AMENDED THIS 8th November PURSUANT TO
MODIFIÉ CE " " CONFORMÉMENT À
☒ RULE/LA RÈGLE 26.02 (A)

☐ THE ORDER OF _____
L'ORDONNANCE DU
DATED / FAIT LE _____

REGISTRAR GREFFIER
SUPERIOR COURT OF JUSTICE COUR SUPÉRIEURE DE JUSTICE

Court File No. 06-CV-321585 CP

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

NICHOLAS BROWN,MANJIT GAINDA, SABJIT GAINDA,
SANDEEP SINGH GAINDA, PAMINDER KAUR GAINDA,
KULDEEP CHANDAN GAINDA, and JOANNE VAUTIER

Plaintiffs

-and-

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

Defendants

Proceedings under the *Class Proceedings Act, 1992*

AMENDED AMENDED FRESH AS AMENDED STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, and file it, with proof of service in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date Apr. 26, 2008 Issued by "G. Findlay"
Local Registrar

Address of court office
10th Floor,
393 University Avenue
Toronto, Ontario

TO: **JANSSEN INC.**
19 Green Belt Drive
Toronto, ON
M3C 1L9

AND TO: **JANSSEN PHARMACEUTICALS, INC.**
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

AND TO: **JOHNSON & JOHNSON**
Douglas K. Chia
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

AND TO: **JOHNSON & JOHNSON INC.**
Douglas K. Chia
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

AND TO: **JANSSEN ORTHO LLC**
The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, Delaware 19801

1. The plaintiffs claim:

   (a) damages in the amount of $25,000,000;

   (b) an order certifying the herein action as a class action;

   (c) an order naming the plaintiffs representative plaintiffsfor the class;

   (d) aggravated damages in the amount of $10,000,000;

   (e) punitive damages in the amount of $10,000,000;

   (f) restitution damages or such other equitable remedy as may be available;

   (g) pre-judgment interest pursuant to section 130 or, in the alternative, section 128 of the *Courts of Justice Act*, R.S.O. 1990, c. C-43;

   (h) post judgment interest pursuant to section 129 of the *Courts of Justice Act*;

   (i) costs on a substantial indemnity scale; and

   (j) such further and other relief as this Honourable Court deems just.

I. THE PARTIES

2. The plaintiff Nicholas Brown ("Brown") is 24 years old and resides in Barrie, Ontario.

3. The plaintiff Brown was first prescribed, and first ingested, Risperdal when he was aged10.

4. Risperdal is the trade name used by the Defendants for risperidone. Risperidone belongs to the class of atypical antipsychotics.

5. Brown was prescribed, and he ingested, Risperdal for a period of approximately three years, until he was about age 13.

6. Neither Brown nor his parents were warned of the risk of gynecomastia from ingesting Risperdal. Gynecomastia is a condition whereby the breasts of males become abnormally enlarged.

7. Commencing about the second year of his use of Risperdal, Brown began developing male breasts.

8. The plaintiff Brown continues to suffer from this condition.

9. Brown has now been diagnosed as suffering from gynecomastia. This diagnosis was made in or about October 2013.

10. Until being diagnosed with gynecomastia, Brown was aware of his condition but had no knowledge that he suffered from gynecomastia or that it was caused by Risperdal.

11. Risperdal is the cause of Brown's gynecomastia. Risperdal or another, related drug, marketed as Invega or Invega Sustenna, is the cause of gynecomastia in the other class members.

12. Beginning in or about November 2103, Brown commenced treatment for gynecomastia. Thus far the treatment is not working.

13. The treatment was scheduled to be completed in or about December 2013.

14. In the event the treatment Brown is receiving does not work, he has been advised that he we will need to undergo a surgical procedure or procedures to treat his gynecomastia.

15. Surgical procedures will also be needed by other class members to address their gynecomastia.

16. The plaintiffs Manjit Gainda and Sarbjit Kaur Gainda (together, the "Gaindas") are individuals residing in Brampton, Ontario. Manjit Gainda was prescribed and ingested Risperdal. Manjit Gainda was prescribed Risperdal by his physician in 1996. He began taking Risperdal on or about mid 1996 and continued taking Risperdal until about February/March 2003. On October 27, 2003, after taking Risperdal, Manjit Gainda was diagnosed with tardive dyskenesia. He will require life-long medical monitoring in relation to this condition. In addition, he is now required to take medications in relation to tardive dyskenesia and will incur expenses for those medications for the duration of his life.Manjit Gainda claims damages on his own behalf, as litigation guardian for his minor child, Kuldeep Chandan Gainda, and on behalf of a class of similarly situated plaintiffs.

17. Sarbjit Kaur Gainda is the wife of Manjit Gainda. Sandeep Singh Gainda, Pamninder Kaur Gainda, and Kuldeep Chandam Gainda are the children of the Gaindas. Sarbjit

Kaur Gainda, Sandeep Singh Gainda and Paminder Kaur Gainda claim damages on their own behalf and on behalf of a class of similarly situated plaintiffs pursuant to section 61 of the *Family Law Act*, R.S.O. 1990, c. F.3.

18. The plaintiff Joanne Vautier ("Vautier") is an individual residing in Belleville, Ontario. Vautier was prescribed and ingested Risperdal. She was prescribed Risperdal by her physician in December, 1998 and continued taking Risperdal until about January, 2006. In August 2000, Vautier was diagnosed with diabetes by her family physician. She will require life-long medical monitoring in relation to her diabetes. In addition, she is now required to take medications in relation to her condition, and will incur expenses for those medications for the duration of her life

19. Brown, Manjit Gainda, and Vautier used Risperdal ~~and/or generic risperidone~~ in accordance with the product monograph and consumer information pamphlets and in the manner Risperdal and ~~generic risperidone~~ were intended to be used.

20. The Janssen Defendants, as defined below, failed to adequately warn Brown, or Brown's parents or the Gaindas of the risk of developing gynecomastia, as well as ~~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,~~ hyperprolactinemia (together, the "Adverse Events") from ingesting Riserpedal. Similarly, the other class members and/or their

parents or guardians were not warned by the Janssen Defendants of the risk of developing ~~gynecomastia and the other~~Adverse Events from ingesting Risperdal, ~~generic risperidone~~, and/or Invega and/or Invega Sustenna.

21. 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 and Invega Sustenna (together, "Invega") in Canada.

22. 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.

23. 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.

24. 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.

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

26. At all material times, the Janssen 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 Ontario and the rest of Canada.

27. The plaintiffs plead that, by virtue of the acts described herein, each of the Janssen 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 Janssen Defendant's business was operated so that it was inextricably interwoven with the business of the other;

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

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

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

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

~~28. The Defendant Excerpta Medica LLC ("Excerpta Medica") is a corporation incorporated pursuant to the laws of the State of Delaware, with offices located in the States of Delaware and New Jersey.~~

~~29. Excerpta Medica provides services, including, but not limited to, medical communication services to pharmaceutical manufacturers, including the Janssen~~

~~Defendants. Excerpta Medica is a wholly owned subsidiary of the Defendant, Elsevier Inc.~~

~~30. The Defendant Elsevier Inc. ("Elsevier") is a corporation incorporated pursuant to the laws of the State of New York.~~

~~31. Elsevier provides services to pharmaceutical manufacturers, including the Janssen Defendants. Elsevier is engaged in the business of publishing scholarly books and journals in many fields of science and social science, including but not limited to those specifically identified in this action.~~

~~32. The Defendants Excerpta Medica and Elsevier (collectively, the "Publishers") were engaged in the regular business of providing information relating to various drugs, including Risperdal and/or Invega, either directly or indirectly, to Health Canada, the public, the plaintiffs, putative class members, physicians and other healthcare providers, for which they derived significant and regular income.~~

~~33. The Publishers have more than 60 years of experience in delivering medical communications to healthcare professional, patients and consumers.~~

II. RISPERDALAND INVEGA

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

35. 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.

36. 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.

37. The Janssen 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.

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

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

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

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

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

~~43. Since patent protection expired for Risperdal in July 2006, numerous generic versions of risperidone were approved by Health Canada for the Canadian market. These generic versions of risperidone are "bioequivalent" to Risperdal, meaning that they share the same active ingredient and that there is no meaningful difference between the generic versions of risperidone and brand-name Risperdal in terms of the drug's safety and the way in which the drug works in the body.~~

III. HARM CAUSED BY RISPERDALAND INVEGA

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

45. Male child and male adolescent patients taking Risperdal~~, generic risperidone,~~ and/or Invega are exposed to an increased risk of developing gynecomastia. All patients taking Risperdal, ~~generic risperidone,~~ and/or Invega are exposed to an increased risk of developing Adverse Events.

IV. THE MISCONDUCT OF THE JANSSEN DEFENDANTS ~~WITH THE PUBLISHERS~~

46. Despite their awareness of this risk, the Janssen 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.

47. The Defendants knew that Risperdal, ~~generic risperidone,~~ and Invega posed certain health risks to children, ~~including~~ namely 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.

48. As a consequence of the Defendants' efforts to promote the use of Risperdal and Invega in minors, there was a manifold increase in the use of Risperdal and Invega by minors.

49. As of the year 2000, when the plaintiff Brown was first prescribed Risperdal, the product monograph stated that the safety and efficacy of Risperdal in children had not been established.

50. The Janssen Defendants failed to perform adequate testing concerning the safety of Risperdal and of Invega which would have shown that Risperdal and Invega posed a serious risk of ~~rapid and/or long-lasting weight gain, hyperprolactinemia, gynecomastia, precocious puberty, tardive dyskinesia, and other~~ Adverse Events, ~~that~~ which would have permitted adequate and appropriate warnings to have been given by Janssen to prescribing physicians and the consuming public, including other class members.

51. After Risperdal was approved for sale in Canada and after the Janssen Defendants targeted minors for the use of Risperdal, adverse events came to be reported by physicians and patients to Health Canada and to the Food and Drug Administration in Canada and the United States, respectively.

52. The Janssen Defendants 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. The Janssen Defendants engaged in these promotional activities so as to increase sales and profits at the expense of the safety, health, and well-being of the public, including the plaintiffs and other class members by means of the following, including, but not limited to:

a. Manipulating clinical trials to produce results favorable to Risperdal and Invega;
b. Failing to publish or report negative studies concerning Risperdal and Invega to Health Canada or to publish the results in the medical literature;
c. Ghostwriting medical journal articles, pertaining to Risperdal and/or Invega, *i.e.*, utilizing hired medical writers, who are not researchers or scientists, to write articles and then submitting them to selected opinion or "thought" leaders to attach their names to them as authors without making any meaningful contribution to the article, to lend false credence to these articles;
d. Presenting false and misleading studies and reports concerning Risperdal and Invega at professional meetings by means of posters and abstracts;
e. Publishing the same studies and/or selected portions of the same studies in multiple journals to create a false impression of scientific acceptability of Risperdal and/or Invega for a variety of uses (a practice known as "salami science");
f. Failing to file accurate and timely reports of ~~adverse events~~ Adverse Events and abnormal laboratory values seen in Risperdal and/or Invega clinical trials with Health Canada;

g. Failing to publish accurate reports of ~~adverse events~~ Adverse Events and abnormal laboratory values in articles concerning Risperdal and/or Invega clinical trials;

h. Failing to file accurate and timely reports of post-marketing ~~adverse events~~ Adverse Events with Health Canada;

i. Failing to publish accurate reports of post-marketing ~~adverse events~~ Adverse Events in articles concerning Risperdal and/or Invega;

j. Failing to recognize signals evidencing association between Risperdal and Invega and ~~adverse events~~ Adverse Events in post-marketing adverse event reports;

k. Conducting marketing and promotion of Risperdal and Invega for off-label use under the guise of continuing medical education;

l. Utilizing "advisory boards" to conduct marketing and promotion of Risperdal and/or Invega;

m. Paying large sums to key opinion leaders to tout Risperdal and/or Invega as treatment for a variety of disorders;

n. Marketing Risperdal and/or Invega as '"broad spectrum" antipsychotics;

o. Hiring consultants involved in creating treatment algorithms in order to achieve favorable treatment of Risperdal and/or Invega in those algorithms;

p. Giving lucrative contracts for "clinical research" as a reward to high prescribers of Risperdal and/or Invega;

q. Distributing promotional materials such as sales aids (including, but not limitedto, children's Lego-like blocks in bright colors adorned with the Risperdal

logo), journal ads, display panels, brochures, letters, flashcards, calendars, and computer programs regarding Risperdal and Invega which were false, misleading, and/or lacking in fair balance; and,

r. Coordinating, with consultants, marketing executives, medical staff, healthcare professionals and scientists, to off-label market and promote Risperdal and Invega for the treatment of the following off-label uses in children: Attention-Deficit/Hyperactivity Disorder("ADHD"), Obsessive-Compulsive Disorder ("OCD"), Oppositional-Defiant Disorder("ODD"), Conduct Disorder ("CD"), Disruptive Behavior Disorder ("DBD"), Tourette's syndrome, and pervasive development disorders ("PDD"), among others.

53. To perform these tasks, the Janssen Defendants engaged certain publishing companies (the "Publishers") to employ other medical marketing companies, physicians and ghostwriters to produce seemingly unbiased and independent publications regarding Risperdal and/or Invega.

54. To implement their scheme of promoting the ~~efficacy and~~ safety of Risperdal and Invega, the Publishers, in partnership with the Janssen Defendants, developed a publication strategy whereby the Publishers would generate favorable articles touting Risperdal and Invega, including their off-label uses. The publications were made to appear as if they emanated from autonomous physicians who were independently investigating Risperdal and/or Invega.

55. The Publishers, in partnership with the Janssen Defendants, assembled a portfolio of articles to be published in the medical community that promoted Risperdal and Invega and the need for and ~~efficacy and~~ safety of the drugs.

56. The portfolio of articles assembled by the Publishers and the Janssen Defendants was primarily written by medical writers or educators in the employ of the Publishers, then academic authors who were approached by the Publishers to become the named "authors" of such articles. This practice, known as "ghost writing," is purposefully calculated to create a positive "buzz" in the medical community that appears to emanate from an unbiased perspective, giving the article and the glowing conclusions about Risperdal and/or Invega stated therein, false credibility. Accordingly, psychiatric thought was shaped though the academic arena to create dissatisfaction in the market, and to establish a "need" for and create a desire for Risperdal and/or Invega.

57. The Publishers did not allow the listed "authors" of these articles either to see the data from the clinical trials or to provide any meaningful input into the writing of the articles. In fact, the Publishers had exclusive responsibility for drafting and revising the articles.

58. Health Canada, the public, the plaintiffs, other putative class members, the family members of the plaintiffs and the family members of other putative class members, the plaintiffs' physicians and physicians of the other putative class members and other healthcare providers relied upon the inadequate and, often, misleading information

provided to them by and through ~~and/or on behalf of~~the Janssen Defendants and the Publishers.

59. 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.

60. 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 the year 2000, the product monograph did not indicate that the use of Risperdal was not recommended in children under the age of 18.

61. During the years Risperdal and Invega were prescribed to and were ingested by the plaintiffs and/or the other putative class members, the product monographs failed properly to warn prescribing physicians and patients of the risk of developing ~~gynecomastia and other~~ Adverse Events.

62. The Janssen Defendants contracted with the Publishers to provide information and data in various forms relating to Risperdal and/or Invega, either directly or indirectly, to Health Canada, to the public, to the plaintiffs and other putative class members, to physicians and to other healthcare providers, for which the Publishers derived significant and regular income.

~~63. The defendant Excerpta Medica touts itself as an "inspired choice" by pharmaceutical companies, including the Janssen Defendants, because it is a branch of the academic publisher, the defendant Elsevier, which publishes many of the world's most prestigious science journals.~~

64. ~~As part of Elsevier, the~~ The Janssen Defendants were ~~defendant Excerpta Medica was~~ able to leverage the resources of the world's largest medical and scientific publishers to market, promote and advertise Risperdal and Invega for off-label uses.

~~65. During the time of their relationship with the Janssen Defendants, the Publishers had more than 120 employees with scientific, business, logistical, and online expertise in the industry.~~

~~66. With the addition of "Excerpta Medica Interactive", Excerpta Medica combined important and timely clinical content with interactive delivery vehicles.~~

67. The Janssen Defendants contracted with the Publishers to leverage the extensive resources of~~the~~ Publishers~~Elsevier~~ in implementing~~the~~ Janssen Defendants' plans for the off-label promotion of Risperdal and Invega.

68. The Publishers offered turnkey execution of initiatives across all projects and life-cycle phases for Risperdal and Invega.

69. The Janssen Defendants met with medical writers and officers, directors, servants, employees, and agents of the Publishers, by video conference, telephone and email, and in person, to discuss and agree on plans to create, publish, distribute, and present posters, abstracts, medical journal articles, and oral and written presentations at Janssen-sponsored events, at professional meetings, and as part of purported Continuing Medical Education events ("CMEs").

70. The relationship between the Publishers and the Janssen Defendants was essentially that of partners in these enterprises to promote Risperdal and Invega throughout the world, including Canada.

71. With limited clinical support, and at the direction of the Janssen Defendants, the Publishers established Risperdal and Invega more prominently within the antipsychotic marketplace by:

    a. Positioning Risperdal and/or Invega as a prominent player in the antipsychotic market by describing it as a "broad spectrum antipsychotic";
    b. Increasing the base of clinical support for off-label uses of Risperdal and/or Invega;
    c. Establishing Risperdal and/or Invega as an attractive therapeutic option to a much larger customer base; and
    d. Building physician awareness of the conditions for which the Janssen Defendants were seeking approved indications.

72. The Publishers drew from their extensive experience in publishing to create company-sponsored publications that focused on providing ostensibly scientific, clinically pertinent, and timely information on off-label and unapproved uses of Risperdal and Invega.

73. The Publishers helped achieve the Janssen Defendants' marketing objectives via strategic communications solutions in the following areas:

    a. Medical education;

    b. Publication planning;

    c. Interactive solutions; and

    d. Outreach efforts to healthcare professionals, patients and consumers.

74. The publications contrived in this way by the Defendants were created to build awareness of diseases and conditions for which Risperdal and/or Invega were not approved, and to prepare the specialist and primary care markets for potential future indications. They were also designed to establish the Janssen Defendants as one of the industry's authorities on psychiatric diseases. The information was presented by opinion leaders through:

    a. Poster presentations;

    b. Abstracts;

    c. Clinical journal articles;

    d. Pathophysiology articles;

    e. Case reports;

f. Literature reviews;

g. Correspondence to journal editors;

h. CMEs; and,

i. Responses to clinical queries.

75. Posters, abstracts and promotional reprints were prepared by the Publishers for the Janssen Defendants' use at professional meetings, and the clinical content was complemented with high-quality photographic images, giving each issue a very professional and attractive appearance.

76. Publications were released to audiences in Europe and Canada where physicians were expected to be exposed to such materials.

~~77. The Publishers' stated goal was to help clients achieve their objectives by ensuring that health care professionals, patients, and consumers have the information they need to make informed decisions regarding medical care and treatment options.~~

78. In fact, the information provided was false and misleading and lacking in fair balance.

~~79. At all relevant times, the Publishers were, and are, accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education to physicians.~~

80. For example, the Publishers offered a CME program, entitled "Broadening Horizons: Advances in Understanding the Etiology, Effect and Treatment of Anxiety Disorders" in 2004 and 2005. At least three of the five programs that formed this CME were funded by the Janssen Research Foundation, J&J and/or another J&J subsidiary. One of the presentations, entitled "Treating Anxiety: Current Therapies and Beyond" was presented by a physician who served as a member of a J&J company Advisory Board and discussed the use of atypical antipsychotics, including Risperdal, for adjunctive anxiety therapy. Risperdal is not approved to treat anxiety disorders. The written supplement for this CME carries a copy right owned by Elsevier Inc.

81. The Publishers also offered a CME in the same time period entitled "Atypical Antipsychotic Drug Augmentation in Resistant Major Depression Disorder." Again, Risperdal is not approved to treat resistant major depression disorder, and Elsevier Inc. owned the copy right for the written materials that accompanied the CME. Three of the four presenters received funding, served as consultants and/or were on the speaker's bureaus for various J&J entities.

82. A 2007 article in Current Therapeutic Research, an Elsevier publication, contained an article about a study done in Vancouver, British Columbia, concerning Risperdal. Excerpta Medica holds the copyright on this article.

83. The Excerpta Medica website, which was accessible from Canada, touted, among others, the following Risperdal-related abstracts (that pre-date any Health Canada approval of Risperdal for these conditions):

    a. From a September 2003 European College of Neuropsycopharmacology Congress in the Czech Republic - "Risperidone monotherapy in acute bipolar mania." This study was funded by Janssen Pharmceutica; and,

    b. From an October 2004 European College of Neuropsycopharmacology Congress in Sweden - "Comparative open-label trial of atypical neuroleptics in children and adolescents with bipolar disorder." This article was authored by Joseph Biederman, M.D., from Massachusetts General Hospital, who is being investigated by various governmental and/or academic entities. The abstract concludes: "This pilot, open-label study suggests that atypical neuroleptics reducemanic symptomatology in children and adolescents with bipolar disorder. This study suggests that this effect is strongest for risperidone."

84. The Janssen Defendants acted in concert with one another and/or with the Publishers fraudulently to convey false and misleading information concerning the safety ~~and efficacy~~ of Risperdal and Invega ~~and~~, namely to conceal the risks of ~~serious adverse events, including weight gain, diabetes mellitus, pancreatitis, metabolic syndrome, hyperprolactinemia, gynecomastia, precocious puberty, tardive dyskinesia and other~~ Adverse Events associated with Risperdal and/or Invega from Health Canada, the public, the plaintiffs, putative class members, the family members of the plaintiffs and putative class members, physicians and other healthcare providers. These concerted efforts

resulted in significant harm to consumers of Risperdal and/or Invega, including the plaintiffs, in the form of Adverse Events. But for the actions of the Defendants, individually, jointly, and in concert with one another, the plaintiffs would not have ingested, or permitted injection of, Risperdal and/or Invega. The Defendants' tortious actions make them each individually liable and responsible for the plaintiffs' and other class members' injuries and damages as described herein from the ingestion and/or injection of Risperdal and/or Invega.

V. THE PROPOSED REPRESENTATIVE PLAINTIFFS AND CLASS

85. The proposed representative plaintiffs seek certification of the following class:

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

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

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

VI. CAUSES OF ACTION

a. Failure to Warn

87. The Janssen Defendants owed the plaintiffs and other class members a duty of care as follows:

a. to warn them and their treating healthcare professionals that ingestion of Risperdal, ~~generic risperidone,~~ and Invega carried significant, and specifically identified, health risks ~~including,~~ namely the ~~risk of gynecomastia and other~~ Adverse Events;

b. to ensure that prescribing physicians and other healthcare professionals were apprised and fully and regularly informed of ~~all of~~ the ~~health~~ risks of Adverse Events associated with ingesting Risperdal, ~~generic risperidone,~~ and Invega;

c. to warn them and their treating healthcare professionals that male children and male adolescents were vulnerable to the risks of Adverse Events associated with the ingestion of Risperdal, ~~generic risperidone,~~ and/or Invega, ~~including gynecomastia and other Adverse Events~~;

d. to inform Health Canada fully, properly, and in a timely manner of the health risks ~~and complaints, including those listed herein;~~ of the Adverse Events associated with the ingestion of Risperdal ~~generic risperidone,~~ and Invega;

e. to provide truthful and complete information to Health Canada when submitting the New Drug Submissions ("NDS") for Risperdal and for Invega;

f. to provide complete and accurate clinical and non-clinical data to 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 for Risperdal, when they submitted to Health Canada for approval the product monographs for Risperdal, and subsequent to the issuance by Health Canada of the Notices of Compliance for Risperdal and Invega;

g. promptly to report to Health Canada all of the ~~adverse events~~ Adverse Events that came to be reported to the Defendants with regards to Risperdal and Invega subsequent to their approval for sale in Canada;

h. to issue prompt, up-to-date, and accurate Health Professional Communications and Public Communications, which are the modes of communication through which manufacturers are required to communicate with healthcare professionals and the public, respectively, regarding the safety concerns affecting a health product;

i. to provide truthful and complete 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~~. The Defendants knew or ought to have known that the manufacturers of generic risperidone would be bound by Health Canada's regulations to reproduce exactly in the product monographs for generic risperidone the safety data contained in the product monographs for Risperdal, such that prescribers and consumers of generic risperidone would necessarily be relying on safety data presented by the Defendants in the product monographs for Risperdal~~; and

j. to advertise Risperdal and Invega to healthcare professionals in ways that adequately disclosed the drugs' risk of harm of Adverse Events.

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

a. The original labelling, product monograph, 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~~; accordingly, the labelling, product monograph, and prescribing information for generic risperidone also failed to disclose, adequately, or at all, that generic risperidone could cause Adverse Events~~;

b. The original product monographs, and prescribing information for Risperdal, ~~generic risperidone,~~ 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~~; accordingly, the product monographs and prescribing information for generic risperidone also failed to adequately warn male children and male adolescents and their parents of the risk of developing Adverse Events with the ingestion of generic risperidone~~;

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 plaintiffs, 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 plaintiffs' 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 Risperdaland/or Invega for ~~gynecomastia and other~~ Adverse Events;

f. They knowingly or recklessly provided misleading or incomplete information to Health Canada when submitting the NDS's for Risperdal and Invega. More particularly~~, but without limitation~~, the Janssen 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~~ hyperprolactinemia generally;

g. 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;

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

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

j. 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~~. Prescribers and consumers, not only of brand name Risperdal but also of generic risperidone, relied on that misleading or incomplete information in the product monograph for Risperdal~~;

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

l. 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;

~~m. 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;~~

n. They failed ~~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;

~~o. 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;~~

p. They failed ~~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);

q. They failed ~~Failed~~to warn that Invega had potential to raise prolactin levels more profoundlythan Risperdal, its parent;

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

s. They failed ~~Failed~~to warn that any elevation of prolactin levels may have severe and long term consequences for the patient.

89. It was as a result of the Janssen Defendants' claims regarding the ~~effectiveness, safety, and benefits~~ of Risperdal and Invega, and the Defendants' failure to warn about the risks of ~~serious injury~~ Adverse Events associated with Risperdal, ~~generic risperidone,~~ and Invega, that the plaintiffs, other class members, and the plaintiffs' 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 plaintiffs and other class members would be exposed to the risk of ~~gynecomastia and other~~ Adverse Events.

90. It was as a result of the Janssen Defendants' failure to warn about the risks of ~~serious injury~~ Adverse Events associated with Risperdal~~, generic risperidone,~~ and Invega, as aforesaid, that the plaintiffs and other class members were unaware of the increased risk for developing ~~life-threatening injuries~~ Adverse Events. Had the plaintiffs, the other class members, their family members, their healthcare providers, and Health Canada known of the risks ~~and dangers~~ of Adverse Events associated with Risperdal, ~~generic risperidone,~~ and Invega~~, as well as the lack of additional benefits~~, the plaintiffs and other class members would not have used Risperdal~~, generic risperidone,~~ and/or Invega.

~~91. It was as a result of the Janssen Defendants' failure to warn about the risks of Adverse Events associated with Risperdal, generic risperidone, and Invega, as aforesaid, that the manufacturers of generic risperidone were unaware of the increased risk of Adverse Events associated with generic risperidone. The Janssen Defendants knew, or ought to have known, that Health Canada requires that the product monographs for generic forms of risperidone be identical to the product monographs for Risperdal insofar as safety information is concerned. Accordingly, the Janssen Defendants knew, or ought to have known, that their failure to warn about the Adverse Events in the product monographs for Risperdal would cause the product monographs for generic risperidone to be identically deficient. It was reasonably foreseeable to the Janssen Defendants that class members, their physicians, pharmacists, and their other healthcare professionals, their parents and guardians, and Health Canada, would rely on the safety information the Janssen Defendants chose to include or omit from the Risperdal product monographs regarding the Adverse Events, when the class members were being prescribed generic risperidone. Accordingly, the Janssen Defendants are liable to those class members who purchased and/or ingested generic risperidone, having failed to warn them about the risks of Adverse Events.~~

92. Prescribing physicians would not have prescribed Risperdal~~, generic risperidone,~~ and/or Invega to the plaintiffs and other class members had

    a. the Janssen Defendants provided ~~said physicians with~~ an appropriate and adequate warning regarding the risks of ~~precocious puberty, hyperprolactinemia, gynecomastia, tardive dyskinesia, and other~~ Adverse

Events associated with the ingestion of Risperdal~~, generic risperidone,~~ 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 plaintiffs' and other putative class members' conditions~~;

b. said physicians not received information and promotional materials through and on behalf of ~~from~~ the Janssen Defendants ~~and/or materials produced by the Publishers~~ suggesting that Risperdal and Invega were safe ~~and efficacious~~ for use in treating children and adolescents or in treating class members' conditions.

93. Further, if properly, completely, and timely warned about the risks of ~~precocious puberty, hyperprolactinemia, gynecomastia, tardive dyskinesia, 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 plaintiffs' 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~~ Adverse Events of Risperdal~~, generic risperidone,~~ and/or Invega, would have discussed the risks of ~~hyperglycemia, precocious puberty, hyperprolactinemia, gynecomastia, tardive dyskinesia, and other~~ Adverse Events, and would have permitted patients to choose whether to be treated with Risperdal~~, generic risperidone,~~ 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, ~~generic risperidone,~~ 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~~, generic risperidone,~~ and/or Invega.

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

a. The plaintiffs and other class members placed their primary reliance regarding the safety of Risperdal, ~~generic risperidone,~~ and Invega, not on healthcare professionals, but on the ~~Janssen Defendants~~ manufacturers themselves;

b. The Janssen Defendants advertised, promoted and marketed Risperdal and Invega directly to the plaintiffs 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 Janssen Defendants also advertised, promoted and marketed Risperdal and Invega directly to the plaintiffs 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.

95. The Janssen Defendants ~~Publishers~~ owed a duty of care to the plaintiffs and other class members:

a. To ensure that the material being provided to Health Canada, the public, the plaintiffs and other class members, and their physicians and other healthcare providers was:

i. Scientifically accurate;

ii. Unbiased in tone and content;

iii. Sufficiently specific and comprehensive;

iv. Presented in an understandable and legible format that is readily comprehensible to consumers;

v. Timely and up-to-date; and/or,

vi. Useful, in that it enables a healthcare provider to prescribe the medicine properly and appropriately, so the patient receives the maximum benefit and avoids harm.

b. In all of their undertakings and contractual obligations, including the dissemination of information concerning Risperdal and Invega, to exercise reasonable care to ensure that they provided accurate information ~~about the risks and benefits of Risperdal and Invega~~ in relation to the Adverse Events.

96. The Janssen Defendants ~~Publishers~~ breached their duty of care as follows:

a. They failed to advise Health Canada, the public, the plaintiffs, the plaintiffs' physicians and other healthcare providers of the risks of developing ~~certain adverse effects, including, but not limited to, weight gain, diabetes,~~

~~gynecomastia, hyperprolactinemia and/or precocious puberty, and other~~ Adverse Events~~,~~ with Risperdal and Invega.

b. They failed to disclose, or to direct the Publishers to disclose, in journal articles, posters at conferences, during CMEs and in various other literature and locations, material safety information regarding the ~~serious and permanent side effects~~ Adverse Events caused by taking Risperdal and Invega.

c. They failed to disclose, or to direct the Publishers to disclose, in journal articles, posters at conferences, during CMEs and in various other locations, material safety information regarding the fact that Risperdal and Invega had not been approved by Health Canada for usage in the pediatric population. In fact, the Publishers worked closely with the Janssen Defendants to market and promote Risperdal and Invega in the child and adolescent market.

97. The Defendants had actual and/or constructive knowledge that Health Canada, the public, the plaintiffs and other class members, the plaintiffs' and other class members' physicians and other healthcare providers would rely upon the information disseminated to them, at the Janssen Defendants' behest, by the Publishers in journal articles, posters at conferences, during CMEs and in various other literature and locations, and that many prescribing physicians would likely prescribe, and many patients would be likely to ingest, Risperdal~~, generic risperidone,~~ and/or Invega without true knowledge of the true risks of Adverse Events associated with the drugs.

~~98. The Publishers knew, or should have known through the exercise of reasonable care, that their drug information, either provided to them by the Janssen Defendants and/or developed on their own, for Risperdal and Invega substantially understated the prevalence of acute and long term side effects of ingesting and/or being injected with the drugs.~~

99. The Janssen Defendants ~~Publishers~~ are liable for the injuries that resulted from ~~their~~ the Publishers' failure to use reasonable care to provide accurate, up-to-date information about Risperdal and Invega to the plaintiffs and other class members' and their physicians as follows:

a. The Publishers' failure increased the risk of ~~harm~~ Adverse Events to the plaintiffs and other class members;

b. The plaintiffs and other class members suffered ~~harm~~ Adverse Events because of reliance on the Publishers' provision of inadequate and misleading Risperdal and Invega drug information, specifically in journal articles that omitted information about ~~gynecomastia and other~~ Adverse Events; and/or

c. The plaintiffs and other class members suffered ~~harm~~ Adverse Events because of, among other things, their prescribing physicians' reliance on the Publishers 'provision of Risperdal and Invega drug information when prescribing, dispensing and counseling regarding Risperdal, ~~generic risperidone,~~ and/or Invega.

b. Negligence

100. The Janssen Defendants additionally owed the plaintiffs and other class members a duty of care as follows:

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

b. to ensure that Risperdal and Invega were not released into the market prior to satisfying themselves that the drugs were safe;

~~c. to ensure that Risperdal and Invega were fit for their intended or reasonably foreseeable uses;~~

c. ~~d.~~ once Risperdal and Invega were, respectively, released into the market, to conduct ongoing tests and clinical trials with long term follow-up to determine the long-term ~~effects and~~ risks of Adverse Events associated with the long-term ingestion of Risperdal, ~~generic risperidone,~~ and/or Invega;

d. ~~e.~~ to monitor the post-market effects of Risperdal, ~~generic risperidone,~~ and Invega;

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

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

g. ~~h.~~ to submit truthful and complete information to Health Canada when submitting the NDS's for Risperdal and Invega;

h. ~~i.~~ to provide Health Canada with complete and accurate clinical and non-clinical data throughout the approval processes for Risperdal and Invega and subsequent to their approval;

i. ~~j.~~ promptly to report to Health Canada all of the ~~adverse events~~ Adverse Events that came to be reported to the Janssen Defendants with regards to Risperdal, ~~generic risperidone,~~ and Invega subsequent to their approval for sale in Canada; and

j. ~~k.~~ to advertise Risperdal and Invega in a manner that adhered with the standards set out in the Pharmaceutical Advertising Advisory Board Code of Advertising Acceptance.

101. The Janssen Defendants breached their duty of care 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 of the Adverse Events associated with ingesting the drugs;

b. They released Risperdal and Invega into the market knowing, or having ought to have known, that Risperdal, ~~generic risperidone~~, 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 plaintiffs 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 Janssen Defendants intended;~~

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

d. ~~e.~~ Once Risperdal and Invega were released into the market, the Janssen Defendants failed to conduct ongoing tests and clinical trials with long term follow-up to determine the long-term ~~effects and~~ risks of Adverse Events associated with the long-term ingestion of Risperdal, ~~generic risperidone~~, and/or Invega;

e. ~~f.~~ They failed to monitor the post-market effects of Risperdal~~, generic risperidone~~, and/or Invega;

f. ~~g.~~ 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;

g. ~~h.~~ 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;

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

i. ~~j.~~ They omitted information concerning ~~these~~ the risks of Adverse Events from Risperdal and Invega product monographs;

j. ~~k.~~ They distributed promotional materials that were false and misleading in that they minimized the risks of ~~serious adverse events~~ Adverse Events;

k. ~~l.~~ They failed to advise physicians to monitor patients for ~~adverse events~~ Adverse

Events;

l. ~~m.~~ They failed to include a 'boxed warning' about ~~gynecomastiaand other~~ the Adverse Events associated with Risperdal and Invega;

m. ~~n.~~ They failed to manufacture, package, label, test, import, distribute and sell Risperdal and Invega in accordance with the *Food and Drugs Act* and the *Food and Drug Regulations*;

n. ~~o.~~ 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;

o. ~~p.~~ 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;

p. ~~q.~~ They failed promptly or at all to report to Health Canada all of the ~~adverse events~~ Adverse Events that came to be reported to the Janssen Defendants with regards to Risperdal, ~~generic risperidone,~~ and Invega subsequent to their approval for sale in Canada;

q. ~~r.~~ They falsely claimed that Risperdal and Invega were safer ~~and more efficacious~~ in relation to the Adverse Events than other antipsychotic medications on the market;

r. ~~s.~~ They~~Publishers worked closely with the Janssen Defendants to~~ marketed and promoted Risperdal and Invega in the child and adolescent market; and

s. ~~t.~~ They advertised Risperdal and Invega in a manner that failed to adhere to ~~with~~ the standards set out in the Pharmaceutical Advertising Advisory Board Code of Advertising Acceptance, in relation to the Adverse Events.

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

103. At all times relevant to this suit, the dangerous propensities of Risperdal, ~~generic risperidone,~~ and Invega to cause Adverse Events were known to the Janssen 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.

104. Despite the fact that the Janssen Defendants knew or should have known that

Risperdal and Invega posed serious risks of ~~bodily harm~~ Adverse Events to consumers ~~and/or did not provide any additional benefits~~, the Janssen Defendants continued to manufacture and market Risperdal and Invega for use by consumers.

105. It was as a direct and proximate result of the Janssen 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 plaintiffs and other class members were exposed to Risperdal, ~~generic risperidone,~~ and/or Invega and thereby suffered personal injury, economic and non-economic damages including pain and suffering related to the Adverse Events. 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 plaintiffs' and other class members' injuries and damages.

106. As a direct and proximate result of using Risperdal, ~~generic risperidone,~~ and/or Invega, the plaintiffs and other class members have suffered severe personal injuries, physical pain and mental anguish related to the Adverse Events.

c. Breach of Express Warranty

107. The Janssen Defendants expressly warranted, through their direct-to-consumer marketing, reminder marketing, labeling, product monographs, and sales representatives, that Risperdal and Invegawere safe ~~and effective~~ antipsychotic agents.

The safety ~~and efficacy~~ of Risperdal and Invega ~~constitute~~ constitutes a material ~~facts~~ fact in connection with the marketing, promotion, and sale of Risperdal and Invega.

108. Risperdal and Invega manufactured and sold by the Janssen Defendants did not conform to these express representations because they caused serious injury to consumers in the form of Adverse Events when taken in recommended dosages.

109. As a direct and proximate result of the Janssen Defendants' breach of warranty, the plaintiffs and other class members have suffered harm, damages and economic loss in relation to Adverse Events, and will continue to suffer such harm, damages and economic loss in the future.

d. Breach of Implied Warranty

110. At the time the Janssen Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released Risperdal and Invega into the stream of commerce, these Defendants knew of the use for which Risperdal and Invega were intended and impliedly warranted these products to be ~~of merchantable quality and~~ safe for such use.

111. The Janssen Defendants breached their implied warranties of the Risperdal and Invega products sold to the plaintiffs and other class members because these products were not safe ~~fit for its common, ordinary, and intended use.~~

112. As a direct, foreseeable and proximate result of the Janssen Defendants' breaches of implied warranties in relation to the Adverse Events, the plaintiffs and other class members suffered bodily injury in the form of Adverse Events and consequential economic and other losses, as described above, when the plaintiffs and other class members ingested Risperdal and/or Invega, in reasonable reliance upon the implied warranties.

e. Breaches of Statutes

113. The plaintiffs plead and rely upon the *Consumer Protection Act, 2002*, S.O. 2002, c.30, Sched. A (the "*Consumer Protection Act*") and equivalent legislation in other provinces.

114. Subection 14(1) of the *Consumer Protection Act* and equivalent legislation in other provinces provides that it is an "unfair practice" for a person to make a false, misleading or deceptive representation. More particularly, section 14(2) of the *Consumer Protection Act* states that a representation that a good has benefits or qualities that it does not have is a false, misleading or deceptive representation. The Janssen Defendants engaged in an unfair practice, contrary to subsection 14(1) of the *Consumer Protection Act*, in claiming that Risperdal and Invega were safe~~, effective cholesterol-lowering agents, and more effective agents than other similar drugs manufactured by the Defendants' competitors~~ in relation to the Adverse Events, which claims were in fact, false, misleading or deceptive, as aforesaid.

115. Section 17 of the *Consumer Protection Act* and equivalent provisions in other provinces prohibit persons from engaging in unfair practices.

116. Sub-section 14(2) of the *Consumer Protection Act* and equivalent provisions in other provinces provides that false, misleading or deceptive representations include using exaggeration, innuendo or ambiguity as to a material fact or failing to state a material fact if such use or failure deceives or tends to deceive. In making the representations regarding the safety of Risperdal and Invega as aforesaid ~~regarding the safety, effectiveness, and effectiveness relative to other comparable drugs~~, the Janssen Defendants acted in breach of the said provision of the *Consumer Protection Act* and equivalent provisions in other provinces.

117. Section 18 of the *Consumer Protection Act* and equivalent provisions in other provinces provide that any agreement entered into after or while a person has engaged in an unfair practice may be rescinded by the consumer and the consumer is entitled to any remedy that is available in law, including damages. If rescission is not available (because, for instance, the return or restitution of the goods or services is no longer possible), a consumer is entitled to recover the amount by which the consumer's payment under the agreement exceeds the value that the goods or services have to the consumer. The plaintiffs and other class members claim the amount by which Risperdal's and Invega's prices exceeded the value of Risperdal and Invega, respectively.

118. Under sub-section 18(12) of the *Consumer Protection Act* and equivalent provisions in other provinces, the various Janssen Defendants are jointly and severally liable as a result of each, or all, having entered into agreements with some of the plaintiffs and other class members for the purchase of Risperdal and Invega.

119. The plaintiffs plead and rely upon section 1 of the *Consumer Protection Act*, and equivalent provisions in other provinces, and more particularly the definitions of "consumer", "consumer agreement", "consumer transaction", "representations", and "supplier". More particularly, the plaintiffs plead that they and other class members had entered into consumer transactions with the Janssen Defendants relative to the purchase of Risperdal. The plaintiffs further plead that they and other class members were parties to consumer agreements with the Defendants for the purchase of Risperdal and/or Invega. The plaintiffs further plead that the Janssen Defendants were suppliers within the meaning of the *Consumer Protection Act* and equivalent legislation in other provinces.

120. The plaintiffs and other class members relied on the Janssen Defendants' representations as to Risperdal's and Invega's safety~~, effectiveness, and effectiveness relative to other comparable drugs~~ in relation to the Adverse Events.

121. To the extent that the Janssen Defendants' breaches of the said statutory provisions do not give rise to independent causes of action, which is not admitted but

denied, the said statutory provisions constitute measures of the Janssen Defendants' conduct as regards other causes of action pleaded, including negligence and misrepresentation.

122. The plaintiffs plead that the Court should waive the requirement that the plaintiffs and other class members, as consumers, give notice to the Janssen Defendants of the plaintiffs' and other class members' intention to seek a remedy under section 18 of the *Consumer Protection Act* and equivalent legislation in other provinces pursuant to ss.18(5) and 101 of the *Consumer Protection Act* and as it is in the interest of justice to do so.

123. Section 9(2) of the *Consumer Protection Act* extends the implied conditions and warranties under the *Sale of Goods Act,* R.S.O. 1990, c.S.1 (the "*Sale of Goods Act*") to goods supplied under a consumer agreement. Risperdal and Invega were purchased by the plaintiffs and other class members pursuant to consumer agreements within the meaning of the *Sale of Goods Act*. The plaintiffs plead and rely upon the *Sale of Goods Act* and equivalent legislation in other provinces, and the implied conditions and warranties contained therein.

124. In particular, the plaintiffs plead and rely upon the implied conditions contained in s.15 of the *Sale of Goods Act* that Risperdal and Invega would be ~~fit for their intended purposes and of merchantable quality as safe and effective~~ safe as anti-psychotic drugs~~.~~ in relation to the Adverse Events.

125. The plaintiffs plead ~~and rely~~ that Risperdal and Invega were ~~neither fit for their intended purpose nor of merchantable quality as effective~~ not safe antipsychotic agents, ~~or as more effective antipsychotic agents than other comparable drugs~~ having regard to the risk of Adverse Events.

126. The plaintiffs further plead and rely upon the *Competition Act*, R.S.C., 1985, c. C-34 (the "*Competition Act*") and equivalent legislation in other provinces.

127. The Janssen Defendants' claims regarding Risperdal's and Invega's safety, ~~effectiveness, and effectiveness~~ in relation to the Adverse Events compared with other comparable drugs, were representations made for the purpose of promoting the business interests of the Janssen Defendants and promoting Risperdal and/or Invega. These representations were made to the public, including the plaintiffs and other injured class members. They were false and misleading in a material respect, they were made by the Defendants knowingly or recklessly, as aforesaid.

128. The plaintiffs and other class members relied on the Janssen Defendants' claims regarding the safety ~~and effectiveness~~ of Risperdal and/or Invega as aforesaid by buying Risperdal and/or Invega and suffered injury and loss as a result, in relation to Adverse Events.

129. Accordingly, the Janssen Defendants have breached s.52 of the *Competition Act*,

in knowingly or recklessly making false and/or misleading representations to the public in relation to the Adverse Events. By reason of such breach, the Janssen Defendants are liable under s.36 of the *Competition Act* in damages, and for the costs of investigating and pursuing this action.

130. The plaintiffs plead and rely upon the *Food and Drugs Act*. Contrary to sections 8 and 11 of the *Food and Drugs Act*, the Janssen Defendants sold to the plaintiffs and other class members batches of Risperdal and/or Invega that were, or included ingredients that were, manufactured, prepared, preserved, packaged or stored under unsanitary conditions, or that were adulterated. Such batches originated in the Defendants' plants. Contrary to s.9 of the *Food and Drugs Act*, the Janssen Defendants labelled, packaged, treated, processed, sold or advertised Risperdal and Invega as aforesaid in a manner that was false, misleading or deceptive or was likely to create an erroneous impression regarding their character, value, quantity, composition, merit or safety.

f. Waiver of Tort

131. The plaintiffs and the other class members are entitled to waive the tort and require the Janssen Defendants to account for all the revenue they received from the sale of Risperdal and Invega ~~and, as regards the Publishers, require them to account for all revenue they received from the Janssen Defendants in Canada in respect of Risperdal and Invega~~.

132. The plaintiffs plead that waiver of tort may be appropriate for the following reasons, among others:

a. Such revenues were acquired in such circumstances that the Defendants cannot in good conscience retain those revenues:

b. The integrity of the pharmaceutical regulations and marketplace would be undermined if the court did not require an accounting:

c. Risperdal and Invega could not have been marketed, and the Defendants would not have received, directly or indirectly, any revenue from their sale in Canada, absent the Defendants' said egregious conduct;

d. The Defendants engaged in wrongful conduct by putting into the marketplace pharmaceutical products that cause or have the potential to cause increased risks of ~~injury and death~~ the Adverse Events;

e. The Publishers engaged in wrongful conduct by misrepresenting the safety ~~and efficacy~~ of Risperdal and Invega in scientific literature in relation to the Adverse Events; and

f. The Defendants would be unjustly enriched if they were permitted to retain revenues realized, directly or indirectly, from the sale of Risperdal and Invega.

g. Unjust enrichment

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

the plaintiffs and other class members did not receive a product of the ~~quality, nature or fitness~~ safety that had been represented by the Defendants or reasonably expected by the plaintiffs and other class members.

134. By virtue of the conscious wrongdoings alleged, the Janssen Defendants have been unjustly enriched at the expense of harm to the plaintiffs and other class members.

135. There is no juristic reason for the Janssen Defendants' enrichment.

h. Conspiracy

136. 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.

137. 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.

138. 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.

139. These meetings between the Defendants as aforesaid were held for an illegal purpose, *i.e.,* in relation to the Adverse Events, 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, ADHD, OCD, ODD, CD, DBD, Tourette's syndrome, Post-Traumatic Stress Disorder, PDD, and substance abuse.

140. All of the Defendants acted with a common purpose negligently, intentionally and/or fraudulently to withhold information regarding the safety of Risperdal and Invega in relation to the Adverse Eventsfor the purpose of earning profits at the expense of the plaintiffs' and class members' health.

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

142. The plaintiffs plead that the Defendants' conspiracy involved unlawful means with the predominant purpose of causing the plaintiffs and putative class members to use Risperdal and/or Invega. In conspiring unlawfully to develop, design, license, manufacture, distribute, sell, and market ~~thes~~ these ~~this~~ unsafe products, ~~the~~ having regard to the Adverse Events, the Defendants knew or ought reasonably to have known that such use would cause harm to the plaintiffs and other class members in the form of Adverse Events.

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

a. causing the plaintiffs 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 plaintiffs and other class members;

f. maintaining their brand and corporate image; and

g. keeping the plaintiffs and other class members, their physicians, and Health Canada in the dark regarding the dangerous properties and effects of Risperdal and Invega, namely the risk of Adverse Events.

144. 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– namely, the risk of Adverse Events –from Health Canada, from health practitioners and from the plaintiffs and other class members;

c. They misled the plaintiffs 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 in relation to Adverse Events became manifest; and

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.

145. As a result of the said conspiracy, the plaintiffs and other class members used Risperdal and/or Invega and thereby have suffered damage and loss.

VII. DAMAGES AND OTHER SUBROGATED CLAIMS

a. General and Special Damages

146. As a result of the Defendants' negligence and other actionable conduct as set out above, the plaintiffs 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, ~~generic risperidone,~~ and Invega as paid for by the plaintiffs, class members and by the Ontario Health Insurance Plan ("OHIP"), 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.

147. As a result of the Defendants' negligence and other actionable conduct as set out above, and the resulting injuries to the plaintiffs and other class members in the form of Adverse Events, members of the family class have suffered loss and damage. They have incurred out-of-pocket expenses for the benefit of the plaintiffs and other class members. They have suffered and will continue to suffer loss of income. They have paid for or provided nursing, housekeeping and other services. They have suffered a loss of support, guidance, care and companionship that they might reasonably have expected to receive if the injuries to the plaintiffs and other class members had not occurred.

b. Subrogated Claims

148. The Ontario Ministry of Health and Long-Term Care provide coverage for healthcare services to Ontario residents through OHIP. Similar programs are available in other provinces.

149. The plaintiffs 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 OHIP and other provincial health insurers.

150. OHIP and other provincial health insurers will continue to provide treatment in the future to the plaintiffs and other class members.

151. The subrogated interest of OHIP and all other provincial health insurers includes the cost of all past and future insured services for the benefit of the plaintiffs and all other class members.

152. The cost of the purchase of Risperdal, ~~generic risperidone,~~ and Invega by the plaintiffs 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.

153. 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, ~~generic risperidone,~~ and Invega on behalf of the plaintiffs and other members of the class and they seek a full indemnification of the purchase price.

154. The plaintiffs state that they and the other class members would not have used Risperdal, ~~generic risperidone,~~ and/or Invega if the Defendants had acted reasonably and responsibly.

155. The plaintiffs and the other class members are entitled to recover from the Defendants as special damages the cost of purchasing Risperdal and/or Invega. But for the Defendants' wrongdoing as particularized above, the plaintiffs and other class members would not have incurred the expense of purchasing Risperdal and/or Invega.

c. Punitive and Aggravated Damages

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

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

158. Despite the Defendants' knowledge of Risperdal's and Invega's defective and unreasonably dangerous nature, the Janssen 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 plaintiffs and other class members, inconscious and callous disregard of the foreseeable harm in the form of Adverse Events caused by Risperdal and Invega. The Janssen Defendants used the Publishers to promote Risperdal and Invega in the scientific literature in order to maximize sales and profits at the expense of the health and safety of the public, including the plaintiffs and other class members, in conscious and callous disregard of the foreseeable harm in the form of Adverse Events caused by Risperdal and Invega.

159. The Defendants' conduct was high-handed, outrageous, reckless, egregious, deliberate, disgraceful, wilful, callous, and in wanton disregard of the rights and safety of the plaintiffs 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 plaintiffs and other members of the class.

160. 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 relation to the Adverse Events 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 plaintiffs and other class members.

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

VIII. DISCOVERABILITY

162. For the reasons stated above as regards the plaintiff Brown discovering that he suffers from gynecomastia and that Risperdal ~~or generic risperidone~~ was the cause of his injuries, the plaintiff was unable to commence the herein action before this time.

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

164. As a result of the Defendants' wrongful conduct, class members suffered, and continue to suffer~~, gynecomastia, other~~ from the Adverse Events, and/or other severe and permanent injuries arising therefrom.

IX. STATUTES

165. The plaintiffs plead and rely upon s.101 of the *Courts of Justice Act*, R.S.O. 1990, c.43, Rule 40 of the Ontario *Rules of Civil Procedure* and, *inter alia,* upon the following legislation:

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

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 A*ct R.S.NW.T. 1988, C.S-2

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

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

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

and all relevant amendments thereto.

X. SERVICE OUTSIDE ONTARIO

166. This originating process may be served without court order outside Ontario in that the claim is:

a. In respect of a tort committed in Ontario (Rule 17.02(g));

b. In respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed (Rule 17.02(h));

c. In respect of property in Ontario (Rule 17.02 (a));

d. Against a person outside Ontario who is a necessary or proper party to a proceeding properly brought against another person served in Ontario (Rule 17.02 (o)); and

e. Against a person carrying on business in Ontario (Rule 17.02 (p)).

167. The plaintiffs, therefore, submits that judgment be granted for the relief sought, together with costs on a substantial indemnity scale.

The plaintiffs propose that the herein action be tried at Toronto.

Dated: January 8, 2014.
November 8, 2017

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NICHOLAS BROWN et al v. JANSSEN INC. et al

Court File No. 06-CV-321585 CP

ONTARIO
SUPERIOR COURT OF JUSTICE

Proceedings commenced at Toronto

Proceedings under the Class Proceedings Act, 1992

AMENDED AMENDED FRESH AS AMENDED STATEMENT OF CLAIM

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