CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

SUPERIOR COURT OF QUÉBEC
(CLASS ACTION)

No.: 500-06-000708-145

Y[redacted] LEBOUTHILLIER et al.

Petitioner

vs.

JANSSEN INC. et al.

Respondents

CORRECTED AMENDED APPLICATION FOR AUTHORIZATION TO INSTITUTE (...) A CLASS ACTION (...)
(Art. 574 (...) C.C.P. and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT OF QUÉBEC, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE PETITIONER STATES THE FOLLOWING:

INTRODUCTION:

1. Petitioner wishes to institute a class action on behalf of the following Group of which Petitioner is a member:

> All residents of Canada (including their estates, executors, personal representatives, dependants and family members), who purchased and/or ingested and/or were injected with the drugs Risperdal and/or Invega, which drugs were manufactured, marketed or distributed by Respondents and/or related companies, and/or any other Group or Sub-Group to be determined by the Court;

(hereinafter referred to as the "**Class Members**", the "**Class**", the "**Group**

Members", the "**Group**", "**Consumer(s)**", "**Patient(s)**" or "**User(s)**");

2. Petitioner wishes to institute this class action on his own personal behalf, as well as on behalf of his (...) son C[redacted] LeBouthillier (hereinafter "**Petitioner's son**" or "**C[redacted]**") who ingested Risperdal and who was not adequately warned of the risks associated with ingesting Risperdal. As a result of taking Risperdal, Petitioner's son developed gynecomastia;

3. Respondent Janssen Inc. ("**Janssen Canada**") is a corporation incorporated pursuant to the laws of the Province of Ontario with a *domicile élu* in the District of Quebec, Province of Quebec, the whole as more fully appears from the CIDREQ report of Respondent Janssen Inc, filed herewith as **Exhibit R-1**. At all material times, Janssen Canada designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold Risperdal for use by Canadians;

4. Respondent Janssen Pharmaceuticals, Inc. ("**Janssen US**") is a corporation incorporated pursuant to the laws of the State of New Jersey. At all material times, Janssen US designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold Risperdal and Invega for use throughout the world, including Canada;

5. Respondent Janssen Ortho LLC ("**Janssen Ortho**") is a corporation incorporated pursuant to the laws of the State of Delaware. At all material times, Janssen Ortho designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold Risperdal and Invega for use throughout the world, including Canada. Janssen Ortho is identified as the manufacturer for Risperdal and Invega in their respective U.S. labels;

6. Respondent Johnson & Johnson is a corporation incorporated pursuant to the laws of the State of New Jersey and is one of the shareholders of Respondent Johnson & Johnson Inc. which is domiciled in the District of Montreal, Province of Quebec, (collectively "J&J"), the whole as more fully appears from the CIDREQ report of Respondent Johnson & Johnson Inc. filed herewith as **Exhibit R-2**. J&J is the parent of Respondents 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 Risperdal and Invega for use throughout the world, including Canada. J&J owns the trademark for Risperdal and Invega in Canada;

7. J&J, Janssen Canada, Janssen Ortho, and Janssen US, are collectively referred to herein as the "**Janssen Respondents**";

8. At all material times, the Janssen Respondents, directly or through their agents, designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold Risperdal and Invega for use by patients throughout the world, including Quebec and the rest of Canada;

9. Risperdal and Invega are antipsychotic medications, belonging to a class of drugs which have become known as "atypical" or "second generation" antipsychotics;

10. Risperdal and Invega are related drugs. When risperidone, the active ingredient in Risperdal, is introduced into the body, it is converted into paliperidone, the active ingredient in Invega. The Canadian product monograph for Invega specifically warns against the concomitant use of Invega with Risperdal because of this, noting that the combination will lead to additive paliperidone exposure. Despite the foregoing, for reasons unknown,

the Canadian product monograph for Risperdal does not warn against concomitant use with Invega;

11. Risperdal was originally developed and approved for use in the treatment of symptoms associated with schizophrenia. Schizophrenia can cause symptoms such as hallucinations (e.g., hearing, seeing, or sensing things that are not there), delusions, unusual suspiciousness, and emotional withdrawal. However, neither Risperdal nor Invega cure schizophrenia or any other mental health condition;

12. The Janssen Respondents first introduced Risperdal into the Canadian market in 1993 and Invega in 2007, and they continue to market both Risperdal and Invega in Canada, through Respondent Janssen Inc., to the present time. Risperdal and Invega were first introduced to the United States in 1994 and 2006 respectively;

13. At one point in time, Risperdal was J&J's best-selling drug, and generated worldwide sales of $24.2 billion from 2003 to 2010. Moreover, the branded version of Risperdal earned the Janssen Respondents' $4.5 billion in 2007, the last full year for which Janssen enjoyed patent protection for Risperdal;

14. Although Risperdal was originally approved for treatment of manifestations of psychiatric disorders in adults, the Janssen Respondents actively sought to expand the approved uses of Risperdal and, later, the approved uses of Invega;

15. In fact, at no time have Risperdal or Invega been approved in Canada for use in children under the age of 18;

16. Male children and male adolescent patients taking Risperdal and/or Invega are exposed to an increased risk of developing gynecomastia and/or hyperprolactinemia (...) (together (...), the "**Adverse Events**").

17. Respondents knew that Risperdal and Invega posed certain health risks to children, including the risk of gynecomastia and elevated levels of prolactin, a hormone that can stimulate breast development and milk production. The condition of elevated levels of prolactin is known as hyperprolactinemia, one of the Adverse Events caused by Risperdal and Invega.;

18. Gynecomastia is a condition whereby the breasts of males become abnormally enlarged. To treat gynecomastia, patients often undergo several treatments as well as expensive and painful surgical procedures;

19. Despite their awareness of the risk of developing gynecomastia, the Janssen Respondents promoted, with the help of the multiple "clinical studies", the use of Risperdal and Invega to minors and downplayed the risk associated with the use of Risperdal and Invega by males under the age of 18;

20. In fact, the Canadian product monograph for Risperdal came to be amended as a consequence of its increased use by minors and the rise in reported adverse events relating to its use by minors;

21. In Canada, the health risks associated with Risperdal are contained within the device's "product monograph", the whole as more fully appears from a copy of the 2008 Risperdal Product Monograph, communicated herewith as **Exhibit R-3**;

22. The product monograph is a factual, scientific document on the drug product that, devoid of promotional material, describes the properties, claims, indications, and conditions of use for the drug, and that contains any other

information that may be required for optimal, safe and effective use of the drug;

23. The product monograph is prepared by a health product's manufacturer and is intended to provide healthcare professionals and patients with the necessary information for the safe and effective use of a health product;

24. As of 2013 the product monographs for Risperdal specifically read: "The safety and efficacy of RISPERDAL® in children under the age of 18 have not been established and its use is not recommended." In 2010, at the time that Petitioner's son was prescribed the said medication, the product monograph did not indicate that the use of Risperdal was not recommended in children under the age of 18;

25. Moreover, although the current product monographs for Risperdal and Invega contain some references to gynecomastia, the said monographs inadequately alerts healthcare professionals, and through them, the public, about the risk of gynecomastia associated with these drugs;

26. This is particularly obvious in contrast with Risperdal and Invega's U.S. prescribing information, which has a superior warning to that being provided by the Respondents to Canadian healthcare professionals in the Canadian product monograph. Therefore the U.S. prescribing information serves as a precedent that was already used by the same company in another jurisdiction;

27. In fact, the U.S. prescribing information for Risperdal and Invega profile the risk of gynecomastia in the "Warnings and Precautions" section, in addition to listing gynecomastia in the "Adverse Reaction" section. By virtue of the fact that the Respondents saw fit to profile gynecomastia in the "Warnings and Precautions" section of the U.S. Prescribing Information, Respondents failed

to adequately warn Class Members by not doing the same in the Canadian Product Monograph, the whole as more fully appears from the June 25, 2014 expert report filed in the context of similar Class Action proceedings being prosecuted in the Province of Ontario, communicated herewith, as though recited at length herein, as **Exhibit R-4;**

28. Indeed, there (...) have been similar Class Action proceedings that have been filed in the Provinces of Ontario, British-Columbia, and Nova Scotia, the whole as more fully appears from a copy of the (...) the most recent Amended Amended Fresh as Amended Statement of Claim, filed in the Ontario proceedings and dated October 31, 2017, communicated herewith, as though recited at length herein, as **Exhibit R-5-A;**

29. Petitioner relies on the allegations contained in the said (...) Ontario proceeding (R-5-A), and the R-4 expert report, as though recited at length herein, in furtherance of his burden to show an arguable case and Petitioner reserves his right to amend these proceedings in order to make specific references to the other similar class action proceedings, filed in other jurisdictions and/or to file documents or proceedings related thereto;

30. During the years Risperdal and Invega were prescribed to and were ingested by the Petitioner's son and/or the other Class Members, the product monographs failed to properly warn prescribing physicians and Patients of the risk of developing gynecomastia and other Adverse Events;

31. Following Risperdal's approval for sale in Canada, physicians and patients reported adverse events to Health Canada, the whole as more fully appears from a copy of the Health Canada Summary of Reported Adverse Reactions, communicated herewith, *en liasse*, as **Exhibit R-6**;

32. It was as a result of the Respondents' claims regarding the effectiveness, safety, and benefits of Risperdal and Invega, and the Respondents' failure to warn about the risks of serious injury associated with Risperdal and Invega, that the Petitioner and/or Petitioner's son, other Class Members, healthcare professionals, and Health Canada, were unaware, and could not reasonably have known or have learned through reasonable diligence that Class Members would be exposed to the risk of (...) the Adverse Events;

33. Further, if properly, completely, and timely warned about the risks of (...) the Adverse Events associated with Risperdal and Invega, and if properly, completely, and timely warned of the need for initial and/or periodic monitoring of patients on Risperdal and/or Invega, Class Members' prescribing physicians:

    a. would have changed the way in which they treated the condition for which Class Members were being treated;
    b. would have warned Class Members, about the signs and symptoms of serious adverse effects of Risperdal and/or Invega;
    c. would have discussed the risks of (...) the serious Adverse Events, and;
    d. would have permitted Patients to choose whether to be treated with Risperdal and/or Invega, or not, after considering the risks.

34. Moreover, if, having been properly, completely and timely warned about the risks inherent in these drugs, the Patients decided nonetheless to take Risperdal and/or Invega, Class Members' prescribing physicians would have more effectively monitored the Class Members (...) and would have performed or requested regular physical examinations and laboratory tests;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

35. Petitioners' son C[redacted] LeBouthillier was (...) born on July 31, 1998, residing in Alma, Quebec;

36. C[redacted] was diagnosed with Tourette's syndrome on March 16, 2010, at the age of 12 years old;

37. It is at that time that C[redacted] was first prescribed, and first ingested Risperdal to treat his Tourette's syndrome. Petitioner purchased the Risperdal for his son;

38. C[redacted] continued to ingest Risperdal for a period of approximately two (2) years, until the end of April 2012;

39. As a result of ingesting Risperdal, C[redacted] developed gynecomastia;

40. Neither C[redacted] nor his parents were warned of the risk of developing gynecomastia from ingesting Risperdal;

41. In fact, when Petitioner filled Christian's first prescription at the pharmacy, he received a document from the pharmacist with instructions and side effects associated with Risperdal. Gynecomastia was not mentioned on the list of "effets secondaires possibles", the whole as more fully appears from the document remitted to Petitioner by the pharmacist, communicated herewith as **Exhibit R-7**;

42. Just a few weeks after ingesting Risperdal, namely on April 7, 2010, C[redacted] went to visit his paediatrician, Dr. Claudynne Rousseau, for his follow-up appointment. During said follow-up, Dr. Rousseau confirmed that C[redacted] started gaining noticeable weight;

43. C[redacted] was later seen by an endocrinologist who diagnosed him as suffering from gynecomastia;

44. As their family doctor advised C[redacted] and his parents, there is no available treatment for gynecomastia at this time. The only available treatment for gynecomastia is to undergo a surgical procedure or procedures. However this treatment is only available once C[redacted] has fully gone through puberty;

45. Until being diagnosed with gynecomastia, Petitioner noticed that C[redacted] was developing male breasts but had no knowledge that he suffered from gynecomastia or that it was caused by Risperdal. At the present time, C[redacted] continues to suffer from this condition;

46. Risperdal is the direct cause of C[redacted]'s gynecomastia. Moreover, Risperdal or another related drug, marketed as Invega or Invega Sustenna, is the cause of gynecomastia in the other Class Members;

47. Surgical procedures will also be needed by other Class Members to address their gynecomastia;

48. C[redacted] would not have used Risperdal had Respondents adequately disclosed the full extent of the risks of gynecomastia associated with and caused by Risperdal;

49. At the time Petitioner purchased and C[redacted] used Risperdal, none of the drug's label, the package insert or the package containing the product provided adequate warnings that using Risperdal carried a risk of gynecomastia;

50. Accordingly, Respondents have failed to discharge their duty to warn and inform the Petitioner and other Class Members about the risk of

gynecomastia;

51. In early 2014, Petitioner was reading the news on the Yahoo Canada website and was for the first time made aware of the fact that similar class action proceedings had been filed elsewhere in Canada and that it was being alleged in said proceedings that Risperdal had caused gynecomastia in other Patients as well;

52. Petitioner conducted a further Google search on the issue and was eventually able to identify the attorneys in British Columbia, Canada, who (...) were prosecuting the said similar class actions proceedings. Petitioner then contacted said attorneys who referred Petitioner to the undersigned attorneys. Petitioner then consulted with and mandated the undersigned attorneys to institute the present class action proceedings on his behalf and on behalf of his son C[redacted];

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE CLASS MEMBERS

53. As mentioned hereinabove, Respondents were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling and marketing, either directly or indirectly through third parties, subsidiaries or related entities, Risperdal and Invega in Canada;

54. As mentioned above, Risperdal is associated with and causes risks of serious Adverse Events;

55. Respondents knew or should have known that Risperdal and Invega is associated with and causes risks of serious Adverse Events, namely without limitation gynecomastia;

56. Respondents failed in their obligation to adequately warn medical professionals, Canadian Consumers and Health Canada of the above mentioned Adverse Events;

57. Had the Class Members been reasonably informed of the risks inherent to Risperdal and/or Invega, more particularly the increased risk of developing gynecomastia, they would not have ingested it;

58. Respondents committed a fault by putting a drug on the market, insufficiently tested according to the norms of the trade and by continuing to market the product despite its risks without adequate warning, namely to minors without approval in Canada;

59. Class Members reasonably relied and rely upon Respondents to ensure that Risperdal was safe;

60. Respondents are liable for the damages suffered by the Petitioner's son and the Class Members in that Respondents were negligent and/or committed a fault when:

    a. They failed to ensure that Risperdal and Invega was not dangerous to Consumers and that the medication was fit for its intended purpose and use;

    b. They failed to warn Class Members and their treating healthcare professionals that ingestion of Risperdal and Invega carried significant, and specifically identified, health risks including the risk of gynecomastia (...);

    c. The original product monographs, and prescribing information for Risperdal and Invega failed to adequately warn male children and

adolescents and their family members of the risk of developing gynecomastia associated with the ingestion of Risperdal and Invega;

d. They failed to advise prescribing physicians, such as C[redacted]'s physician, to instruct patients that Risperdal and Invega were associated with an increased risk of gynecomastia, to exclude male children and male adolescents as patients to whom Risperdal and Invega are prescribed, and to monitor patients being administered Risperdal and/or Invega for signs of gynecomastia;

e. They failed to conduct adequate tests and clinical trials prior to releasing Risperdal and Invega into the market to determine the degree of risk associated with ingesting the drugs;

f. Once Risperdal and Invega were released into the market, they failed to conduct ongoing tests and clinical trials with long term follow-up to determine the long-term effects and risks associated with the long-term ingestion of Risperdal and/or Invega;

g. They failed to monitor the post-market effects of Risperdal and Invega;

h. They failed promptly or at all to report to Health Canada all the adverse events that came to be reported to them with regards to Risperdal and to Invega subsequent to their approval for sale in Canada;

i. They knowingly or recklessly provided misleading or incomplete information in the product monographs for Risperdal and Invega,

and particularly in Parts I and III of such monographs, which are directed to healthcare professionals and patients, respectively;

j. They failed to warn that specially-trained personnel, such as endocrinologists, are necessary to examine children ingesting Risperdal and/or Invega at regular intervals to determine if the child or adolescent has growth of breast tissue that may become permanent, or ordinary weight gain;

61. It was as a result of the Respondents' claims regarding the effectiveness, safety, and benefits of Risperdal and Invega, and the Respondents' failure to warn about the risks of serious injury associated with Risperdal and Invega, that the Petitioner and his son C[redacted], other Class Members, physicians and other healthcare professionals, and Health Canada, were unaware that they would be exposed to the risk of gynecomastia;

62. As a direct and proximate result of the Respondents' negligence, the Class Members suffered pain, damages and injuries for which Respondents are solely liable;

63. At all times, the Janssen Respondents' warnings to Canadians with respect to Risperdal and Invega lagged behind their state of knowledge regarding the drugs' risks, and their warnings in relation to Risperdal and Invega abroad;

64. Each Member of the Group is entitled to claim damages because of the faults committed by the Respondents, which include but are not limited to the reimbursement of the purchase price for the drug, personal injuries suffered, economic and financial losses (i.e. loss of income and earning capacity), pain and suffering, loss of amenities and enjoyment of life, cost of surgeries (for instance to treat gynecomastia), such further and other damages, the particulars of which may be proven at the trial on the merits;

65. Moreover, Respondents' conduct, through actions, omissions, wrongdoings, and their awareness of the serious hazards of said drugs, and their failure to fully, clearly, and in a timely way disclose and publicize the serious health effects resulting from Risperdal and Invega (all detailed hereinabove), subject the Respondents to punitive and/or exemplary damages;

66. In fact, Respondents' above detailed actions qualify its fault as intentional which is a result of wild and foolhardy recklessness in disregard for the rights of the Class Members, with full knowledge of the immediate and natural or at least extremely probable consequences that its action would cause to the Class Members;

67. Respondents' negligence has shown a malicious, oppressive and high-handed conduct that represents a marked departure from ordinary standards of decency. In that event, punitive damages should be awarded to Class Members;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

68. The composition of the Group makes it difficult or impracticable to apply the rules for mandates to sue on behalf of others or for consolidation of proceedings (Article 575 (3) C.C.P.) (...) the following reasons:

a. The number of potential Class Members is so numerous that the joinder of all Members is impracticable. While the exact number of Class Member is unknown to Petitioner at the present time can only be ascertained from sales and distribution records maintained by the Respondents and their agents, it can be reasonably estimated that there are thousands of potential Class Members located throughout Quebec and the rest of Canada;

b. Based on the number of potential Class Members, it is impossible for the Petitioner to identify all potential Class Members and obtain a mandate from each of them. Petitioner does not possess the names and addresses of potential Class Members;

69. The recourses of the members raise identical, similar or related (...) issues of fact or law, namely;

a. Were Respondents negligent or did they commit fault in the developing, testing, manufacturing, marketing, distributing, labelling or selling of Risperdal and/or Invega?

b. Did the Respondents know or should Respondents have known that Risperdal and/or Invega posed serious risk of (...) gynecomastia and/or hyperprolactinemia (...)?

c. Did the use Risperdal and/or Invega cause or increase the likelihood of gynecomastia and/or hyperprolactinemia in patients?

d. Was Risperdal and/or Invega defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Respondents? If so, in what way or ways was Risperdal and/or Invega defective or unfit?

e. Did Respondents breach a duty to warn or inform the users of the Adverse Events associated with the use of Risperdal and/or Invega?

f. Are Respondents liable to pay damages equal to the purchase price of Risperdal and/or Invega, or part of the purchase price of Risperdal and/or Invega, and if so in what amount?

g. Are Respondents liable to pay other compensatory damages to the Class Members, and if so in what amount?

h. Are the Respondents liable to pay moral damages to the Class Members, and if so in what amount?

i. Are Respondents liable to pay exemplary and/or punitive damages to the Class Members, and if so in what amount?

70. The majority of the issues to be dealt with are issues common to every Class Member;

71. The interests of justice favour that this motion be granted in accordance with its conclusions;

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

72. The action that the Petitioner wishes to institute for the benefit of the Class Members is an action in damages for product liability;

73. The conclusions that the Petitioner wishes to introduce by way of an Originating Application (...) are:

GRANT Plaintiff's action against Defendants;

CONDEMN Defendants solidarily to reimburse to Plaintiff and the Class Members the purchase price paid of Risperdal and/or Invega;

CONDEMN Defendants solidarily to pay an amount in compensatory damages to Plaintiff and the Class Members, amount to be determined by the Court;

CONDEMN Defendants solidarily to pay an amount in moral damages to Plaintiff and the Class Members, amount to be determined by the Court;

CONDEMN Defendants solidarily to pay an amount in punitive and/or exemplary damages to Plaintiff and the Class Members, amount to be determined by the Court;

CONDEMN the Defendants solidarily to pay interest and additional indemnity on the above sums according to the Law from the date of service of the original application for authorization to institute a class action;

GRANT the class action of Plaintiff on behalf of all Class Members;

ORDER the Defendants to deposit in the office of this Court the totality of the sums which forms part of the collective recovery, with interest, additional indemnity, and costs;

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternatively by individual liquidation (...);

RENDER any other order that this Honorable Court shall determine and that is in the interest of the Class Members;

THE WHOLE with interest and additional indemnity provided for in the *Civil Code of Quebec* and with full costs and expenses including

experts' fees and publication fees to advise members;

74. Petitioner suggests that this class action be exercised before the Superior Court in the District of Montreal for the following reasons:

a. Respondent Johnson & Johnson Inc. is domiciled in the District of Montreal, Province of Quebec;
b. Risperdal and/or Invega is sold in the District of Montreal;
c. Many Class Members are domiciled, work, or are treated in the District of Montreal;
d. Petitioner's legal counsel and Defendants' legal counsel practice law in the District of Montreal;

75. Petitioner, who is requesting to be appointed as Representative Plaintiff, is in a position to properly represent the Class Members (Article 575 (4) C.C.P.) (...) since:

a. Petitioner purchased Risperdal to treat his son C[redacted]'s Tourette's syndrome without being made aware of the health risks associated with the use thereof;
b. As more fully detailed above, as though recited at length, C[redacted] suffered damages and injuries from ingesting Risperdal, namely the development of gynecomastia which will ultimately require surgical removal;
c. Petitioner understands the nature of the action and has the capacity and interest to fairly and adequately protect and represent the interests of the Members of the Group;
d. Petitioner is available to dedicate the time necessary for the present action before the Courts of Quebec and to collaborate with Class attorneys in this regard;
e. Petitioner is ready and available to manage and direct the present action

in the interest of the Class Members that Petitioner wishes to represent, and is determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Class Members;

f. Petitioner does not have interests that are antagonistic to those of other Class Members;

g. Petitioner has given the mandate to the undersigned attorneys to obtain all relevant information to the present action, including but not limited to the maintaining of the designated webpage about this case on the undersigned attorneys' website in order to inform other Class Members and in order for said Class Members to be able to sign up in order to receive future notices going forward, and Petitioner intends to keep informed of all developments;

h. Petitioner is, with the assistance of the undersigned attorneys, ready and available to dedicate the time necessary for this action and to collaborate with other Class Members and to keep them informed;

76. The present (...) Application is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present (...) Application;

AUTHORIZE the institution of a class action in the form of an originating application in damages for product liability;

APPOINT the Petitioner as the Representative Plaintiff representing all persons included in the Classes herein described as: (...)

All residents of Canada (including their estates, executors, personal representatives, dependants and family members), who purchased and/or ingested and/or were injected with the drugs Risperdal

and/or Invega, which drugs were manufactured, marketed or distributed by Respondents and/or related companies and/or any other Group or Sub-Group to be determined by the Court;

IDENTIFY the principle (...) issues of fact and law to be treated collectively as the following:

a. Were Respondents negligent or did they commit fault in the developing, testing, manufacturing, marketing, distributing, labelling or selling of Risperdal and/or Invega?

b. Did the Respondents know or should Respondents have known that Risperdal and/or Invega posed serious risk of (...) gynecomastia and/or hyperprolactinemia (...)?

c. Did the use Risperdal and/or Invega cause or increase the likelihood of gynecomastia and/or hyperprolactinemia in patients?

d. Was Risperdal and/or Invega defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Respondents? If so, in what way or ways was Risperdal and/or Invega defective or unfit?

e. Did Respondents breach a duty to warn or inform the users of the Adverse Events associated with the use of Risperdal and/or Invega?

f. Are Respondents liable to pay damages equal to the purchase price of Risperdal and/or Invega, or part of the purchase

price of Risperdal and/or Invega, and if so in what amount?

g. Are Respondents liable to pay other compensatory damages to the Class Members, and if so in what amount?

h. Are the Respondents liable to pay moral damages to the Class Members, and if so in what amount?

i. Are Respondents liable to pay exemplary and/or punitive damages to the Class Members, and if so in what amount?

IDENTIFY the conclusions sought by the action to be instituted as being the following:

GRANT Plaintiff's action against Defendants;

CONDEMN Defendants solidarily to reimburse to Plaintiff and the Class Members the purchase price paid of Risperdal and/or Invega;

CONDEMN Defendants solidarily to pay an amount in compensatory damages to Plaintiff and the Class Members, amount to be determined by the Court;

CONDEMN Defendants solidarily to pay an amount in moral damages to Plaintiff and the Class Members, amount to be determined by the Court;

CONDEMN Defendants solidarily to pay an amount in punitive and/or exemplary damages to Plaintiff and the Class Members, amount to be determined by the Court;

CONDEMN the Defendants solidarily to pay interest and additional indemnity on the above sums according to the Law from the date of service of the original application for authorization to institute a class action;

GRANT the class action of Plaintiff on behalf of all Class Members;

ORDER the Defendants to deposit in the office of this Court the totality of the sums which forms part of the collective recovery, with interest, additional indemnity, and costs;

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternatively by individual liquidation (...);

RENDER any other order that this Honorable Court shall determine and that is in the interest of the Class Members;

THE WHOLE with interest and additional indemnity provided for in the *Civil Code of Quebec* and with full costs and expenses including experts' fees and publication fees to advise members;

DECLARE that all Class Members that have not requested their exclusion from the Group in the prescribed delay to be bound by any Judgment to be rendered on the class action to be instituted;

FIX the delay of exclusion at thirty (30) days from the date of the publication or notification of the notice to the Class Members;

ORDER the publication or notification of a notice to the Class Members in accordance with Article (...) 579 C.C.P. and pursuant to a further hearing to be held, and **ORDER** Respondents to pay for said publication costs;

THE WHOLE with legal costs, including all costs related to preparation and publication of notices to the Class Members.

MONTREAL, (...) DECEMBER 21, 2017
LEX GROUP INC.

(S) Lex Group Inc.

LEX GROUP INC.
Attorneys for Petitioners