Form 4.02A

2014

Hfx No. 429715

Supreme Court of Nova Scotia

Between:

RYAN HANNA

Plaintiff

- and -

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

Defendants

Notice of Action

Proceeding under the *Class Proceedings Act*, S.N.S 2007, c. 28

To: JANSSEN INC.

To: JANSSEN PHARMACEUTICALS, INC.

To: JANSSEN ORTHO LLC

To: JOHNSON & JOHNSON

To: JOHNSON & JOHNSON INC.

Action has been started against you

The plaintiff takes action against you.

The plaintiff started the action by filing this notice with the court on the date certified by the prothonotary.

The plaintiff claims the relief described in the attached statement of claim. The claim is based on the grounds stated in the statement of claim.

Deadline for defending the action

To defend the action, you or your counsel must file a notice of defence with the court no more than the following number of days after the day this notice of action is delivered to you:

- 15 days if delivery is made in Nova Scotia
- 30 days if delivery is made elsewhere in Canada
- 45 days if delivery is made anywhere else.

Judgment against you if you do not defend

The court may grant an order for the relief claimed without further notice, unless you file the notice of defence before the deadline.

You may demand notice of steps in the action

If you do not have a defence to the claim or you do not choose to defend it you may, if you wish to have further notice, file a demand for notice.

If you file a demand for notice, the plaintiff must notify you before obtaining an order for the relief claimed and, unless the court orders otherwise, you will be entitled to notice of each other step in the action.

Rule 57 - Action for Damages Under $100,000

Civil Procedure Rule 57 limits pretrial and trial procedures in a defended action so it will be more economical. The Rule applies if the plaintiff states the action is within the Rule. Otherwise, the Rule does not apply, except as a possible basis for costs against the plaintiff.

This action is **not within** Rule 57.

Filing and delivering documents

Any documents you file with the court must be filed at the office of the prothonotary, 1815 Upper Water Street, Halifax, Nova Scotia (telephone # 424-4900).

When you file a document you must immediately deliver a copy of it to each other party entitled to notice, unless the document is part of an ex parte motion, the parties agree delivery is not required, or a judge orders it is not required.

Contact information

The plaintiff designates the following address:

McPhadden Samac Tuovi LLP
Lawyers

8 King Street East, Suite 300
Toronto, ON, M5C 1B5

Tel: (416) 363-5195
Fax: (416) 363-7485

Documents delivered to this address are considered received by the plaintiff on delivery.

Further contact information is available from the prothonotary.

Proposed place of trial

The plaintiff proposes that, if you defend this action, the trial will be held in Halifax, Nova Scotia.

Signature
Signed , May 29, 2014

per: **Bryan C. McPhadden** as counsel
for Ryan Hanna

Prothonotary's certificate

I certify that this notice of action, including the attached statement of claim, was filed with the court on , July 21 2014 .

Bonnie Dalton
Prothonotary

Bonnie Dalton
Deputy Prothonotary

Form 4.02B

Statement of Claim

Proceeding under the *Class Proceedings Act*, S.N.S 2007, c. 28

THE PLAINTIFF

1. The plaintiff, Ryan Hanna, is 18 years of age and a resident of Sydney Forks, Nova Scotia.

2. At the age of five he was diagnosed with severe attention deficit hyperactivity disorder, as well as generalized and social anxiety disorder.

3. At thirteen years of age he was diagnosed with four major learning disabilities.

4. Ryan was prescribed and he ingested Riserpdal. Risperdal is the trade name used by the defendants for risperidone. Risperidone belongs to the class of atypical antipsychotics. It is a drug designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold by the defendants.

5. Commencing in or about age 9 or 10, Ryan began to develop enlarged male breasts.

6. Eventually, this condition became quite pronounced.

7. When Ryan was 11 years old, he was diagnosed with gynecomastia.

8. Risperdal is the cause of Ryan's gynecomastia. Risperdal or another, related drug, marketed by the defendants as Invega or Invega Sustenna, is the cause of gynecomastia in the other class members.

9. On February 11, 2014 Ryan underwent surgery to remove the oversized breasts.

10. The surgery has left Ryan with scars that remain clearly visible to the date of this pleading.

THE DEFENDANTS

11. 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, labelled, promoted, distributed, licensed, and sold Risperdal for use by Canadians. Janssen Canada is the sponsor or market authorization holder for Risperdal, meaning that it is the entity authorized by Health Canada to sell Risperdal and Invega or Invega Sustenna (together, "Invega"), in Canada.

12. 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, labelled, promoted, distributed, licensed, and sold Risperdal and Invega for use throughout the world, including by Canadians. Janssen US is identified as the manufacturer for Risperdal in the U.S. label. Janssen US also authors, publishes, and maintains the Risperdal and Invega websites, which are sources of information regarding the safety and efficacy of Risperdal and Invega that are used by consumers worldwide, including by Canadians. Janssen US is the sponsor of Risperdal and Invega in the United States.

13. 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 New Castle, 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 by Canadians. Janssen Ortho is identified as the manufacturer for Risperdal and Invega in the U.S. labels, respectively.

14. The defendant Johnson & Johnson, ("J&J") also known as "Johnson & Johnson Inc.", is a corporation incorporated pursuant to the laws of the State of New Jersey with its head office located in New Brunswick, New Jersey. 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 Risperdal and Invega for use throughout the world, including by Canadians. J&J owns the trademark for Risperdal and Invega in Canada.

15. J&J, Janssen Canada, Janssen Ortho, and Janssen US, are referred to herein as the "Defendants".

16. At all material times, the Defendants, 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 Nova Scotia and the rest of Canada.

17. The plaintiff pleads that, by virtue of the acts described herein, each of the Defendants is vicariously liable for the act and omissions of the others for the following reasons:

a. Each was the agent of the other;

b. Each Defendant's business was operated so that it was inextricably interwoven with the business of the other;

c. Each Defendant entered into a common advertising and business plan with the other to distribute and sell Risperdal and Invega;

d. Each Defendant operated pursuant to a common business to develop, test, manufacture, market distribute and sell Risperdal and Invega;

e. Each Defendant intended that the businesses be run as one business organization; and

f. All the Defendants are related, associated or affiliated.

RISPERDAL AND INVEGA

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

19. Risperdal and Invega are related drugs. When risperidone, the active ingredient in Risperdal, is introduced into the body, it is converted into paliperidone (also known as 9-hydroxy-risperidone), 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.

20. 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. The pharmacologic action of Risperdal and Invega is unknown but is thought to be dependent on their ability to block or moderate the level of dopamine, a chemical found in the brain that in excessive amounts is believed to cause abnormal thinking and hallucinations.

21. The Defendants 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 the defendant Janssen Inc., to the present time. Risperdal was first introduced in the United States in 1994 and Invega was first introduced there in 2006.

22. Risperdal was originally approved for treatment of manifestations of psychiatric disorders in adults. The approved uses in adults have been expanded over time.

23. After the original and limited approved use of Risperdal, the Defendants actively sought to expand the approved uses of Risperdal and, later, the approved uses of Invega.

24. In seeking the expanded uses of Risperdal and Invega, the Defendants relied on studies they knew or ought to have known were of questionable scientific value.

25. At one time, Risperdal was J&J's best-selling drug, and generated worldwide sales of $24.2 billion from 2003 to 2010.

26. The branded version of Risperdal earned the Defendants $4.5 billion in 2007, the last full year for which Janssen enjoyed patent protection for Risperdal.

HARM CAUSED BY RISPERDAL AND INVEGA

27. At no time have Risperdal or Invega been approved in Canada for use in children under the age of 18.

28. Male child and male adolescent patients taking Risperdal and/or Invega are exposed to an increased risk of developing gynecomastia. All patients taking Risperdal and/or Invega are exposed to an increased risk of developing other adverse medical conditions including coma and death, cerebrovascular adverse events, excess blood sugar and diabetes, tardive dykinesia, neuroleptic malignant syndrome, heart problems (including hypotension, arrhythmias, lengthened Q.T. intervals, and tachycardia) and extrapyramidal symptoms (together, including gynecomastia, the "Adverse Events").

THE CLASS

29. The proposed representative plaintiff seeks certification of the following class:

a. All persons throughout Canada who purchased and/or ingested and/or were injected with the drugs Risperdal and/or Invega, and their estates, administrators or other legal representatives ("the Class"); and

b. All persons who have a derivative claim on account of a family relationship with a person in (i.) ("the Family Class").

30. The plaintiff will fully and adequately represent and protect the interests of the proposed classes. Neither the plaintiff nor his lawyers have interests that are contrary to or conflicting with the interests of the proposed classes.

CAUSES OF ACTION

a. Failure to Warn

31. The Defendants owed the plaintiff and other class members a duty of care to warn them, their treating healthcare professionals, and Health Canada, that ingestion of Risperdal and Invega carried significant, and specifically identified, health risks including the risk of gynecomastia and other Adverse Events.

32. The Janssen Defendants breached their duty of care as follows:

a. The original labelling, product monographs, and prescribing information for Risperdal and Invega failed to disclose, adequately or at all, that Risperdal and Invega could cause gynecomastia and other Adverse Events;

b. The original labelling, product monographs, and prescribing information for Risperdal and Invega failed to adequately warn male children and male adolescents and their parents of the risk of developing gynecomastia and other Adverse Events with the ingestion of Risperdal and Invega;

c. They failed to warn that gynecomastia is the growth of female-like breast in young males, which are often permanent and require mastectomies to remove;

d. They failed to warn the plaintiff, other class members, healthcare professionals, and Health Canada, that Risperdal and Invega were associated with an increased risk of gynecomastia and other Adverse Events;

e. They failed to advise prescribing physicians, such as the plaintiff' 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 gynecomastia and other Adverse Events;

f. Despite their awareness of the risk of Adverse Events associated with gynecomastia, the Defendants promoted the use of Risperdal and Invega by minors and downplayed the risk associated with the use of Risperdal and Invega by males under the age of 18;

g. They knowingly or recklessly provided misleading or incomplete information to Health Canada when submitting the New Drug Submission ("NDS") for Risperdal and Invega. More particularly, but without limitation, the Defendants did not disclose to Health Canada complete evidence regarding the clinical effectiveness of Risperdal and Invega, the drugs' contra-indications and side effects, and the fact that the drugs were associated with an increased risk of gynecomastia in male children and male adolescents, or with an increased risk of other Adverse Events generally;

h. They withheld important clinical and non-clinical data from Health Canada throughout the approval processes for Risperdal and Invega and subsequent to their approval, including when they submitted to Health Canada for approvals the NDS's for Risperdal and Invega, when they submitted to Health Canada for approval the product

monographs for Risperdal and Invega, and subsequent to the issuance by Health Canada of the Notices of Compliance for Risperdal and Invega;

i. 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;

j. They failed to issue prompt, up-to-date, and accurate Health Professional Communications and Public Communications;

k. 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;

l. They advertised Risperdal and Invega to healthcare professionals in a manner that did not adequately or at all disclose the drugs' risk of harm;

m. They failed to warn that weight gain, which the defendants knew to be a well-known side effect of the atypical antipsychotic class, masks the ability of physicians to detect potentially permanent breast growth;

n. They failed to warn that as compared to other atypical antipsychotics, Risperdal and/or Invega have a much greater potential to cause rapid and long-lasting weight gain;

o. 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;

p. They failed to warn that testicular growth in boys may be effected by Risperdal and/or Invega and that boys' testicle growth need to be regularly evaluated;

q. They failed to warn that if breast tissue is detected or abnormal testicular growth or Tanner stage for age is abnormal that Risperdal and/or Invega should be halted and the child or adolescent must be evaluated for treatment of these abnormalities by a qualified physician(s);

r. They failed to warn that Invega had potential to raise prolactin levels more profoundly than Risperdal, its parent;

s. They failed to warn that Risperdal and Invega had the potential to raise prolactin levels more than any other atypical antipsychotic or conventional antipsychotic; and,

t. They failed to warn that any elevation of prolactin levels may have severe and longterm consequences for the patient.

33. It was as a result of the Defendants' claims regarding the effectiveness, safety, and benefits of Risperdal and Invega, and the Defendants' failure to warn about the risks of serious injury associated with Risperdal and Invega, that the plaintiff, other class members, and the plaintiff's and other class members' physicians and other healthcare professionals, and Health Canada, were unaware, and could not reasonably have known or have learned through reasonable diligence that the plaintiff and other class members would be exposed to the risk of gynecomastia and the other risks and injuries described herein other Adverse Events.

34. It was as a result of the Defendants' failure to warn about the risks of serious injury associated with Risperdal and Invega, as aforesaid, that the plaintiff and other class members were unaware of the increased risk for developing life-threatening injuries. Had the plaintiff, the other class members, their parents family members, their healthcare providers, and Health Canada known of the risks and dangers associated with Risperdal and Invega, as well as the lack

of additional benefits, the plaintiff and other class members would not have used Risperdal and/or Invega.

35. Prescribing physicians would not have prescribed Risperdal and/or Invega to the plaintiff and other class members had

a. the Defendants provided said physicians with an appropriate and adequate warning regarding the risks of precocious puberty, hyperprolactinemia, gynecomastia, and tardive dyskinesia, and death other Adverse Events associated with the ingestion of Risperdal and/or Invega and regarding the fact that there were not adequate well-controlled studies showing that Risperdal and Invega were safe and efficacious for treatment of the plaintiff's and other putative class members' conditions; and

b. said physicians not received information and promotional materials from the Defendants suggesting that Risperdal and Invega were safe and efficacious for use in treating children and adolescents or in treating class members' conditions.

36. Further, if properly, completely, and timely warned about the risks of precocious puberty, hyperprolactinemia, gynecomastia, and tardive dyskinesia, death and other 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, the plaintiff and class members' prescribing physicians would have changed the way in which they treated the condition for which class members were being treated, would have warned class members, about the signs and symptoms of serious adverse effects of Risperdal and/or Invega, would have discussed the risks of hyperglycemia, precocious puberty, hyperprolactinemia, gynecomastia, and tardive dyskinesia, and other serious adverse events other Adverse Events, and would have

permitted patients to choose whether to be treated with Risperdal and/or Invega, or not, after considering the risks. 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' physical appearance and weight, and would have performed or requested regular physical examinations and laboratory tests, while class members were on Risperdal and/or Invega.

37. Even if the Defendants had properly warned physicians, pharmacists, or other healthcare professionals regarding the safe and effective use of Risperdal and Invega, this fact alone would be insufficient to discharge the Defendants' duty to warn the plaintiff and other class members. This is so because:

a. The plaintiff and other class members placed their primary reliance regarding the safety of Risperdal, not on healthcare professionals, but on the Defendants themselves;

b. The Defendants advertised, promoted and marketed Risperdal and Invega directly to the plaintiff and other class members by means of so-called "reminder advertising", in which the name of a product, its strength, dosage, form and price are revealed, but not the product's indication or effectiveness. The Defendants also advertised, promoted and marketed Risperdal and Invega directly to the plaintiff and other class members by means of cross-over advertising, promotion, and marketing that was, or may have been, targeted to patients outside of Canada, but that was nonetheless received by Canadians; and

c. There was a high degree of consumer involvement regarding the prescription of Risperdal and Invega.

b. Negligence

38. The Defendants additionally owed the plaintiff and other class members a duty of care to ensure that Risperdal was safe and fit for its intended purpose. The Defendants breached that duty as follows:

a. 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;

b. They released Risperdal and Invega into the market knowing, or having ought to have known, that Risperdal and/or Invega use was associated with an increased risk in developing gynecomastia and other Adverse Events;

c. They released Risperdal and Invega into the market knowing, or having ought to have known, that they were fit neither for their intended uses nor for their reasonably foreseeable uses. Indeed, the drugs were unreasonably dangerous to an extent beyond that which could reasonably be contemplated by the plaintiff and class members and their physicians. Accordingly, any benefits of Risperdal and Invega were outweighed by the serious and undisclosed risks of their use when prescribed and used as the Defendants intended;

d. The Risperdal and Invega distributed by the Defendants were defective;

e. Once Risperdal and Invega were released into the market, the Defendants 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;

f. They engaged in promotional activities that were not only false and misleading as to the safety and efficacy of Risperdal and Invega, but, in many cases, were designed irresponsibly to expand the use of Risperdal and/or Invega for off-label uses, without scientific proof of the drug products' safety and efficacy in treating such disorders

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

h. They failed to exercise reasonable care in designing, researching, developing, testing, manufacturing, marketing, packaging, promoting, distributing, licensing, inspecting, labelling, advertising, supplying and selling Risperdal and Invega;

i. They failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Risperdal and Invega;

j. They over-promoted the benefits of Risperdal and Invega and understated the risk of gynecomastia and other Adverse Events;

k. They omitted information concerning these risks from Risperdal and Invega product monographs;

l. They distributed promotional materials that were false and misleading in that they minimized the risks of serious adverse events;

m. They failed to advise physicians to monitor patients for adverse events;

n. They failed to include a 'boxed warning' about gynecomastia and other Adverse Events associated with Risperdal and Invega;

o. They failed to manufacture, package, label, test, import, distribute and sell Risperdal and Invega in accordance with *Food and Drugs Act* R.S.C., 1985, c. F-27 (the "Food and Drugs Act") and the *Food and Drug Regulations*;

p. They knowingly or recklessly provided misleading or incomplete information to Health Canada when submitting the NDSs for Risperdal and Invega. More particularly, but without limitation, the defendants did not disclose to Health Canada complete evidence regarding the clinical effectiveness of Risperdal and Invega, the drugs' contra-indications and side effects, and the fact that Risperdal and Invega are associated with an increased risk of gynecomastia and other Adverse Events;

q. They withheld important clinical and non-clinical data from Health Canada throughout the approval process for Risperdal and Invega and subsequent to their approval, including when they submitted to Health Canada for approval the NDS's for Risperdal and Invega, when they submitted to Health Canada for approval the Product Monographs for Risperdal and Invega, and subsequent to the issuance by Health Canada of the Notices of Compliance for Risperdal and Invega;

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

s. They failed to recognize and/or report to Health Canada scientific "signals" evidencing an association between Risperdal and Invega and adverse events being reported post-marketing of the drug;

t. They falsely claimed that Risperdal and Invega were safer and more efficacious than other antipsychotic medications on the market; and,

u. They advertised Risperdal and Invega in a manner that failed to adhere with the standards set out in the Pharmaceutical Advertising Advisory Board Code of Advertising Acceptance.

39. At all times, the Defendants' warnings to Canadians with respect to Risperdal and Invega lagged behind the Defendants' state of knowledge regarding the drugs' risks, and lagged both in their timing and comprehensiveness behind the Defendants' warnings in relation to Risperdal and Invega abroad.

40. At all times relevant to this suit, the dangerous propensities of Risperdal and Invega were known to the Defendants, or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drugs for their patients.

41. Despite the fact that the Defendants knew or should have known that Risperdal and Invega posed serious risks of bodily harm to consumers and/or did not provide any additional benefits, the Defendants continued to manufacture and market Risperdal and Invega for use by consumers.

42. It was as a direct and proximate result of the Defendants' failure to exercise reasonable care in the design, research, development, testing, manufacture, marketing, packaging, promotion, distribution, licensing, inspecting, labelling, advertising, supplying and sale of Risperdal and Invega, that the plaintiff and other class members were exposed to Risperdal and/or Invega and thereby suffered personal injury, economic and non-economic damages including pain and suffering. The Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, labeling, and/or manufacturing of Risperdal and Invega was a proximate cause of the plaintiff's and other class members' injuries and damages.

c. Breach of Warranty

43. The Defendants expressly or impliedly warranted, through their direct-to-consumer marketing, reminder marketing, labeling, product monographs, and sales representatives, that Risperdal and Invega were safe and effective antipsychotic agents. The safety and efficacy of Risperdal and Invega constitute material facts in connection with the marketing, promotion, and sale of Risperdal and Invega.

44. Risperdal and Invega manufactured and sold by the Defendants did not conform to these express representations because they caused serious injury to consumers when taken in recommended dosages.

45. As a direct and proximate result of the Defendants' breach of warranty, the plaintiff and other class members have suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

d. Waiver of Tort

46. The plaintiff and the other class members are entitled to waive the tort and require the Defendants to account for all the revenue they received from the sale of Risperdal and Invega in Canada.

e. Unjust enrichment

47. The Defendants voluntarily accepted and retained profits and benefits, derived from the plaintiff and other class members, with full knowledge and awareness that, as a result of the Defendants' conscious and intentional wrongdoings, the plaintiff and other class members did

not receive a product of the quality, nature or fitness that had been represented by the Defendants or reasonably expected by the plaintiff and other class members. By virtue of the conscious wrongdoings alleged, the Defendants have been unjustly enriched at the expense of harm to the plaintiff and other class members. There is no juristic reason for the Defendants' enrichment.

f. Conspiracy

48. At all material times, the Defendants, by their directors, officers, servants and agents, wrongfully, unlawfully, and maliciously conspired and agreed together and with persons unknown as set out below.

49. The Defendants, in a combination of two or more persons, acted with a common purpose to do an illegal act and/or to do a lawful act by unlawful means or for an unlawful purpose.

50. The Defendants conspired to recruit and use, and did use, academicians and other influential persons in the medical community as "key opinion leaders" to serve as named authors and presenters, despite the fact that the authors and presenters had little or no personal involvement in research on Risperdal and/or Invega, or in the analysis of data, or in the actual authorship of these materials.

51. These meetings between the Defendants as aforesaid were held for an illegal purpose, *i.e.*, the promotion of inappropriate off-label uses of Risperdal and/or Invega and the creation of false and misleading promotional materials designed to create a false impression in the minds of physicians that Risperdal and/or Invega were safe and effective for a variety of uses, labeled and unlabeled, that Risperdal and/or Invega were "broad spectrum antipsychotics," that Risperdal

and/or Invega were safe and effective in the treatment of children and adolescents (despite the lack of approval of any use in children and adolescents in Canada), and that Risperdal and/or Invega were safe and effective in the treatment of conditions for which Risperdal and/or Invega have never been approved in Canada, *i.e.* ,autism, Attention-Deficit/Hyperactivity Disorder, Obsessive-Compulsive Disorder, Oppositional-Defiant Disorder, Conduct Disorder, Disruptive Behavior Disorder, Tourette's syndrome, Post-Traumatic Stress Disorder, pervasive development disorders, and substance abuse.

52. All of the Defendants acted with a common purpose negligently, intentionally and/or fraudulently to withhold information regarding the safety of Risperdal and Invega for the purpose of earning profits at the expense of the plaintiff's and class members' health.

53. The plaintiff and other class members have been damaged as a direct and proximate result of Defendants' concerted actions, as alleged above.

54. The plaintiff pleads that the Defendants' conspiracy involved unlawful means with the predominant purpose of causing the plaintiff and putative class members to use Risperdal and/or Invega. In conspiring unlawfully to develop, design, license, manufacture, distribute, sell, and market this unsafe product, the defendants knew or ought reasonably to have known that such use would cause harm to the plaintiff and other class members.

55. More particularly, the Defendants engaged in the said conspiracy for the purpose, *inter alia*, of:

a. causing the plaintiff and other class members to use Risperdal and/or Invega.

b. maximizing profit from the sale of Risperdal and/or Invega;

c. increasing or maintaining their market share in the anti-psychotic pharmaceutical drug market;

d. avoiding adverse publicity;

e. placing their economic interests above the safety of the plaintiff and other class members;

f. maintaining their brand and corporate image; and

g. keeping the plaintiff and other class members, their physicians, and Health Canada in the dark regarding the dangerous properties and effects of Risperdal and Invega.

56. In furtherance of the conspiracy, the following, *inter alia*, are some of the acts carried out by the Defendants:

a. They submitted false, inaccurate and misleading information to Health Canada for the purpose of obtaining approval to market and sell Risperdal and Invega in Canada;

b. They concealed and disguised information about the dangerous properties and effect of Risperdal and Invega from Health Canada, from health practitioners and from the plaintiff and other class members;

c. They misled the plaintiff and other class members, health practitioners and others about the efficacy, safety and effect of Risperdal and Invega;

d. They refused to issue warnings and to make monograph changes regarding the use of Risperdal and Invega or to stop selling the drugs even after their harmful effects and properties became manifest;

e. They developed and used marketing and promotional strategies that covered up the truth about Risperdal's and Invega's dangerous properties and side effects.

57. As a result of the said conspiracy, the plaintiff and other class members used Risperdal

and/or Invega and thereby have suffered damage and loss.

g. Statutory Breaches

58. The plaintiff relies on, and pleads a breach of, the *Competition Act*, R.S. 1985, c. C-34. The Defendants' claims regarding Risperdal's and Invega's safety, effectiveness, and effectiveness compared with other comparable drugs, were representations made for the purpose of promoting the business interests of the Defendants and promoting these drugs. These representations were made to the public, including the plaintiff and other class members. They were false and misleading in a material respect, and they were made by the Defendants knowingly or recklessly. The Defendants have breached s.52 of the *Competition Act* in knowingly or recklessly making such false and/or misleading representations to the public. By reason of such breach, the Defendants are liable under s.36 of the *Competition Act* in damages, and for the costs of investigating and pursuing this action.

59. The plaintiff pleads and relies upon the *Consumer Protection Act*, R.S. c. 92, ss. 2 and 26 and equivalent legislation in other provinces. The plaintiff and other putative class members were "purchasers" who entered into "consumer sales" of Risperdal and/or Invega with the Defendants, who were "sellers". The plaintiff pleads that the Risperdal and/or Invega so purchased was not reasonably fit for their approved indications and was not of merchantable quality.

60. The plaintiff pleads and relies upon the *Sale of Goods Act*, R.S. c. 408, ss. 2 and 17 and equivalent legislation in other provinces. Risperdal and Invega were purchased by the plaintiff and other class members pursuant to contracts of sale within the meaning of the *Sale of Goods Act*. The Defendants represented that Risperdal and Invega were safe and effective for their

indications. These representations were in fact false, misleading or deceptive. The plaintiff pleads that neither Risperdal nor Invega was fit for its intended purpose nor of merchantable quality as an effective treatment for their approved indications, or as a more effective treatment for those indications than older antipsychotics or other comparable drugs. In making contrary representations, the Defendants acted in breach of section 17 of the *Sale of Goods Act*.

DAMAGES AND OTHER SUBROGATED CLAIMS

a. General and Special Damages

61. As a result of the Defendants' negligence and other actionable conduct as set out above, the plaintiff and the other class members have suffered and will continue to suffer damages and loss including:

a. Personal injury;

b. Out-of-pocket expenses including those connected with medical care and treatment, medications, the cost of Risperdal and Invega as paid for by the plaintiff, class members and by the Nova Scotia's Health Insurance Programs, and other provincial health insurers and drug benefit plans, and private third party payors as set out above;

c. Cost of past care and services;

d. Cost of future care and services; and

e. Past loss of income and future loss of income.

b. Subrogated Claims

62. The Nova Scotia Department of Health and Wellness provides coverage for healthcare services to Nova Scotia residents through the Nova Scotia's Health Insurance Programs. Similar programs are available in other provinces. The plaintiff and other class members required hospitalization and other medical services as a result of the conduct of the defendants as aforesaid. These medical services were paid for by the Nova Scotia's Health Insurance Programs and other provincial health insurers. The Nova Scotia's Health Insurance Programs and other provincial health insurers will continue to provide treatment in the future to the plaintiff and other class members. The subrogated interest of the Nova Scotia's Health Insurance Programs and all other provincial health insurers includes the cost of all past and future insured services for the benefit of the plaintiff and all other class members. The cost of the purchase of Risperdal and Invega by the plaintiff and class members was covered, in whole or in part, individually or by third party parties, including private or group health insurers and private drug benefit plans, or by provincial health insurers and public drug benefit plans.

63. Class members who paid for their own Risperdal and Invega seek a full indemnification of the purchase price. Third party payors have a subrogated interest in their expenditures for Risperdal and Invega on behalf of the plaintiff and other members of the class and they seek a full indemnification of the purchase price.

c. Punitive and Aggravated Damages

64. At all material times, the Defendants knew or should have known that Risperdal and Invega were inherently dangerous.

65. Despite their knowledge, the Defendants continued aggressively to market Risperdal and Invega to consumers, including the plaintiff and other class members, without disclosing their dangerous side effects when there existed safer alternative products.

66. Despite the Defendants' knowledge of Risperdal's and Invega's defective and unreasonably dangerous nature, the Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute it so as to maximize sales and profits at the expense of the health and safety of the public, including the plaintiff and other class members, in conscious and callous disregard of the foreseeable harm caused by Risperdal and Invega.

67. The Defendants' conduct was high-handed, outrageous, reckless, egregious, deliberate, disgraceful, wilful, callous, and in wanton disregard of the rights and safety of the plaintiff and of the other members of the class. The defendants' conduct was indifferent to the consequences and motivated by economic considerations such as the maintaining of profits and market share. Such conduct renders the defendants liable to pay punitive damages to the plaintiff and other members of the class.

68. The Defendants' conduct as described above, including, but not limited to, their failure to adequately test their products, to provide adequate warnings, their promotion of Invega and Risperdal as being safe and efficacious in the scientific literature, and their continued manufacture, sale, and marketing or their products when they knew or should have known of the serious health risks created, evidences a flagrant disregard of human health as to warrant the imposition of punitive damages as the acts or omissions were committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including the

plaintiff and other class members.

69. The Defendants' conduct, as aforesaid, was injurious to the feelings of pride, dignity and self-respect of the plaintiff and the other class members. The Defendants are therefore liable to the plaintiff and other class members for aggravated damages.

LIMITATIONS

70. Relative to any applicable limitations statutes or any applicable common law limitation periods, the plaintiff and putative class members plead and rely on the doctrine of discoverability.

STATUTES

71. The plaintiff pleads and relies upon section 43(9) of the *Judicature Act*, R.S.N.S. 1989, c. 240, Rules 41 and 68 of the *Nova Scotia Civil Procedure Rules* and, *inter alia,* upon the legislation listed under Schedule "A" and all relevant amendments thereto.

RELIEF SOUGHT

72. The plaintiff repeats the foregoing paragraphs and states that the Defendants are jointly and severally liable for the following:

a. an Order certifying this proceeding as a class proceeding and appointing the plaintiff as Representative Plaintiff for the Class;
b. general damages. including aggravated damages for personal injuries;
c. special damages for medical expenses and other expenses related to the use of Risperdal and Invega;

d. aggravated, punitive and exemplary damages;

e. further or alternatively the plaintiff claims, on his own behalf and on behalf of the other class members:

i. a declaration that the benefits that accrued to the Defendants as a result of their wrongful acts unjustly enriched the Defendants;

ii. an accounting of the benefits that accrued to the Defendants as a result of their wrongful acts;

iii. a declaration that the Defendants hold in trust for the Class the benefits that accrued to the Defendants as a result of their wrongful acts;

f. disgorgement of the benefits that accrued to the Defendants as a result of their wrongful acts;

g. damages for the funding of a "Medical Monitoring Program", supervised by the Court, for the purpose of retaining appropriate health and other experts to review and monitor the health of the class members, and to make recommendations about their treatment;

h. subrogated claims on behalf of the Provincial providers of medical services;

i. interest pursuant to the *Judicature Act*;

j. costs; and

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

PLACE OF TRIAL: Halifax, Nova Scotia

DATED at Toronto, Ontario this 10th day of July, A.D., 2014.

Signed this 21st day of July, 2014.

per:

Bryan C. McPhadden
McPhadden Samac Tuovi LLP

8 King Street East, Suite 300
Toronto, ON, M5C 1B5

Tel: (416) 363-5195
Fax: (416) 363-7485
Counsel for the plaintiff

SCHEDULE "A"

Nova Scotia

- *Class Proceedings Act*, S.N.S 2007, c. 28
- *Consumer Protection Act*, R.S.N.S. 1989, c.92
- *Contributory Negligence Act*, R.S.N.S. 1989, c 95
- *Fatal Injuries Act*, R.S.N.S. 1989, c. 163, amended 2000, c. 29, ss 9-12
- *Health Services Insurance Act*, R.S.N.S. 1989, c. 197
- *Hospitals Act*, R.S.N.S. 1989, c. 208
- *Sale of Goods Act*, R.S., c.408
- *Tortfeasors Act*, R.S.N.S. 1989, c. 471
- *Trustee Act*, RSNS 1989, c 479

Alberta

- *Alberta Health Care Insurance Act*, R.S.A., 2000, C.A-20
- *Class Proceedings Act*, SA 2003, c C-16.5
- *Contributory Negligence Act*, R.S.A. 2000, c.C-27
- *Domestic Relations Act*, R.S.A. 2000, c. D10.5, was repealed by R.S.A. 2003, c. F-4.5 [Family Law Act]
- *Fair Trading Act*, R.S.A. c. F-2
- *Fatal Accidents Act*, R.S.A. 2000, c. F-8
- *Hospitals Act*, R.S.A. 2000, c. H-12
- *Sale of Goods Act*, S-2 R.S.A 2000
- *Tort-feasors Act*, R.S.A. 2000, c. T-5
- *Trustee Act*, R.S.A. 2000, c T-8

British Columbia

- *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2
- *Class Proceedings Act*, R.S.B.C. 1996, c.60
- *Family Compensation Act*, R.S.B.C. 1996, c.126
- *Hospital Insurance Act*, R.S.B.C. 1996, c. 204 [en. 1994, c. 37, s. 4; am. 1996, c. 24, s. 1(3)]
- *Negligence Act*, R.S.B.C. 1996, c.333
- *Sale of Goods Act*, R.S.B.C. 1996, c.410
- *Trustee Act*, RSBC 1996, c 464

Manitoba

- *Class Proceedings Act*, C.C.S.M. c. C130
- *Fatal Accidents Act*, C.C.S.M. c. F50, as amended
- *Manitoba Public Insurance Corporation Act*, C.C.S.M. c. P215
- *Sale of Goods Act*, C.C.S.M. c. S10
- *The Business Practices Act*, C.C.S.M. c. B120
- *The Consumer Protection Act*, C.C.S.M. c. C200
- *The Health Services Insurance Act*, R.S.M. 1987, c. H35
- *The Tortfeasors and Contributory Negligence Act*, C.C.S.M. c T90
- *Trustee Act*, C.C.S.M. c.T160

New Brunswick

- *Class Proceedings Act*, S.N.B. 2006, c.C-5.15
- *Consumer Product Warranty and Liability Act*, c. C-18.1
- *Contributory Negligence Act*, R.S.N.B. 2011, c 131
- *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7

- *Family Services Act*, S.N.B. 1980, c F-2.2
- *Hospital Services Act*, R.S.N.B. 1973, c. H-9
- *Prescription and Catastrophic Drug Insurance Act*, S.N.B. 2014, c 4
- *Sale of Goods Act*, R.S.N.B. 1973, c.S-1
- *Tortfeasors Act*, R.S.N.B. 2011, c 231

Newfoundland

- *Class Actions Act*, S.N.L. c.C-18.1
- *Consumer Protection Act*, R.S.N.L. 1990 c. C-31
- *Contributory Negligence Act*, R.S.N.L. 1990, c C-33
- *Fatal Accidents Act*, R.S.N.L. 1990, c. F-6
- *Hospital Insurance Agreement Act*, R.S.N.L. 1990, c. H-7
- *Medical Care Insurance Act*, 1999 S.N.L. 1999, c. M-5.1
- *Sale of Goods Act*, R.S.N.L. 1990, c.S-6
- *Trustee Act*, RSNL 1990, c T-10

Northwest Territories

- *Children's Law Act*, S.N.W.T. 1997,c.14
- *Consumer Protection Act*, R.S.N.W.T. 1988, c. C-17
- *Contributory Negligence Act*, R.S.N.W.T. (Nu) 1988, c C-18
- *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- *Sale of Goods Act*, R.S.N.W.T. 1988, c. S-2
- *Trustee Act* R.S.NW.T. 1988, C.S-2

Nunavut

- *Consumer Protection Act*, R.S.N.W.T. 1988, c. C-17
- *Contributory Negligence Act*, R.S.N.W.T. (Nu) 1988, c C-18
- *Guardianship and Trusteeship Act*, S.N.W.T. (Nu) 1994, c 29
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- *Medical Care Act*, R.S.N.W.T. (Nu) 1988, c M-8
- *Sale of Goods Act*, R.S.N.W.T. (Nu) 1988, c S-2

Ontario

- *Class Proceedings Act*, R.S.O. 1992, S.O. 1992, c.6;
- *Consumer Protection Act*, 2002 S.O. 2002, c.30, Sched. A;
- *Courts of Justice Act*, R.S.O. 1990, c.43;
- *Family Law Act*, R.S.O. 1990, c. F.3;
- *Health Insurance Act*, R.S.O. 1990, c. 11.6;
- *Negligence Act*, R.S.O. 1990, c. N.1;
- *Sale of Goods Act*, R.S.O. 1990, c. S.1;
- *Trustee Act*, R.S.O. 1990, c. T.23

Prince Edward Island

- *Consumer Protection Act*, R.S.P.E.I. 1988, c. C-19
- *Contributory Negligence Act*, RSPEI 1988, c C-21
- *Family Law Act*, R.S.P.E.I 1988, c F-2.1
- *Fatal Accidents Act*, R.S.P.E.I. 1988, c. F-5, as amended
- *Health Services Act*, R.S.P.E.I. 1988, c H-1.6
- *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c H-8

- *Sale of Goods Act*, R.S.P.E.I. 1988, c. S-1

Quebec

- *Civil Code of Quebec Articles* 1002 and 1003
- *Consumer Protection Act*, R.S.Q. chapter P-40.1

Saskatchewan

- *Class Actions Act*, S.S. 2001, c.C-12.01
- *Department of Health Act*, R.S.S. 1978, c. D-17
- *The Children's Law Act, 1997*, SS 1997, c C-8.2
- *The Consumer Protection Act*, 1996, c. C-30.1
- *The Contributory Negligence Act*, R.S.S. 1978, c C-31
- *The Fatal Accidents Act*, R.S.S. 1978, c. F-11 as amended
- *The Sale of Goods Act*, R.S.S. 1978, c. S-1
- *The Saskatchewan Medical Care Insurance Act*, R.S.S. 1978, c S-29
- *The Trustee Act, 2009*, SS 2009, c T-23.01

Yukon

- *Consumers Protection Act*, R.S.Y. 2002, c. 40
- *Contributory Negligence Act*, R.S.Y. 2002, c 42
- *Fatal Accidents Act*, R.S.Y. 2002, c 86
- *Hospital Insurance Services Act*, R.S.Y. 2002, c. 112
- *Sale of Goods Act*, R.S.Y. 2002, c. 198
- *Trustee Act*, R.S.Y. 2002, c 223

Canada

- *Competition Act*, R.S.C., 1985, c. C-34
- *Food and Drugs Act*. R.S.C, 1985, c. F-27