

**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN:

RUSALBA JOUDRY

Plaintiff

- and -

**JANSSEN INC., JANSSEN PHARMACEUTICALS, INC.,
JANSSEN ORTHO LLC, JOHNSON & JOHNSON, and
JOHNSON & JOHNSON INC.**

Defendants

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM

TO THE DEFENDANT(S)

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. 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 plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, 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.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date: September 10th, 2015

Issued by:  Beverley Pinto

Local Registrar
393 University Avenue 10th Floor
Toronto, Ontario M5G 1E6



TO: JANSSEN INC.
19 Green Bell Drive
Toronto, Ontario
M3C 1T9

AND TO: JANSSEN PHARMACEUTICALS, INC.
1125 Trenton Harbourton Rd
Titusville, New Jersey
08560

AND TO: JANSSEN ORTHO LLC
Stateroad 933 Km 0 1 Street
Gurabo, Puerto Rico
00778

AND TO: JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New-Brunswick, New Jersey
08933

AND TO: JOHNSON & JOHNSON INC.
Suite 300, 8565 Autoroute Transcanadienne
Ville St.-Laurent, Quebec
H4S 1Z6

CLAIM

1. The Plaintiff claims on her own behalf and on behalf of all of the members of the Class (as preliminarily defined below):

- (a) general damages in excess of \$500,000,000, or as this Honourable Court deems fit;
- (b) special damages in excess of \$500,000,000, or as this Honourable Court deems fit;
- (c) an accounting or disgorgement of the benefits which accrued to the Defendants as a result of their negligence, statutory breaches, and restitutionary law;
- (d) damages and statutory compensation available under the *Consumer Protection Act*;
- (e) punitive damages;
- (f) pre-judgment interest; and,
- (g) costs.

1. PARTIES

The Plaintiff

2. Rosalba Joudry has at all material times resided in Scarborough, Ontario.

The Proposed Class

3. Rosalba brings this proposed class action on behalf of all persons in Canada who have purchased or ingested Invokana (hereinafter the "Class" or "Class Members"), and all persons who are family members of the Class who are entitled to assert a claim pursuant to section 61 of the *Family Law Act*, R.S.O. 1990, c. F.3, as amended, and equivalent provincial legislation (hereinafter the "Family Class" or "Family Class Members").

The Defendants

4. The Defendant Janssen Pharmaceuticals, Inc. ("Janssen US") is a corporation incorporated pursuant to the laws of the State of New Jersey with its head office located in Titusville, New Jersey. At all material times, Janssen US designed, researched, developed, tested, manufactured, marketed, packaged, labeled, promoted, distributed,

licensed, and sold Invokana for use throughout the world, including Canada. Janssen US is identified as the manufacturer for Invokana in the U.S. label. Janssen US also authors, publishes, and maintains the Invokana web sites, which are sources of information regarding the safety and efficacy of Invokana that are used by consumers worldwide, including by Canadians. Janssen US is the sponsor of Invokana in the United States.

5. The Defendant Janssen Inc. ("Janssen Canada") is a corporation incorporated pursuant to the laws of the Province of Ontario with its registered head office located in Don Mills, Ontario. At all material times, Janssen Canada designed, researched, developed, tested, manufactured, marketed, packaged, labeled, promoted, distributed, licensed, and sold Invokana for use by Canadians. Janssen Canada is the sponsor or market authorization holder for Invokana, meaning that it is the entity authorized by Health Canada to sell Invokana in Canada. Janssen Canada sells Invokana under the Drug Identification Numbers 02425483 and 02425491 in 100mg and 300mg dosages, respectively.

6. The Defendant Janssen Ortho LLC ("Janssen Ortho") is a corporation incorporated pursuant to the laws of the State of Delaware with its head office located in Gurabo, Puerto Rico. At all material times, Janssen Ortho designed, researched, developed, tested, manufactured, marketed, packaged, labeled, promoted, distributed, licensed, and sold Invokana for use throughout the world, including Canada. Janssen Ortho is identified as the manufacturer for Invokana in the U.S. labels.

7. The Defendant Janssen Ortho LLC ("Janssen Ortho") is a corporation incorporated pursuant to the laws of the State of Delaware with its head office located in Gurabo, Puerto Rico. At all material times, Janssen Ortho designed, researched, developed, tested, manufactured, marketed, packaged, labeled, promoted, distributed, licensed, and sold Invokana for use throughout the world, including Canada. Janssen Ortho is identified as the manufacturer for Invokana in the U.S. labels.

8. The Defendant Johnson & Johnson, is a corporation incorporated pursuant to the laws of the State of New Jersey with its head office located in New Brunswick, New Jersey and is one of the shareholders of Johnson & Johnson Inc., which is domiciled in

the District of Montreal, in the Province of Quebec, (collectively "J&J"). J&J is the parent of the Defendants Janssen Canada, Janssen Ortho, and Janssen US. At all material times, J&J designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold Invokana for use throughout the world, including Canada. J &J owns the trademark for Invokana in Canada.

8. The Defendants are research-based pharmaceutical companies. They develop, design, test, manufacture, label, package, market, distribute, and sell various pharmaceutical products. The Defendants individually and jointly manufactured, tested, marketed, labelled, distributed, promoted, and sold drugs under the brand name Invokana in Ontario and across Canada.

9. The Defendants engage in "harmonization" and "coordination" of matters involving labeling, marketing, the efficacy of the products, and the collecting and sharing of clinical research or trial information, and adverse event reporting. The Defendants engaged in a joint enterprise for the development, promotion, and sale of Invokana in Ontario and Canada.

10. Each of the Defendants acted in concert with the others. Each of the Defendants is vicariously liable for the actions of the others. Each of the Defendants were part of one worldwide corporate entity acting together and in common ways. The Plaintiff and Class Members cannot reasonably be expected to know which of the Defendants has committed which individual wrong because the Defendants work secretly and collectively but each is responsible for the wrongdoing of the other.

11. Therefore, all the Defendants are jointly and severely liable for the acts and omissions of each other, and Janssen Canada, Janssen US, Janssen Ortho, and J&J will be referred to collectively as "**Janssen**".

II. PARTICULARS OF THE CLAIM

The Drug

12. Janssen researched, developed, designed, tested, manufactured, marketed, and distributed prescription drugs containing the active ingredient Canagliflozin

("Invokana").

13. Invokana was approved for sale in Canada by Health Canada on May 28, 2014 under the DINs 02425483 and 02425491 in 100mg and 300mg doses, respectively.

14. Invokana is a glucose co-transporter 2 (SGLT2) inhibitor marketed by Janssen for the treatment of treat Type 2 diabetes.

15. Type 2 diabetes is a disease in which your pancreas does not produce enough insulin, or your body does not properly use the insulin it makes. As a result, glucose (sugar) builds up in your blood instead of being used for energy.

16. SGLT2 is a protein in humans that facilitates glucose reabsorption in the kidney. SGLT2 inhibitors block the reabsorption of glucose in the kidney, increase glucose excretion through urination, and thus lowers blood glucose levels.

17. According to Janssen:

"INVOKANA® is proven to lower blood sugar (A1C).

Used along with diet and exercise, INVOKANA® is the first in the newest class of diabetes medicines that's proven to significantly lower A1C in adults with type 2 diabetes."

18. Janssen failed to conduct sufficient long-term studies on kidney health to determine the short and long-term effects of inhibiting SGLT2 proteins.

19. When used as directed in the product monograph, or when used foreseeably, for short and long term, while Invokana is being used and after a patient ceases to use it, Invokana can cause, contribute, or increase the risk of a number of serious side effects (the "Side Effects") including:

- a) diabetic ketoacidosis;
- b) kidney failure; or
- c) death.

20. The warnings provided in the Invokana product monographs are inadequate. Janssen downplayed the seriousness of Invokana's side effects, or alternatively, failed to

provide a clear, complete, and current warning of Invokana's side effects.

21. Janssen failed to provide a clear, complete and current warning to Invokana users and medical professionals that Invokana can cause the aforementioned Side Effects, denying the Plaintiff and Class Members the ability to make an informed decision as to whether to take Invokana or consider taking another drug.

22. Even if the probability of injury is small or may only affect a small group of users, this risk must be balanced against considerations such as the nature of the drug, the necessity for taking it, the seriousness of the danger, and the magnitude of the increased danger to the consumer.

23. Janssen ought to have been aware of the risks of Invokana based on Invokana's mechanism of action, the class of drugs to which Invokana belongs, and numerous studies, trials, and medical journal articles.

24. Janssen has ignored all of the aforementioned information and continues to promote their product as safe, downplaying the seriousness of Invokana's potential side effects, and failing or refusing to provide a clear, complete, and current warning to medical professionals and consumers.

25. Janssen fails and continues to fail to provide a clear, complete and current warning in their product monographs as doing so would affect the sales of Invokana, which is very profitable for Janssen.

26. Janssen has placed the profits of their conjoined companies ahead of the health and safety of Canadian consumers.

Rosalba's Harms

27. In or around October 2014, Rosalba was prescribed Invokana by Dr. Peter Roslas for the management of high blood glucose levels associated with Type 2 Diabetes.

28. Rosalba began ingesting Invokana, as prescribed by her doctor.

29. In or around June of 2014, while watching TV, Rosalba saw an advertisement from the US television commercial warning Invokana users that they may experience diabetic ketoacidosis or kidney failure.

30. Immediately after seeing the US television commercial, Rosalba contacted Dr. Rostas, who advised her to stop taking Invokana, and go see him.

31. After tests were conducted by Dr. Rostas, it was determined that Rosalba was experiencing kidney failure.

32. Rosalba had not been warned by her doctor, or advised by Invokana's product monograph, that Invokana can cause, contribute to, or increase the risk of diabetic ketoacidosis or kidney failure. Had Rosalba been warned of Invokana's Side Effects, she would not have taken the drug.

III. CAUSES OF ACTION

Negligence

33. In discharging their duties of care, the Defendants breached the standards of care expected of them.

34. As manufacturers and marketers of prescription pharmaceutical drugs, Janssen owed Class Members duties:

- (a) to conduct proper design, development, and testing of its drug;
- (b) not to market an unreasonably dangerous drug; and
- (c) to warn of the risks of serious side effects.

35. Before marketing Invokana in Canada, and after putting Invokana on to the market in Canada, Janssen failed to conduct proper design, development, and testing of its drug by:

- (a) conducting no prospective or retrospective population studies, animal studies, or trial studies on the long-term effects of inhibiting SGLT2 proteins;
- (b) hiring no outside epidemiologist, endocrinology, hematology, or nephrology experts; and

- (c) failing to review or, in the alternative, reviewing but failing to take appropriate action with regard to medical literature, journals, and trials regarding the potential effects of inhibiting SGLT2 proteins.

36. Janssen breached their duty of care by marketing Invokana in Canada at all and by failing to withdraw Invokana from markets in Canada, because Invokana is an unreasonably dangerous or unfit drug.

50. Additionally and alternatively, Janssen breached their duty of care by failing to include a clear, complete, and current warning in the Invokana product monograph that Invokana can cause, contribute, or increase the risk of aforementioned Side Effects, which Janssen knew or should have known about.

51. The Plaintiff pleads that the Invokana product monograph should have stated prominently and in all appropriate sections that:

- (a) Invokana can cause diabetic ketoacidosis;
- (b) Invokana can cause, contribute, or increase the risk of kidney failure; and
- (c) Invokana can cause, contribute, or increase the risk of death.

51. The warnings provided by Janssen were not clear, complete, and current.

Consumer Protection Act

37. The Defendants' advertising, marketing, sales and supply of Invokana for personal use by Rosalba and Class Members were "consumer transactions" within the meaning of the *Consumer Protection Act*, 2002, SO 2002, c 30, Sch. A ("*CPA*"), and equivalent legislation in other Canadian jurisdictions. Class Members who purchased Invokana for personal use are "consumers" and the Defendants are "suppliers" within the meaning of the *CPA*.

38. The Defendant's conduct in the advertising, marketing, sales, and supply of Invokana constituted unfair practices under Part III of the *CPA* and in particular made false, misleading, or deceptive representations contrary to s. 14 of the *CPA*. These unfair practices included the Defendants' failure to properly disclose all material facts

regarding the efficacy and safety of Invokana.

39. As a consequence of the Defendants' conduct, the Plaintiff and the Class suffered the damages described herein. Rosalba seeks damages and statutory compensation pursuant to the CPA on her own behalf, and on behalf of Class Members.

Waiver of Tort

40. The Defendants deliberately withheld information about the risks of Invokana.

41. 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.

42. The Plaintiff and Class Members therefore claims a money judgment in an amount equal to the revenues which the Defendants received from to sale of Invokana in Canada.

Damages

43. 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 Rosalba and the Class which were caused by the acts and omissions of the Defendants include:

- (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.

44. 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 consortium, 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.

45. The Family Class relies on common law and legislation in Ontario 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

46. The Plaintiff and the Class are entitled to elect to waive the tort and require the Defendants to account for the revenues they received from the sale of Invokana to the Class.

47. The Defendants tortiously introduced and maintained the marketing and distribution of Invokana in the Canadian market.

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

49. 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

50. The Defendants' conduct, through actions and inactions, the awareness of the Defendants of the serious risks of Invokana, and the failure by the Defendants to provide a clear, complete, and current warning, and publicize the dangers of Invokana, subject the Defendants to aggravated, punitive, and exemplary damages.

51. In addition to their failure to provide a clear, complete, and current warning concerning the dangers inherent in the use of Invokana, 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 Invokana, 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 Invokana.

52. As a direct and proximate result of the conduct of the Defendants and the imminent hazard posed to the 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 the seriousness of the wrongful conduct of the Defendants and the opprobrium with which the judicial arm of governance in Ontario and Canada views such conduct.

53. 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 willful, wanton, and reckless manner with regard 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.

54. Rosalba, and Class Members relied on the Defendants to fully and accurately inform them of Invokana's safety and had no way to determine the efficacy and safety of Invokana on their own.

55. The conduct of the Defendants warrants an award of punitive or exemplary damages.

Service outside of Ontario

56. This claim may be served, without a court order, on the Defendants outside Ontario on the basis that:

- (a) the damage was sustained in Ontario (Ontario Rule 17.02(h));
- (b) the tort was committed in Ontario (Ontario Rule 17.02(g));
- (c) the Defendants carry on business in Ontario (Ontario Rule 17.02(p));
- (d) the claim is authorized by statute, the *Consumer Protection Act, 2002* (Ontario Rule 17.02(n)).

Place of Trial

57. The Plaintiff proposes that this action be tried at the City of Toronto, in the Province of Ontario.

Date of Issue: _____

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v.

JANSSEN INC. ET AL.

Court File No.

Plaintiff

Defendants

W-15-536111

**ONTARIO
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at Toronto

STATEMENT OF CLAIM

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