

CANADA
PROVINCE OF QUEBEC
DISTRICT OF MONTRÉAL

No.: 500-06-000906-186

(Class Action)
SUPERIOR COURT

STEVEN VARNAI

and

JOANNE GIROUX

Applicants

v.

JANSSEN INC.

JANSSEN PHARMACEUTICALS INC.

JANSSEN ORTHO LLC.

JOHNSON & JOHNSON INC.

and

JOHNSON & JOHNSON

Defendants

**APPLICATION OF THE DEFENDANTS FOR LEAVE TO EXAMINE
THE APPLICANT STEVEN VARNAI AND FOR COMMUNICATION
OF DOCUMENTS
(Articles 574, 575 & 587 C.C.P.)**

TO THE CASE MANAGEMENT JUDGE TO BE APPOINTED HEREIN, THE DEFENDANTS
RESPECTFULLY SUBMIT THE FOLLOWING:

I. INTRODUCTION

1. The Defendants, JANSSEN INC., JANSSEN PHARMACEUTICALS INC., JANSSEN ORTHO LLC., JOHNSON & JOHNSON INC. and JOHNSON & JOHNSON (collectively **Johnson & Johnson**) hereby respectfully requests leave to examine the Applicant Steven Varnai (**Mr. Varnai**) out of court and an order for Mr. Varnai to communicate certain documents prior to the examination and provide consent with respect to delivery of his relevant medical files.

II. THE PROCEDURAL CONTEXT

2. By way of the *Application for Authorization to Institute a Class Action and to Appoint the Status of Representatives Plaintiffs* (the **Application**), Mr. Varnai and the Applicant Joanne Giroux seek authorization to bring a class action against Johnson & Johnson on behalf of all individuals residing in Québec who have used canagliflozin marketed under the brand names Invokana or Invokamet; as well as all individuals in Québec who suffered damages from the use of canagliflozin marketed under the brand names Invokana or Invokamet by one of the persons concerned in the preceding sentence.
3. Mr. Varnai alleges the following with respect to his individual claim:
 - (a) He was prescribed Invokana in 2014 to manage his diabetes;

- (b) In December 2015, he began feeling unwell, tired and short of breath;
- (c) On December 18, 2015, he was taken by his wife to the Lakeshore General Hospital where he learned that he had very severe heart complications, and was transferred to the Jewish General Hospital for treatment;
- (d) While undergoing cardiac care, a previously existing sore on his leg became infected and grew in size;
- (e) His doctors were unable to control the infection and advised him that he required a left leg amputation below the knee;
- (f) He alleges that he received no warning as to the extent of the risks of developing injuries and complications resulting from Invokana;
- (g) He alleges that as a result of his health condition and reduced mobility, he is unable to independently manage his business.

4. Mr. Varnai claims that Johnson & Johnson:

- (a) Failed to adequately warn physicians and consumers of risk of injuries and complications caused by Invokana and Invokamet;
- (b) Did not provide adequate safety data to the FDA or Health Canada with respect to Invokana and Invokamet;

as appears from paragraphs 59 and 60 of the Application.

5. On behalf of the putative class members, Mr. Varnai and the Applicant Joanne Giroux are seeking: (a) compensatory damages for bodily, moral and/or material injuries for all members who have used Invokana or Invokamet; (b) compensatory damages for all members who have suffered damages as a result of someone close using Invokana or Invokamet; (c) punitive damages in an amount of \$20,000,000; (d) all costs and expenses related to the distribution of money to members of the class.

III. THE RIGHT TO EXAMINE MR. VARNAI AND THE NEED FOR RELEVANT EVIDENCE

- 6. At the hearing on the Application, this Court will be required to analyse the allegations found in the Application in view of determining whether the criteria outlined at article 575 CCP and developed by jurisprudence are met.
- 7. This Court is entitled to a sufficient disclosure of the facts rather than general and vague allegations that are unsupported by relevant documentary evidence.
- 8. Mr. Varnai's individual claim, his adequacy as proposed class representative and the existence of a group are among the main issues to be analysed by the Court in the context of this Application.
- 9. Article 574 CCP empowers this Court to authorize the presentation of appropriate evidence, relevant to the analysis of the conditions set out in articles 574 and 575 CCP, including the production of relevant documentary evidence and the examination out of court of Mr. Varnai.
- 10. In the Application, Mr. Varnai puts himself forward to act as class representative. When this Court will assess the Application in light of articles 575(2), 575(3) and 575(4) CCP, it must do so in view of the Mr. Varnai's personal situation.

11. The allegations in the Application are vague, incomplete and unsupported by relevant documentary evidence. The vagueness is particularly striking with respect to the alleged individual claim of Mr. Varnai, who has filed no documentary evidence in support of any of his personal allegations.

A. Mr. Varnai's Personal Right of Action

12. As appears from the Application, Mr. Varnai has put his medical conditions, diagnoses and treatments at issue. In fact, these allegations are at the heart of the present matter.
13. Mr. Varnai makes the following unsupported allegations with respect to his alleged medical condition and treatments:
- (a) At paragraph 72, an unidentified physician whose specialty is not alleged would have prescribed Invokana to Mr. Varnai to manage his diabetes;
 - (b) At paragraph 73, he alleges that he began feeling unwell, tired and short of breath in December of 2015;
 - (c) At paragraph 74, he alleges that he also developed a sore on his leg that was not healing;
 - (d) At paragraph 75, it is alleged that on December 18, 2015 his wife took him to the Emergency Room of Lakeshore General Hospital to assess his shortness of breath;
 - (e) At paragraph 76, he alleges that he learned that he had very severe heart complications and that he needed to be transferred to the Jewish General Hospital for treatment;
 - (f) At paragraph 77, he alleges that while undergoing cardiac care at the Jewish General Hospital, the sore on his leg became infected and grew in size;
 - (g) At paragraph 78, he alleges that his treating doctors were unable to control the infection and determined that he required a left leg amputation below the knee;
 - (h) At paragraph 79, he alleges that as a result of his cardiac complications and amputation, he was hospitalized for approximately six months and subsequently completed rehabilitation;
 - (i) At paragraph 80, he alleges that he now walks with a prosthetic leg and has very limited mobility;
 - (j) At paragraph 84, he alleges that prior to being prescribed and taking Invokana, he received no warnings as to the extent of the risks of developing injuries and complications, resulting from Invokana.
14. However, Mr. Varnai does not produce a single medical record with respect to any of the allegations above, which necessarily exist, and which best demonstrate his alleged conditions, diagnoses, treatments, information received, time spent in hospitals and rehabilitation centers, and medications prescribed and filed over the relevant period of time, including Invokana.
15. The Application is vague and incomplete in regards to the consistency with which he took Invokana over the relevant period of time, limiting itself to the year of an initial prescription (2014) and without specifying whether and why he has ever been required to stop taking Invokana.
16. It is also incomplete in that it does not detail the dosage Mr. Varnai took or was administered, despite alleging that Invokana is available in both 100 mg and 300 mg dosages (paragraph 29).

17. Mr. Varnai further alleges that he received no warning as to the *extent* of the risks of developing injuries and complications resulting from Invokana and that he would never have agreed to use Invokana had he been aware of the *extent* of the risks. He does not however explain what information regarding the risks of side effects, injuries or complications he received from his physician prior to prescribing him Invokana or from the pharmacist(s) who filled his prescription(s).
18. Without any medical documents, it is impossible for the Court and Johnson & Johnson to evaluate whether Mr. Varnai is an appropriate representative for the putative class and whether he has a personal cause of action.

B. Composition of the Group

19. The Application does not contain any information on the composition of the group.
20. In fact, Mr. Varnai alleges that he is unaware of how many persons throughout Quebec used Invokana or Invokamet. While he estimates that several hundred individuals have taken the products, there is no information on whether they have in fact suffered any alleged damage related to their use.
21. As such, Johnson & Johnson does not know whether the Applicants have any information on group size and characteristics, or whether they have attempted to communicate with any potential members, whether before or since institution of the Application.

C. Suitability as Representative

22. Finally, the existence of a putative national class (Art. 575(3) CCP) will also be analyzed in view of the investigation made by Mr. Varnai.
23. As such, in order to determine whether Mr. Varnai qualifies as an adequate representative pursuant to Article 575(4) CCP, this Court needs to be apprised as to the investigation conducted regarding the issues at stake and the situation of the other putative class members, including those who were prescribed and ingested Invokana and Invokamet.
24. Yet, the Application contains only generic allegations regarding the Applicants' suitability as representatives (paragraph 104 of the Application).
25. It does not disclose the investigation, if any, that Mr. Varnai carried out respecting the allegations in the Application, the composition of the proposed class, the situation of other alleged members, if there are any, and his involvement in the preparation of this Application.

IV. THE PROPOSED EXAMINATION AND ORDER FOR THE COMMUNICATION OF DOCUMENTS

26. Based on the foregoing, in order to assess the applicable threshold criteria, Johnson & Johnson respectfully submits that it should be granted leave to examine Mr. Varnai with respect to:
 - (a) Mr. Varnai's diagnosis of diabetes and other treatments received for this condition;
 - (b) The symptoms that Mr. Varnai experienced due to his diagnosis of diabetes, prior to taking Invokana;
 - (c) Any other possible diagnoses he may have received;
 - (d) Other possible treatments proposed by his physicians to treat diabetes and/or its related conditions;

- (e) The information and documentation that were provided to Mr. Varnai prior to being prescribed Invokana, either by a physician or a pharmacist;
- (f) The specific doses of Invokana that he took or was administered and for what period of time;
- (g) The dates on which he stayed in the various hospitals and/or rehabilitation centers;
- (h) The circumstances regarding his stays at the various hospitals and rehabilitation centers, and the duration of his stays;
- (i) The treatments received while at various hospitals and rehabilitation centers;
- (j) Information regarding his medical follow-ups further to his amputation;
- (k) The circumstances surrounding his decision to stop taking Invokana, if applicable;
- (l) Whether he discussed the decision to stop taking Invokana with his physician and whether he began to take another other medications in its place;
- (m) Whether, to his knowledge, his amputation was reported to Health Canada's adverse effects registry;
- (n) The investigation conducted by Mr. Varnai as to the existence and the personal situation of other putative class members;
- (o) Any investigations undertaken by the Applicants to contact members of the proposed class and the results of these efforts;
- (p) The Applicants' participation in the preparation of the Application.

27. Furthermore, Johnson & Johnson respectfully requests that this court order Mr. Varnai to:

- (a) Provide to Johnson & Johnson a list of all the physicians and other health professionals that he consulted, the hospitals and rehabilitation centers that he stayed in, the pharmacies where he filed prescriptions and any other medical facility or professional that may have in their possession medical records relevant to the present proposed class action in regards to consultations, symptoms experienced, diagnosis or treatments for:
 - (i) Diabetes;
 - (ii) Sores on his legs;
 - (iii) Lower limb amputation;
 - (iv) The persistence of any side-effects related to the foregoing;
- (b) Sign consent forms that would allow Johnson & Johnson to obtain the relevant medical records from the professionals and facilities comprised in a list referenced-above.

28. Once Johnson & Johnson has the requested documents in hand, the requested examination should be held at least forty-five (45) days following such reception, to allow time for Johnson & Johnson to evaluate such documents.

29. Such examination should last approximately three hours and should be conducted out of court, in Montreal, on a date agreed upon by the parties or as directed by this Court in absence of any agreement between the parties.

FOR THESE REASONS, MAY IT PLEASE THE COURT TO:

GRANT the present *Application of the Defendants for Leave to Examine the Applicants and for Communication of Documents*;

AUTHORIZE the Defendants, **JANSSEN INC., JANSSEN PHARMACEUTICALS INC., JANSSEN ORTHO LLC., JOHNSON & JOHNSON INC. and JOHNSON & JOHNSON** to examine out of court the Applicant Mr. Steven Varnai, at a date to be determined by the parties or by this Court in the absence of any agreement, but not less than forty-five (45) days following reception of the documents requested herein, on the following topics:

- (a) Mr. Varnai's diagnosis of diabetes and other treatments received for this condition;
- (b) The symptoms that Mr. Varnai experienced due to his diagnosis of diabetes, prior to taking Invokana;
- (c) Any other possible diagnoses he may have received;
- (d) Other possible treatments proposed by his physicians to treat diabetes and/or its related conditions;
- (e) The information and documentation that were provided to Mr. Varnai prior to being prescribed Invokana, either by a physician or a pharmacist;
- (f) The specific doses of Invokana that he took or was administered and for what period of time;
- (g) The dates on which he stayed in the various hospitals and/or rehabilitation centers;
- (h) The circumstances regarding his stays at the various hospitals and rehabilitation centers, and the duration of his stays;
- (i) The treatments received while at various hospitals and rehabilitation centers;
- (j) Information regarding his medical follow-ups further to his amputation;
- (k) The circumstances surrounding his decision to stop taking Invokana, if applicable;
- (l) Whether he discussed the decision to stop taking Invokana with his physician and whether he began to take other medications in its place;
- (m) Whether, to his knowledge, his amputation was reported to Health Canada's adverse effects registry;
- (n) The investigation conducted by Mr. Varnai as to the existence and the personal situation of other putative class members;
- (o) Any investigations undertaken by the Applicants to contact members of the proposed class and the results of these efforts;
- (p) The Applicants' participation in the preparation of the Application.

ORDER the Applicant Mr. Steven Varnai to:

- (a) Provide to Johnson & Johnson a list of all the physicians and other health professionals that he consulted, the hospitals and rehabilitation centers that he stayed in, the pharmacies where he filed prescriptions and any other medical facility or professional that may have in their possession medical records relevant to the present proposed class action in regards to consultations, symptoms experienced, diagnosis or treatments for:
 - (i) Diabetes;
 - (ii) Sores on his legs;
 - (iii) Lower limb amputation;
 - (iv) The persistence of any side-effects related to the foregoing;
- (b) Sign consent forms that would allow Johnson & Johnson to obtain the relevant medical records from the professionals and facilities comprised in a list referenced-above.

RESERVE the rights of the Defendants **JANSSEN INC.**, **JANSSEN PHARMACEUTICALS INC.**, **JANSSEN ORTHO LLC.**, **JOHNSON & JOHNSON INC.** and **JOHNSON & JOHNSON** to apply to this Court for leave to adduce relevant evidence in the form of an expert report or affidavit interpreting the medical and health files received from the physicians, health professionals, hospitals, rehabilitation centers, pharmacies, referenced herein, in order to aid this Court in assessing the authorization criteria at article 575 CCP;

THE WHOLE without costs, unless contested.

Montréal, June 19, 2018



NORTON ROSE FULBRIGHT CANADA LLP
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NOTICE OF PRESENTATION

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TAKE NOTICE that the present *Application of the Defendants for Leave to Examine the Applicants and for Communication of Documents* will be presented for adjudication before the case management judge to be appointed in the present matter, on a date, at a time and in a room to be determined by such judge of the Montreal courthouse located at 1, East Notre-Dame Street, Montreal, Quebec, H2Y 1B6.

DO GOVERN YOURSELF ACCORDINGLY.

Montréal, June 19, 2018



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Objet: NOTIFICATION / Steven Varnai and Joanne Giroux v. Janssen inc., Janssen Pharmaceuticals inc., Janssen Ortho LLC., and Johnson & Johnson | 500-06-000906-186
Pièces jointes: Application of defendants for leave to examine and comm of documents.pdf

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NOTIFICATION PAR COURRIEL / NOTIFICATION BY EMAIL (Articles 133 et/and 134 C.p.c. / C.C.P.)

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NO: 500-06-000906-186

**SUPERIOR COURT
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Plaintiffs

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