwide agreement in 1999.

22. Apotex began to manufacture, market and distribute a generic form of PIO, APO-Pioglitazone, in Canada on December 5, 2007.

23. Sandoz Canada also began to manufacture, market and distribute a generic form of PIO, Sandoz® Pioglitazone, in Canada on December 5, 2007.

24. PIO is in a class of drugs known as thiazolidinediones ("TZDs"), also known as glitazones, which act, in part, to decrease insulin resistance.

25. TZDs, including ACTOS and the defendants' generic forms of PIO, work by activating receptor molecules inside the cell nucleus, specifically peroxisome proliferator-activated receptor-gamma (PPARγ) which, once activated, modulate the expression of genes involved in lipid and glucose metabolism, insulin signal transduction and adipocyte and other tissue differentiation.

26. Both generic drugs have precisely the same chemical composition as ACTOS.

Defendants' Knowledge of Risks of Bladder Cancer with PIO

27. TZD PPARγ ligands, such as PIO, have been shown to have significant effects on tumour cells, and to alter cell proliferation rates and differentiation in human cancer cell lines, including bladder cancer cells lines.

28. As early as 2005 results of a randomized controlled trial assessing the potential protective effect of PIO in preventing macrovascular events (known as the PROactive study) were published in the *Lancet.* Among the results was a significant excess in cases of bladder cancer reported in the PIO treatment group, compared to the placebo-control group. Specifically, there were 14 cases of bladder cancer in the treatment group compared to only 6 cases in the placebo group.

29. On September 17, 2010 the U.S. Food and Drug Administration ("FDA") issued a Safety Announcement which advised of this on-going ten-year epidemiological study designed to evaluate whether PIO was associated with an increased risk of bladder cancer. It was further disclosed that an *interim analysis* of the study data revealed an increased risk

of bladder cancer among patients with longer exposure to the drug and for those individuals exposed to the highest dosage.

30. These *interim results* were published in April 2011 and they confirmed an increased risk of bladder cancer among patients with longer exposure. In particular, the risk for bladder cancer was found to be **30% higher** among those whose duration of PIO use was 12-24 months and **50% higher** among those with greater than 24 months' exposure.

31. Also noted in the September, 2010 FDA Safety Announcement was a three-year controlled clinical study on liver safety which also demonstrated a higher percentage of bladder cancer cases in patients receiving PIO versus a comparator. To date, the results of this study have not been published by the defendants or otherwise.

32. In June of 2011, results were published of a study that reviewed adverse events reported to the FDA between 2004-2009 and which assessed the extent of association between PIO use and bladder cancer. This study found a clear epidemiological signal for bladder cancer associated with PIO; the reporting odds ratio (ROR) was indicative of a definite risk for PIO (4.30 [95% CI 2.82-6.52] – where an odds ratio of greater than 1 implies a statistically significant result).

33. On June 9, 2011, results were published from a broad retrospective cohort study conducted by the Caisse national de l'assurance maladie, involving almost 1.5 million French patients using PIO between 2006-2009. The results of this analysis demonstrated a statistically significant correlation between exposure to PIO and the occurrence of bladder cancer, and that the risk increased with exposure of longer than one year. As a

result of these findings, the French regulator suspended sales of drugs containing PIO on June 9, 2011.

34. On June 10, 2011, it was reported by Reuters that the German regulator had also suspended sales of the drug in Germany after that country's Federal Institute for Drugs and Medical Devices reviewed the results of the French epidemiological study.

35. On June 15, 2011, the FDA issued a further Safety Announcement related to PIO in which it advised that use of the drug for more than one year may be associated with an increased risk of bladder cancer and ordered that such risk was to be incorporated into the Warnings and Precautions section of the drug's label. The FDA reported that the risk of bladder cancer increased in a dose-dependeant manner and was associated with the duration of use of PIO.

36. The Safety Announcement also noted that exposure to PIO for greater than 12 months was associated with a 40% increase in risk and that use of PIO for more than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years' follow up.

37. On June 17, 2011, Health Canada issued a press release advising of the study results that demonstrated an increased risk of bladder cancer with the use of PIO and announcing that it was undertaking a review of the drug's status.

38. However, despite the ever growing body of knowledge which the defendants were aware of or ought to have been aware of in relation to the increased risk for bladder cancer with PIO exposure, the Canadian product monograph did not include information about

this the risk of developing bladder cancer in the Warnings section. In addition, the Canadian patient information sheet contained no information whatsoever about an association between PIO and bladder cancer to allow the plaintiffs, Class Members, and their physicians to make an informed decision about using the drug.

39. It was not until April 23, 2012, following the completion of Health Canada's review of ACTOS, that Takeda issued a public communication, endorsed by Health Canada, disclosing "new safety information regarding ACTOS and a potential risk of bladder cancer" and stating that based on Health Canada's assessment, the ACTOS Product Monograph had been updated to reflect this new risk.

40. Thus, since before the inception of marketing of PIO in Canada, there has been concern for and evidence of an increased risk for bladder cancer with the use of this drug. Although a robust body of scientific evidence demonstrates that the product is inherently dangerous and can cause, materially contribute to or materially increase the risk of bladder cancer and had resulted in numerous cases of bladder cancer worldwide, the defendants have failed to withdraw PIO from the Canadian stream of commerce and have continued to profit from the sale of PIO in Canada. Moreover, these defendants sought market approval for their generic PIO in the face of the documented risks to Canadian consumers.

CAUSES OF ACTION

Negligence

41. PIO was designed, developed, tested, manufactured, licensed, assembled, distributed, imported and/or exported, marketed, and/or sold by the defendants. At all

material times, the defendants owed a duty of care to the plaintiffs and to the Classes to provide a safely manufactured product. The defendants breached the standard of care expected in the circumstances.

42. The defendants also owed a duty to the plaintiffs and other Class Members to initiate rigorous scientific studies to assess the possible association between PIO and the development of bladder cancer, to carefully monitor the safety and post-market performance of PIO and to warn the plaintiffs and the other Class Members and their health care professionals and Canadian regulators of the defective nature of PIO and to recall it from the Canadian market when it became obvious that the product could not be safely used, thereby causing risk of or actual serious personal injury and/or death.

43. The circumstances of the defendants being in the business of designing, manufacturing and placing PIO into the Canadian stream of commerce are such that the defendants were in a position of legal proximity to the Class Members and therefore under an obligation to be fully aware of their safety when designing, manufacturing, assembling and marketing a product such as PIO.

44. It was reasonably foreseeable that a failure by the defendants to design and manufacture a reasonably safe product, and thereafter to monitor its performance following market introduction (and to take corrective measures when required) would cause, materially contribute to, or materially increase the risk of harm to the plaintiffs and the other members of the Classes.

45. The defendants were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, importing and/or exporting, marketing and sale of PIO. Particulars of some, but not all, of the defendants' acts of negligence follow:

a) they knew or should have known that PIO was unreasonably and dangerously defective and failed to warn the public, health care providers and the regulatory authorities in a timely manner;

b) they failed to adequately test the safety and efficacy of PIO before marketing and distributing it;

c) they failed to conduct any or adequate follow-up studies on the efficacy and safety of PIO;

d) they failed to adequately design, manufacture and/or test PIO to ensure that it was safe and free from defects prior to selling or distributing it;

e) they failed to assemble and manufacture PIO in such a manner that it would work safely and effectively without exposing the defendants' consumers to injury or loss;

f) they knew or ought to have known that PIO was defective and that PIO would not properly perform the functions or purposes for which it was intended;

g) after receiving actual or constructive notice of problems with PIO, they failed to issue adequate or any warnings, withdraw or recall PIO, amend the product monograph, publicize the problem(s) and/or otherwise act properly and in a timely manner to alert the plaintiffs and Class Members, the public and health care providers and regulators that PIO was defective;

h) they failed to provide clear instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damages from PIO;

i) they concealed the fact that PIO was defective from the public, health care providers and the regulatory authorities, including the FDA and Health Canada;

j) they concealed adverse information regarding the testing and safety of PIO from the public, health care providers and regulatory authorities, including the FDA and Health Canada;

k) they failed to monitor and follow up on reports of adverse reactions to PIO;

l) they failed to ensure that their employees complied with the appropriate quality system standards applicable to the manufacturing process;

m) they failed to properly supervise their employees, subsidiaries and licensees;

n) they failed to issue a safety notice or to recall PIO in a timely manner or at all; and

o) such further and other particulars of negligence within the knowledge of the defendants.

46. At all times relevant to this action the defendants knew, and had reason to know, that PIO was not safe for the patients for whom it was prescribed and the defendants knew and had reason to know of the defects in PIO, but concealed this information and did not warn Peter ~~Jean~~, Randolph, the Class Members, physicians, or regulators, thereby preventing Peter ~~Jean~~, Randolph, the Class Members and their physicians, and the medical community, from making informed choices about the prescription and use of PIO.

Breach of Express and Implied Warranties

47. By marketing, advertising, distributing and selling PIO without adequate warnings as to its propensity to cause, materially contribute to, or materially increase the risk of serious adverse reactions, including the development of bladder cancer and the risk of fractures, and other known adverse health risks, the defendants misrepresented the safety of PIO to Peter ~~Jean~~, Randolph, and other Class Members and their treating physicians. In doing so, the defendants created and breached both express and implied warranties that PIO was ~~were~~ safe for its intended uses.

48. The defendants warranted to Peter ~~Jean~~ and Randolph and to other Class Members that PIO was of merchantable quality and fit for use. The defendants breached this

warranty to Peter ~~Jean~~ and Randolph and other Class Members by manufacturing, marketing, distributing and selling PIO which was inherently dangerous to users.

49. In consenting to the use of PIO, Peter ~~Jean~~, Randolph, and other Class Members and their physicians relied on the skill, judgment, representation and warranties of the defendants. These warranties and representations were false in that PIO was not safe and was unfit for the uses for which it was intended. The defective condition of PIO existed at the time it left the defendants' control.

50. As a result of these breaches and breach of express and implied warranties, the plaintiffs herein and other Class Members have suffered damages in an amount to be proven at the trial of this action.

DAMAGES

51. As a result of the negligence of the defendants, the plaintiffs and Classes have suffered the following damages:

a) serious injury and, in some cases, death;

b) emotional and psychological trauma;

c) special damages for out of pocket expenses;

d) cost of future care and services;

e) loss of income; and,

f) such further and other damages the particulars of which will be provided prior to trial.

52. As a result of the defendants' negligence, Sharon ~~Anne~~ and other members of the Family Class have suffered the following damages:

a) expenses reasonably incurred for the benefit of a Class Member;

b) a reasonable allowance for travel expenses actually incurred in visiting the Class Member during his or her treatment or recovery;

c) where, as a result of the injury, nursing, housekeeping or other services have been provided for a Class Member, a reasonable allowance for loss of income or the value of the services; and

d) an amount to compensate for the loss of guidance, care and companionship that the Family Class Member might reasonably have expected to receive from a related Class Member if the injury or death had not occurred.

53. The plaintiffs and the other Class Members are also entitled to recover, as damages or costs in accordance with the *Class Proceedings Act, 1992*, S.O. 1992, c. 6, the costs of administering the plan to distribute the recovery of this action.

PUNITIVE DAMAGES

54. The plaintiffs plead that the defendants have acted in such a high-handed, wanton and reckless manner, without regard to public safety, as to warrant a claim for punitive damages. In particular, the defendants' conduct in the design, development, testing, manufacture, licensing, assembly, distribution, marketing, and sale of PIO, the failure to recall all PIO sooner or at all, and the facts pleaded above were entirely without care, deliberate, callous, disgraceful, wilful, and an intentional disregard of the Class Members' rights and safety, indifferent to the consequences, and motivated by economic considerations such as maintaining revenue and market.

PROVINCIAL HEALTH INSURERS

55. The provincial and territorial health insurers in Canada have incurred various expenses with respect to the medical treatment of Peter ~~Jean~~, Randolph, and other Class

Members as a result of the defendants' negligence. As a result, they have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their subrogated and direct rights of action in respect of all past and future insured services. This action is maintained on behalf of all such provincial and territorial health insurers.

LEGISLATION

56. The plaintiffs plead and rely upon, *inter alia*, the following statutes and the regulations made thereunder (all as amended):

a) *Alberta Health Care Insurance Act*, R.S.A. 200, c. A-20;

b) *Class Proceedings Act*, R.S.O. 1992, S.O. 1992, c.6;

c) *Courts of Justice Act*, R.S.O. 1990, c.43;

d) *Family Law Act*, R.S.O. 1990, c. F.3;

e) *Fatal Accident Act*, R.S.N.I. 1990, c. F.6;

f) *Fatal Accidents Act*, C.C.S.M. c.F.50;

g) *Fatal Accidents Act*, R.S.A. 2000, c. F-8;

h) *Fatal Accidents Act*, R.S.N.B. 1973, c.F-7;

i) *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3;

j) *Fatal Accidents Act*, R.S.P.E.T. 1988, c. F-5;

k) *Fatal Accidents Act*, R.S.S. 1978, c.F-11, s.3;

l) *Fatal Accidents Act*, R.S.Y. 2002, c.86;

m) *Fatal Injuries Act*, R.S.N.S. 1989, c. 163;

n) *Health Insurance Act*, R.S.O. 1990, c. 11.6;

o) *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197;

p) *Health Services Insurance Act*, C.C.S.M., C.1135;

q) *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8;

r) *Hospital Insurance Agreement Act*, R.S.N.I. 1990, c.11-7;

s) *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3;

t) *Hospital Insurance Services Act*, R.SY. 2002, c. 112;

u) *Hospital Services Act*, R.S.N.B. 1973, c. 11-9;

v) *Hospitals Act*, R.S.A. 2000, c. 11-12;

w) *Negligence Act*, R.S.O. 1990, c. N.1;

x) *Trustee Act*, C.C.S.M. c. T160;

y) *Trustee Act*, R.S.N.W.T. 1988, c. T-8; and

z) *Trustee Act*, R.S.O. 1990, c. T.23.

REAL AND SUBSTANTIAL CONNECTION

57. There is a real and substantial connection between the subject matter of this action and the Province of Ontario for the following reasons:

a) the defendants have registered places of business in Ontario and manufacture, distribute, market, promote and/or sell PIO in Ontario and derive substantial revenue from such sales;

b) Peter ~~Jean~~ and other members of the Class were prescribed and used PIO in Ontario;

c) Peter, Sharon, ~~Jean, Anne,~~ and other members of the Classes resident in Ontario sustained their damages in Ontario; and

d) approval for the sale of PIO in Canada was granted in Ottawa, Ontario.

SERVICE OUTSIDE OF ONTARIO

58. This statement of claim may be served without court order outside Ontario because the claim is:

a) in respect of a tort committed in Ontario (rule 17.02(g));

b) in respect of damages sustained in Ontario arising from a tort or breach of contract however committed (rule 17.02(h));

c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and

d) against a person carrying on business in Ontario (rule 17.02(p)).

PLACE OF TRIAL

59. The plaintiffs propose that this action be tried in Toronto.

Date: ~~October 25, 2013~~
~~October XX, 2014~~ a
Oct 25/13

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Court File No.: CV-13-491534-00CP

~~JEAN ROBERT, ANNE ROBERT and~~ RANDOLPH CARRIER, PETER NELSON AND SHARON NELSON
Plaintiffs

-and -

APOTEX INC.et al
Defendants

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AMENDED STATEMENT OF CLAIM

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