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London

Court File No.:

ONTARIO
SUPERIOR COURT OF JUSTICE

Raymond Duck

Plaintiff

- and -

JANSSEN INC., JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON INC., JOHNSON & JOHNSON

Defendants

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM

TO THE DEFENDANTS

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 March 15, 2018 Issued by _____

Local registrar

Address of court office: 80 Dundas Street
London, Ontario N6A 6A3

TO: **JANSSEN INC.**
19 Green Belt Drive
North York, Ontario, M3C 1L9

AND TO: **JANSSEN PHARMACEUTICALS INC.**
1125 Trenton Harbourton Road
Titusville, New Jersey, 08560 USA

AND TO: **JOHNSON & JOHNSON INC.**
88 McNabb Street
Markham, Ontario, L3R 5L2

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

CLAIM

1. The Plaintiff, Raymond Duck, claims on behalf of himself and others similarly situated in Canada:

   (a) an Order certifying this proceeding as a class proceeding and appointing him as Representative Plaintiff for the class(es), to be further defined on the motion for certification;

   (b) a declaration that the Defendants were negligent in the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Invokana Products (as defined in paragraph 19);

   (c) a declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees, and representatives;

   (d) pecuniary and special damages in the amount of $500,000 for each person prescribed one of the Defendants' Invokana Products or as aggregated following a trial on the common issues;

   (e) non-pecuniary damages in an amount to be assessed for each person who was implanted with one of the Defendants' Invokana Products;

   (f) in the alternative to the claim for damages, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from the sales of their Invokana Products;

(g) damages pursuant to the *Family Law Act*, RSO 1990, c F.3 s.61 and similar legislation and common law in other provinces, where applicable, in the amount of $100,000 for each such plaintiff;

(h) punitive, aggravated, and exemplary damages in the amount of $20,000,000;

(i) the costs of distributing all monies received to class members;

(j) prejudgement interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;

(k) costs on a substantial indemnity basis, plus applicable taxes; and

(l) such further and other relief as this Honourable Court may deem just.

NATURE OF THE ACTION

2. This proposed class proceeding involves Invokana Products− Invokana (canagliflozin) is a prescription medication indicated to lower blood sugar in adults with type two diabetes. This action arises out of the Defendants' unlawful, negligent, inadequate, improper, unfair, and deceptive practices and misrepresentations related to, *inter alia*, their design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Invokana Products.

3. The Defendants misrepresented that their Invokana Products are safe and effective, when in fact these devices cause serious Injuries, Conditions, and Complications (as defined in paragraph 29).

4. Patients prescribed the Defendants' Invokana Products were misled as to the drug's safety and efficacy, and as a result have suffered serious Injuries, Conditions, and Complications.

THE PLAINTIFF

5. The Plaintiff Raymond Duck resides in Espanola, Ontario.

6. In June of 2017, Mr. Duck was prescribed one of the Defendants' Invokana Products to manage his type two diabetes.

THE DEFENDANTS

7. The Defendant Janssen Pharmaceuticals, Inc. is an American corporation, headquartered in Titusville, New Jersey.

8. Janssen Pharmaceuticals, Inc. is identified as the manufacturer for Invokana in the U.S. Janssen Pharmaceuticals, Inc. authors, publishes, and maintains the Invokana websites, which are sources of information regarding the safety and efficacy of Invokana that are used by consumers worldwide, including in Canada.

9. The Defendant Janssen Inc. is a Canadian corporation, headquartered in Don Mills, Ontario. Janssen Inc. is the sponsor or market authorization holder for Invokana, meaning that it is the entity authorized by Health Canada to sell Invokana in Canada.

10. The Defendant Johnson & Johnson is an American corporation, headquartered in New-Brunswick, New Jersey.

11. The Defendant Johnson & Johnson Inc., a wholly owned subsidiary of Johnson & Johnson, is a Canadian corporation, headquarter in Markham, Ontario.

12. The Johnson & Johnson is parent of Janssen Pharmaceuticals, Inc.

13. Hereinafter, each of the above Defendants shall be collectively referred to as the "Defendants".

14. The business of each of the Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, Invokana Products in Canada. At all material times, the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling Invokana Products in Canada. The development of Invokana Products for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Invokana Products, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in Ontario and elsewhere.

15. In bringing this action on behalf of all persons resident in Canada who were implanted with Invokana Products at any time on or before the date of the certification order, which as manufactured, marketed and/or sold or otherwise placed into the stream of

commerce in Canada by one or more of the Defendants, the Plaintiff pleads and relies upon the provisions of the *Class Proceedings Act*, *1992*, S.O. 1992, c.6, the *Negligence Act*, R.S.O. 1990, c. N-1, as amended and regulations thereunder, and the *Food and Drugs Act,* R.S.C. 1985, c. F.27 and regulations thereunder. The Plaintiff also brings this action on behalf of all persons resident in Canada entitled to claim by virtue of a personal or familial relationship to any one or more of the persons described above, and plead and rely upon the Ontario *Family Law Act,* RSO 1990, C F.3 and regulations thereunder, and any analogous provincial legislation.

THE DEFENDANTS' INVOKANA PRODUCTS

16. Invokana is a prescription sodium-glucose co-transporter-2 (SGLT2) inhibitor that is indicated for use with diet and exercise to lower blood sugar in adults with type two diabetes. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine.

17. Invokana was approved by Health Canada in June, 2014. Invokana is available in 100 mg and 300 mg oral tablets.

18. Invokana is also available in combination with metformin (another oral anti-diabetic drug) under the brand name Invokamet. Invokamet was approved by Health Canada in 2016.

19. The Defendants' products listed in paragraphs 16 – 18 above, are collectively referenced herein as "Invokana Products."

THE RISKS

Increased Risk of Lower Limb Amputations

20. On September 6, 2017, Health Canada issued a Dear Healthcare Professional Letter advising practitioners that an approximately two-fold increased risk of surgical lower limb amputation has been observed in two long-term clinical studies in type two diabetes patients who had either established cardiovascular disease or were at risk for cardiovascular disease and treated with Invokana.

21. These studies were the CANVAS (Canagliflozin Cardiovascular Assessment Study) and the CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus). Amputations of the toe and mid-foot were the most frequent (99 out of 140 patients with amputations receiving canagliflozin in the two trials). However, amputations involving the leg, below and above the knee, were also observed (41 out of 140 patients with amputations receiving canagliflozin in the two trials). Lower limb infections, gangrene, diabetic foot ulcers, and ischemia were the most common precipitating medical events leading to an amputation

22. In July, 2017, the Defendants amended the product monograph of their Invokana Products to include an increased risk of lower limb amputations as a "black-boxed" serious warning and precaution.

Diabetic Ketoacidosis

23. On May 16, 2016, Health Canada issued a Dear Healthcare Professional Letter advising that serious, sometimes life-threatening and fatal cases of diabetic ketoacidosis (DKA) have been reported in patients prescribed Invokana and other SGLT2 inhibitors.

24. Health Canada reported that the majority of affected patients required hospitalization, and that many cases occurred in the first two months of treatment. Additionally, a number of these cases, the presentation of the condition was atypical with only moderately increased blood glucose levels observed. Such atypical presentation of DKA in patients with diabetes resulted in a delay in diagnosis and treatment in some cases.

25. In 2016, the Defendants amended the product monograph of their Invokana Products to include DKA as a "black-boxed" serious warning and precaution.

Acute Kidney Injury

26. In October of 2015, Health Canada released a Summary Safety Review “Sodium Glucose Cotransporter 2 (SGLT2) Inhibitors INVOKANA (canagliflozin) and FORXIGA (dapagliflozin) - Evaluation of a Potential Risk of Acute Kidney Injury”.

27. Health Canada's safety review found a link between reported events of acute kidney injury and the use of Invokana. This issue was identified following new safety information received from the manufacturers of Invokana following the marketing of the product.

28. Health Canada required the manufacturers to update the Canadian prescribing information of Invokana to strengthen the wording relating to kidney injury to reflect this risk.

29. The increased risk of lower leg amputations, diabetic ketoacidosis, and acute kidney injury, described in paragraphs 20 - 28 above, are collectively referred to as “Injuries, Conditions, and Complications”.

THE PLAINTIFF'S EXPERIENCE

30. In or around June, 2017, Mr. Duck was prescribed Invokana to manage his type two diabetes.

31. Several weeks before starting Invokana, Mr. Duck developed an ulcer on his right heel as a result of ill-fitting shoes. Due to his diabetic status, his foot wound was monitored and treated by Diabetes Care Services provided by Health Sciences North in Sudbury, Ontario. At the time Mr. Duck was prescribed Invokana, his foot wound was nearly completely healed.

32. Within a few months of taking daily Invokana, Mr. Duck's foot wound rapidly deteriorated. Mr. Duck was advised by his care team that the ulcer and infection in his right foot would not heal, and that he required a below the hip amputation of his leg.

33. As a result of Mr. Duck's foot wound and amputation, he was hospitalized for about five weeks at the Science North Centre, and then for an additional four weeks at the Espanola Hospital where he received rehabilitative therapy. After nine weeks of hospitalization, Mr. Duck was discharged home with home care nursing support.

34. After his amputation, Mr. Duck requires a wheel chair to support his mobility.

35. Mr. Duck lives alone. His home is not wheelchair accessible. He needed to install a wheelchair lift to enter the home after being discharged from the hospital. Currently, he is unable to access the second floor of his house.

36. As a result of his amputation, Mr. Duck is unable to drive. He was advised that the necessary modifications to his vehicle will cost around $15,000.00.

37. Mr. Duck relies on external supports to complete his activities of daily living, such as home maintenance, attending appointments, and grocery shopping.

38. As a result of his amputation, Mr. Duck continues to suffer from chronic pain which is managed with daily prescription pain medication.

39. Prior to and at the time when Mr. Duck was prescribed the Defendants' Invokana Product, he received no or inadequate warning about the risk of developing Injuries, Conditions, and Complications.

40. Had Mr. Duck been aware of the magnitude of risks of developing Injuries, Conditions, and Complications, he would never have agreed to being prescribed the Defendants' Invokana Product. But for the Defendants' wrongful conduct, the Plaintiff would not have incurred damages.

CAUSES OF ACTION

41. The Defendants at all material times owed a duty of care to the Plaintiff to:

(a) ensure that their Invokana Products were fit for their intended and/or reasonably foreseeable use;

(b) conduct appropriate testing to determine whether and to what extent use of their Invokana Products posed serious health risks, including the magnitude of risk of developing Injuries, Conditions, and Complications;

(c) properly, adequately, and fairly warn the Plaintiff and physicians of the magnitude of the risk of developing Injuries, Conditions, and Complications with use of their Invokana Products compared to alternative treatments;

(d) ensure that physicians were kept fully and completely warned and informed regarding all risks associated with their Invokana Products;

(e) monitor, investigate, evaluate and follow up on adverse reactions to the use of their Invokana Products; and

(f) properly inform Health Canada and other regulatory agencies of all risks associated with their Invokana Products.

42. The Defendants negligently breached their duty of care.

43. The Plaintiff states that his damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following:

(a) the Defendants failed to ensure that their Invokana Products were not dangerous to recipients during the course of their use and that they were fit for their intended purpose and of merchantable quality;

(b) the Defendants failed to adequately test their Invokana Products in a manner that would fully disclose the magnitude of the risks associated with their use, including but not limited to Injuries, Conditions, and Complications;

(c) the Defendants failed to provide Health Canada complete and accurate information with respect to their Invokana Products as it became available;

(d) the Defendants failed to conduct any or any adequate follow-up studies on the efficacy and safety of their Invokana Products;

(e) the Defendants failed to conduct any or any adequate long-term studies of the risks of their Invokana Products;

(f) the Defendants failed to provide the Plaintiff, his physicians and Health Canada with proper, adequate, and/or fair warning of the risks associated with use of their Invokana Products, including but not limited to risk of Injuries, Conditions, and Complications;

(g) the Defendants failed to adequately monitor, evaluate and act upon reports of adverse reactions to their Invokana Products in Canada and elsewhere;

(h) the Defendants failed to provide any or any adequate updated and/or current information to the Plaintiff, physicians and/or Health Canada respecting the risks of their Invokana Products as such information became available from time to time;

(i) the Defendants failed to provide adequate warnings of the risks associated with their Invokana Products, including the risk of Injuries, Conditions, and Complications in all persons receiving their Invokana Products on the patient information pamphlets in Canada;

(j) the Defendants, after noticing problems with their Invokana Products, failed to issue adequate warnings, timely recall their Invokana Products, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiff and their physicians of their Invokana

Products' inherent dangers, including but not limited to the danger of Injuries, Conditions, and Complications;

(k) the Defendants failed to establish any adequate procedures to educate their sales representatives and physicians respecting the risks associated with their Invokana Products;

(l) the Defendants represented that their Invokana Products were safe and fit for their intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

(m) the Defendants misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of their Invokana Products and their associated risks, including the risk of Injuries, Conditions, and Complications;

(n) the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known by the Defendants;

(o) the Defendants failed to timely cease the manufacture, marketing and/or distribution of their Invokana Products when they knew or ought to have known that their Invokana Products caused Injuries, Conditions, and Complications;

(p) the Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;

(q) the Defendants failed to properly supervise their employees, subsidiaries and affiliated corporations;

(r) the Defendants breached other duties of care to the Plaintiff and putative class members, details of which breaches are known only to the Defendants; and

(s) in all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of the Plaintiff and putative class members.

44. The Defendants' Invokana Products were defective because they are unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by the Plaintiff, putative class members, or their physicians. Any benefit from using the Defendants' Invokana Products was outweighed by the serious and undisclosed risks of their use when used as the Defendants intended. There are no individuals for whom the benefits of the Defendants' Invokana Products outweigh the risks, given that there are many alternative products and treatments that are at least as efficacious as the Defendants' Invokana Products and carry far less and/or less serious risks than the Invokana Products.

45. The risks associated with use of the Defendants' Invokana Products, including Injuries, Conditions, and Complications in all persons receiving their Invokana Products, were in the exclusive knowledge and control of the Defendants. The extent of the risks were not known to, and could not have been known by, the Plaintiff. The Plaintiff's injuries would not have occurred but for the negligence of the Defendants in failing to ensure that their Invokana Products were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their Invokana Products to the Plaintiff and putative class members, and to their physicians.

DAMAGES

46. The Plaintiff's and other putative class members' injuries and damages were caused by the negligence of the Defendants, their servants and agents.

47. As a result of the Defendants' negligence, the Plaintiff has suffered and continues to experience serious personal injuries and harm with resultant pain and suffering.

48. The Plaintiff and other putative class members have suffered special damages for medical costs incurred in the screening, diagnosis, and treatment of Injuries, Conditions, and Complications related to use of the Defendants' Invokana Products.

49. As a result of the conduct of the Defendants, the Plaintiff and other putative class members suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.

50. Family members of the Plaintiff and putative class members have suffered and continue to suffer damages including loss of care, guidance, companionship and consortium, as well as financial expenses and special damages due to the wrongful conduct of the Defendants.

51. Some of the expenses related to the medical treatment that the Plaintiff and putative class members have undergone, and will continue to undergo, have been borne by the various provincial health insurers.

52. The Plaintiff claims punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendants.

SERVICE OUTSIDE OF ONTARIO

53. The Plaintiff pleads and relies on sections 17.02 (g) and (p) of the Rules of Civil Procedure, allowing for service *ex juris* of the foreign defendants. Specifically, this originating process may be served without court order outside Ontario in that the claim is:

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

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

March 15, 2018

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ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding commenced at London
Proceeding under the *Class Proceedings Act*, *1992*

STATEMENT OF CLAIM

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