Form 4.02A

2014

Hfx No. 428996

Supreme Court of Nova Scotia

Between:

DAWN RAE DOWNTON as executor of
THE ESTATE OF MARION WISEMAN

Plaintiff

and

BOEHRINGER INGELHEIM (CANADA) LTD., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM PHARMA GMBH & CO KG, and BOEHRINGER INGELHEIM INTERNATIONAL GMBH

Defendants

Notice of Action

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

To: BOEHRINGER INGELHEIM (CANADA) LTD.

To: BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

To: BOEHRINGER INGELHEIM PHARMA GMBH & CO KG

To: BOEHRINGER INGELHEIM INTERNATIONAL GMBH

Action has been started against you

The Plaintiff takes action against you.

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

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

Deadline for defending the action

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

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

Judgment against you if you do not defend

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

You may demand notice of steps in the action

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

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

Rule 57 - Action for Damages Under $100,000

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

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

Filing and delivering documents

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

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

Contact information

The Plaintiff designates the following address:

McPhadden Samac Tuovi LLP
Lawyers

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

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

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

Further contact information is available from the prothonotary.

Proposed place of trial

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

Signature
Signed , June 27, 2014

per.

Bryan C. McPhadden as counsel
for Dawn Rae Downton as executor
of the Estate of Marion Wiseman

Prothonotary's certificate

I certify that this notice of action, including the attached statement of claim, was filed with the court on , Sep 2nd, 2014 .

~~Prothonotary~~
Theaston White
Deputy Prothonotary

Form 4.02B

Statement of Claim

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

THE PLAINTIFF

1. Marion Wiseman ("Marion") was a resident of Nova Scotia until her death in December 2013.

2. On or about April 2, 2013, Marion underwent hip replacement surgery.

3. Marion had for some years also suffered from atrial fibrillation.

4. On or about April 16, 2013, Marion was prescribed and she ingested the drug marketed as Pradaxa.

5. On or about April 22, Marion suffered internal and uterine bleeding.

6. Marion's use of Pradaxa was immediately discontinued.

7. Dawn Rae Downton ("Dawn") is Marion's daughter.

8. By the terms of the Plaintiff's Will, Dawn and her sister are co-executrices of Marion's estate. The sister of Dawn predeceased Marion, dying in November 2013, leaving Dawn as sole executor of Marion's estate.

9. Dawn is, therefore, the sole representative of Marion's estate with authority to commence the herein action on behalf of Marion's estate.

10. As Marion's daughter, Dawn is also bringing the herein action on behalf of family members of putative class members who, like Marion, were injured as a result of using Pradaxa (the "Family Class", as defined below).

THE DEFENDANTS

a. Boehringer Ingelheim (Canada) Ltd

11. The Defendant Boehringer Ingelheim (Canada) Ltd. ("BICL") is a corporation incorporated pursuant to the laws of the Dominion of Canada, with its registered head office and principal place of business in the city of Burlington in the Province of Ontario.

12. BICL is the "sponsor" or "market authorization holder" for Pradaxa in Canada. A sponsor or market authorization holder is the entity registered with Health Canada to submit for approval a drug and, if approval is granted, to market the drug in Canada.

13. BICL was responsible, as the sponsor, to warn Health Canada (and by extension, putative class members) about the risks associated with the new drug it was submitting for approval. As the sponsor of Pradaxa, BICL shouldered a duty to warn class members about the risk of bleeding and the lack of a reversal agent should bleeding occur. To use Health Canada's language, BICL had the "primary responsibility" for the safety of any Pradaxa it sold, manufactured, imported or distributed to the Canadian public.

14. The manufacturer of a drug and its sponsor need not be the same company. While the sponsor is the company that conducts clinical studies in respect of a drug and seeks its approval, a manufacturer is the company that actually sells the drug in Canada. BICL is identified as the

manufacturer of Pradaxa in Health Canada communications issued to the public and health-care professionals. BICL is also identified by Health Canada as the "Manufacturer/Sponsor" of Pradaxa in the Summary Basis for Decision for the drug. The Summary Basis for Decision is the document issued by Health Canada to a drug's sponsor when a decision has been made by the regulator approving a drug for sale in Canada.

15. According to an organizational chart published on Boehringer Ingelheim's website, BICL is involved in "distribution" of drugs, presumably including Pradaxa.

16. BICL sold Pradaxa to Marion and other putative class members.

17. BICL received reports of adverse reactions regarding Pradaxa from class members, health care professionals, and the other Defendants. It was BICL to which Health Canada directed that adverse reactions be reported.

18. As the drug's sponsor, BICL had an obligation to monitor the post-marketing experience of putative class members' use of Pradaxa and to report to Health Canada, to health-care professionals, and to patients using Pradaxa, any signals of excessive bleeding as an adverse reaction.

19. Pradaxa was approved for sale in Canada and abroad on the strength of safety data that was generated from a clinical trial known by its acronym as RE-LY. RE-LY was conducted by Ontario entities unrelated to the Defendants. BICL was involved in sponsoring, coordinating, administering, supervising, designing, and implementing the RE-LY trial, either directly or through the Ontario entities that conducted it. According to Boehringer Ingelheim's organizational chart, BICL is involved in research and development, presumably including Pradaxa.

20. BICL was involved in the packaging, labelling, and marketing of Pradaxa in Canada, as seen from a January 2013 letter from BICL to health-care providers announcing the change in name from Pradax, as it was then marketed, to Pradaxa.

21. BICL participated in the decision to introduce Pradaxa into the stream of commerce without first making available a reversal agent to correct excessive bleeding.

22. BICL made or participated in the decision not to warn Health Canada, Canadian health-care professionals, and Canadian class members about the risk of irreversible excessive bleeding caused by Pradaxa.

b. Boehringer Ingelheim Pharmaceuticals, Inc.

23. The Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation incorporated in the State of Delaware, in the United States of America.

24. Just as BICL sponsored the application to have Pradaxa approved in Canada, BIPI sponsored the drug's "New Drug Application" with the U.S. Food and Drug Administration ("FDA"). The first U.S. approval for Pradaxa was issued to BIPI. Accordingly, it was BIPI with which the FDA charged the task of informing patients about the serious risks associated with the use of Pradaxa.

25. BIPI authored the labelling for Pradaxa in the U.S. The U.S. labelling for Pradaxa directs the public and health-care professionals to report suspected adverse reactions to BIPI.

26. BIPI conducted some of the testing on Pradaxa prior to its approval. BIPI presented the results of its studies to the FDA as part of the approval process for Pradaxa in the U.S.

27. BIPI is also described as being involved in "research and development" in Boehringer Ingelheim's corporate organizational chart.

28. BIPI is the entity to which visitors of the website www.pradaxa.com are referred when they visit the "Contact Us" page hosted on that website. As the internet and that site are universally accessible, it is reasonable to presume that Canadian class members would have received health and safety information from BIPI's website. Especially because there is no stand-alone Canadian website for Canada (www.pradaxa.ca simply redirects to BICL's homepage), any information obtained by Canadians through the Canadian site would originate from BIPI's site. BIPI's www.pradaxa.com website hosts prescribing information, safety information, and a medication guide, which putative class members read and relied upon.

29. BIPI distributed Pradaxa in the U.S. and Canada.

30. Health Canada relied on information originating with BIPI and the other foreign Defendants in deciding to approve Pradaxa for sale in Canada.

31. BIPI participated in the decision to introduce Pradaxa into the stream of commerce without first making available a reversal agent to correct excessive bleeding.

32. BIPI made or participated in the decision not to warn Health Canada, Canadian health-care professionals, and Canadian class members about the risk of irreversible excessive bleeding caused by Pradaxa.

33. BIPI suppressed internally generated and unfavourable safety data regarding Pradaxa, fearing that the release of such data would impact on sales. The suppression of such data resulted in harm to Canadian putative class members.

c. Boehringer Ingelheim Pharma GmbH & Co KG

34. The Defendant Boehringer Ingelheim Pharma GmbH & Co KG ("BIP") is a corporation incorporated in the Republic of Germany.

35. BIP, like BICL and BIPI, has a great deal of involvement with Pradaxa, and participated heavily in both the manufacturing and the development of the drug.

36. According to documents filed with the FDA as part of the New Drug Application for Pradaxa, BIP was involved in all aspects of the manufacturing process of the drug product, testing of excipients, testing of drug product intermediates, primary and secondary packaging of drug product, labeling of drug product, testing of drug product, including stability testing. BIP provided the FDA with data that informed the FDA's decision to approve Pradaxa for sale in the United States. Health Canada similarly relied on information provided by BIP.

37. BIP participated in the decision to introduce Pradaxa into the stream of commerce without first making available a reversal agent to correct excessive bleeding.

38. BIP made or participated in the decision not to adequately warn Health Canada, Canadian health-care professionals, and Canadian class members about the risk of irreversible excessive bleeding caused by Pradaxa.

39. The trademark for Pradaxa in Canada is owned by BIP, which licenses its use to BICL and BIPI. As the holder of the marks for Pradaxa, BIP had the right and the duty to control the use of the marks by BIPI and BICL.

40. BIP is identified as a sponsor of some of the studies regarding Pradaxa according to other FDA documents.

d. Boehringer Ingelheim International GmbH

41. The Defendant Boehringer Ingelheim International GmbH ("BII") is a corporation incorporated in the Republic of Germany.

42. BII owns the patent for the manufacture of Pradaxa in Canada.

43. BII manufactured Pradaxa that was consumed by putative class members.

44. BII was involved in the development of Pradaxa and participated in the decision to introduce Pradaxa into the stream of commerce without first making available a reversal agent to correct excessive bleeding.

45. BII made or participated in the decision not to warn Health Canada, Canadian health-care professionals, and Canadian class members about the risk of irreversible excessive bleeding caused by Pradaxa.

e. The Defendants Generally

46. At all material times, the Defendants, directly or through their agents, designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold Pradaxa for use by patients throughout the world, including Nova Scotia and the rest of Canada.

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

a. Each was the agent of the other;

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

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

d. Each Defendant operated pursuant to a common business plan to distribute and sell Pradaxa;

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

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

THE CLASS

48. Dawn brings this action on behalf of Marion's estate and on behalf of a class defined as follows ("the Class").

a. All persons throughout Canada who purchased and/or ingested the drug Pradaxa (formerly marketed as Pradax) and their estates, administrators or other legal representatives ("the Class"); and

b. All persons who have a derivative claim on account of a family relationship with a person in (a.) under any of the Dependants Statutes in Canada as a result of the death or personal injury of such member of the Class (the "Family Class").

c. "Dependants Statutes" means the Family Law Act (Ontario), Family Compensation Act (B.C.), Fatal Accidents Act (Alberta), Tort-feasors Act

(Alberta), Fatal Accidents Act (Saskatchewan), Fatal Accidents Act (Manitoba), Code Civil (Quebec), Consumer Protection Act (Quebec), Fatal Accidents Act (New Brunswick) Fatal Accidents Act (P.E.I), Fatal Injuries Act (Nova Scotia), Fatal Accidents Act (Newfoundland), Fatal Accidents Act (Nunavut), Fatal Accidents Act (Northwest Territories) and Fatal Accidents Act (Yukon).

PRADAXA

49. Pradaxa is a blood thinner used to prevent blood clotting in certain patients. Blood clotting can cause the occurrence of strokes.

50. Pradaxa is approved for use by patients who suffer from atrial fibrillation, as well as patients who had hip and knee surgery. Atrial fibrillation is a condition in which the heart beats irregularly, increasing the chance of clots forming in the body and possibly causing strokes. Atrial fibrillation accounts for about 15 to 20 per cent of all strokes in Canada and mostly affects the elderly.

51. Pradaxa was approved by Health Canada for hip and knee surgery patients on June 10, 2008. It was subsequently approved for atrial fibrillation patients in October of 2010. Health Canada approved three dosages, 75 mg, 110 mg and 150 mg, to be taken twice daily.

52. Pradaxa is among a class of blood thinners (or "anticoagulants") known as direct thrombin inhibitors. Also in that class is the drug, warfarin, a drug that has been on the market for approximately 50 years. Unlike patients who use Pradaxa, users of warfarin must follow dietary restrictions and regularly monitor their blood levels by undergoing blood tests and potentially adjusting the dose of their medication.

53. Prior to Health Canada's approval of Pradaxa, warfarin was the only oral anticoagulation available in Canada for reducing stroke and systemic embolism in patients with atrial fibrillation.

54. The Defendants promoted Pradaxa as a novel medicine for patients with atrial fibrillation. The Defendants' marketing campaign for Pradaxa included promoting it as being more effective than warfarin in preventing stroke and systemic embolism and, providing a convenient alternative to warfarin therapy because (i) it does not require blood monitoring or dose adjustments and (ii) it does not require dietary restrictions.

HARM CAUSED BY PRADAXA

55. Shortly after Pradaxa was first approved for sale in the United States and Canada, adverse event came to be reported to the FDA and to Health Canada in the United States and Canada, respectively.

56. In the United States, within 12 weeks of initial marketing approval, Pradaxa was the suspected drug in 307 reported serious adverse events. Most of the adverse event reports involved serious bleeding or blood clots in the elderly. From October 2010 to the end of June 2011, there were almost 1,800 Pradaxa-associated "Serious Adverse Events" ("SAEs") reported to the FDA, including over 1,000 reports of life-threatening bleeding. As of December 31, 2011, the FDA received over 500 reports of deaths of people in the U.S. linked to Pradaxa. In addition, as of December 31, 2011, there were over 900 reports of gastrointestinal hemorrhages, over 300 reports of rectal hemorrhages, and over 200 reports of cerebrovascular accidents suffered by U.S. citizens associated with Pradaxa.

57. In Canada, the SAEs are known as Adverse Event Reports ("AERs"). The first AER regarding Pradaxa was submitted to Health Canada in March 2009.

58. As of June 2014, 1,700 AERs had been registered with Health Canada regarding Pradaxa.

59. Many of those AERs registered with Health Canada indicated that death had resulted from Pradaxa.

60. The harm caused by Pradaxa has also come to the attention of regulators in other jurisdictions where it has been approved for sale:

a. On January 21, 2011, Pradaxa (under the brand name Prazaza), in 75mg and 110mg doses only, was approved for sale in Japan to treat non-valvular atrial fibrillation. On August 11, 2011, Japan's pharmaceutical regulatory authority announced that it was requiring that a "boxed warning" be added to Pradaxa/Prazaza to call attention to reports of severe hemorrhages in patients treated with Pradaxa/Prazaza, including reports of fatalities.

b. On July 11, 2011, Pradaxa was approved for sale in New Zealand with lower dosing (lowered from 150mg to 110mg twice a day) required for patients over 80 years of age and recommended for patients with moderate renal impairment. On September 1, 2011, the New Zealand pharmaceutical regulatory authority issued a "Prescriber Update" entitled "Dabigatran – Is there a Bleeding Risk" in which physicians were alerted that Pradaxa had a higher incidence of gastrointestinal bleeds than warfarin and that there was no reversal agent to neutralize the

anticoagulation effects of Pradax. A follow-up report issued in December 2011, indicated that among 10,000 New Zealanders who had taken Pradaxa, there were 78 reports of serious bleeding events associated with Pradaxa including 60 reports of gastrointestinal and rectal bleeding. Among the 78 serious events were 10 patient deaths and 55 hospitalizations. Three months later in March, 2012 the New England Journal of Medicine published two letters from physicians in New Zealand addressing bleeding events associated with Pradaxa. In one letter, physicians wrote, "We are concerned that the potential risks of this medication are not generally appreciated. The serious consequences of a lack of an effective reversal agent should not be underestimated."

61. The harm caused by Pradaxa has also been the subject of scientific scholarship. On July 25, 2011, the Archives of Internal Medicine published "The Use of Dabigatran [Pradaxa] in Elderly Patients", a report in which the authors concluded that "[t]he risk of major overdosage of...[Pradaxa] in this [elderly] population is, however, much increased owing to frequent renal function impairment, low body weight, drug interactions that cannot be detected with a routine coagulation test and no antagonist available."

62. The harm caused by Pradaxa is two-fold. Like other anti-coagulants such as warfarin, it causes excessive bleeding, which can result in severe injury and death; unlike warfarin, however, in which such excessive bleeding can readily be stopped through the administration of vitamin K, there is no known antidote to excessive bleeding caused by Pradaxa. Elderly patients and patients with renal impairments are particularly vulnerable to the excess bleeding caused by Pradaxa.

CAUSES OF ACTION

a. Failure to Warn

63. The Defendants owed Marion and other class members a duty of care as follows:

a. to warn them and their treating healthcare professionals that ingestion of Pradaxa carried significant, and specifically identified, health risks including the risk of bleeding;

b. to warn them and their treating healthcare professionals that, unlike warfarin, there existed no antidote to excess bleeding caused by Pradaxa;

c. to ensure that prescribing physicians and other healthcare professionals were apprised and fully and regularly informed of all of the health risks associated with ingesting Pradaxa;

d. to warn them and their treating healthcare professionals that elderly patients, patients with impaired renal functions, and patients with a history of gastro-intestinal bleeding are particularly vulnerable to the risks of unstoppable, excessive bleeding caused by Pradaxa;

e. to inform Health Canada fully, properly, and in a timely manner of the health risks and complaints, including those listed herein, associated with the ingestion of Pradaxa;

f. to provide truthful and complete information to Health Canada when submitting the New Drug Submission ("NDS") for Pradaxa;

g. to provide complete and accurate clinical and non-clinical data to Health Canada throughout the approval process for Pradaxa and subsequent to its approval, including when they submitted to Health Canada for approval the NDS for Pradaxa, when they submitted to Health Canada for approval the product monographs for Pradaxa, and subsequent to the issuance by Health Canada of the Notice of Compliance for Pradaxa;

h. promptly to report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to Pradaxa subsequent to its approval for sale in Canada;

i. 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;

j. to provide truthful and complete information in the product monographs for Pradaxa, and particularly in Parts I and III of such monographs, which are directed to healthcare professionals and patients, respectively; and

k. to advertise Pradaxa to healthcare professionals in a manner that adequately discloses the drug's risk of harm and the lack of an effective antidote in the event of bleeding caused as a side effect by Pradaxa.

64. The Defendants breached their duty of care as follows:

a. The Defendants' original labelling, product monograph, and prescribing information for Pradaxa failed to disclose, adequately or at all, that Pradaxa could cause excess bleeding;

b. The Defendants' original labelling, product monograph, and prescribing information for Pradaxa failed to warn patients with renal impairments and elderly patients that they were particularly vulnerable to excess bleeding caused by Pradaxa;

c. The Defendants' original labelling, product monograph, and prescribing information for Pradaxa, failed to disclose, adequately or at all, that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa;

d. The Defendants failed to warn Marion, other class members, healthcare professionals, and Health Canada, that Pradaxa was prone to cause excess bleeding, that elderly patients and patients with renal impairments were particularly vulnerable to harm from excess bleeding caused by Pradaxa, and that there was no known antidote for the excess bleeding caused by Pradaxa;

e. The Defendants failed to advise prescribing physicians, such as Marion's physician, to instruct patients that Pradaxa was prone to cause excess bleeding, to monitor the renal function of patients being prescribed Pradaxa, to exclude those patients identified as having severe renal impairment or a history of gastro-intestinal bleeding, to monitor patients being administered Pradaxa for renal function and be alert to a decline in renal function, and to warn patients that there was no agent to reverse the anticoagulation effects of Pradaxa;

f. The Defendants failed to warn Marion, other class members, healthcare professionals, and Health Canada, that it is difficult or impossible to assess the degree/ or extent of anticoagulation in patients taking Pradaxa;

g. The Defendants knowingly or recklessly provided misleading or incomplete information to Health Canada when submitting the NDS for Pradaxa. More particularly, but without limitation, the Defendants did not disclose to Health Canada complete evidence regarding the clinical effectiveness of Pradaxa, the drug's contra-indications and side effects, and the fact that there was no effective antidote for excessive bleeding caused by Pradaxa;

h. The Defendants withheld important clinical and non-clinical data from Health Canada throughout the approval process for Pradaxa and subsequent to its approval, including when they submitted to Health Canada for approval the NDS for Pradaxa, when they submitted to Health Canada for approval the product monographs for Pradaxa, and subsequent to the issuance by Health Canada of the Notice of Compliance for Pradaxa;

i. The Defendants failed promptly or at all to report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to Pradaxa subsequent to its approval for sale in Canada;

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

k. The Defendants knowingly or recklessly provided misleading or incomplete information in the product monographs for Pradaxa, and particularly in Parts I and

III of such monographs, which are directed to healthcare professionals and patients, respectively; and

l. The Defendants advertised Pradaxa to healthcare professionals in a manner that did not adequately or at all disclose the drug's risk of harm and the lack of an effective antidote in the event of bleeding caused as a side effect by Pradaxa.

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

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

b. The Defendants advertised, promoted and marketed Pradaxa directly to Marion and other class members by means of so-called "reminder advertising", in which the name of a product, its strength, dosage, form and price are revealed, but not the product's indication or effectiveness. The Defendants also advertised, promoted and marketed Pradaxa directly to Marion 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 consumed by Canadians; and

c. There was a high degree of consumer involvement regarding the prescription of Pradaxa given that Pradaxa was the first new anti-coagulant approved for sale in Canada in over 50 years.

b. Negligence

66. The Defendants additionally owed Marion and other class members a duty of care as follows:

a. to conduct adequate tests and clinical trials prior to releasing Pradaxa into the market to determine the degree of risk associated with ingesting the drug;

b. to ensure that Pradaxa was not released into the market prior to satisfying themselves that there existed an agent or means with which to reverse the excessive bleeding that could be caused by Pradaxa;

c. to ensure that Pradaxa was fit for its intended or reasonably foreseeable use;

d. once Pradaxa was released into the market, to conduct ongoing tests and clinical trials with long term follow-up to determine the long-term effects and risks associated with the long-term ingestion of Pradaxa;

e. to monitor the post-market effects of Pradaxa;

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

g. to manufacture, package, label, test, import, distribute and sell Pradaxa 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*;

h. to submit truthful and complete information to Health Canada when submitting the NDS for Pradaxa;

i. to provide Health Canada with complete and accurate clinical and non-clinical data throughout the approval process for Pradaxa and subsequent to its approval;

j. promptly to report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to Pradaxa subsequent to its approval for sale in Canada; and

k. to advertise Pradaxa in a manner that adhered with the standards set out in the Pharmaceutical Advertising Advisory Board Code of Advertising Acceptance.

67. The Defendant breached their duty of care as follows:

a. They failed to conduct adequate tests and clinical trials prior to releasing Pradaxa into the market to determine the degree of risk associated with ingesting the drug;

a. They released Pradaxa into the market knowing, or having ought to have known, that there existed no agent or means with which to reverse the excessive bleeding that could be caused by Pradaxa;

b. They released Pradaxa into the market knowing, or having ought to have known, that it was fit neither for its intended use nor for its reasonably foreseeable use. Indeed, the drug was unreasonably dangerous to an extent beyond that which

could reasonably be contemplated by Marion and class members and their physicians. Accordingly, any benefit of Pradaxa was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended;

c. The Pradaxa distributed by the Defendants was defective;

d. Once Pradaxa was released into the market, they failed to conduct ongoing tests and clinical trials with long term follow-up to determine the long-term effects and risks associated with the long-term ingestion of Pradaxa;

e. They failed to monitor the post-market effects of Pradaxa;

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

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

h. They over-promoted the benefits of Pradaxa for anticoagulation therapy in patients suffering from atrial fibrillation and understated the risk of excessive and/or uncontrollable bleeding;

i. They failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa;

a. They failed to include a 'boxed warning' about serious bleeding events associated with Pradaxa;

b. They failed to manufacture, package, label, test, import, distribute and sell Pradaxa in accordance with the *Food and Drugs Act* and the *Food and Drug Regulations*;

c. They knowingly or recklessly provided misleading or incomplete information to Health Canada when submitting the NDS for Pradaxa. More particularly, but without limitation, the Defendants did not disclose to Health Canada complete evidence regarding the clinical effectiveness of Pradaxa, the drug's contra-indications and side effects, and the fact that there was no effective antidote for excessive bleeding caused by Pradaxa;

d. They withheld important clinical and non-clinical data from Health Canada throughout the approval process for Pradaxa and subsequent to its approval, including when they submitted to Health Canada for approval the NDS for Pradaxa, when they submitted to Health Canada for approval the Product Monographs for Pradaxa, and subsequent to the issuance by Health Canada of the Notice of Compliance for Pradaxa;

e. They failed promptly or at all to report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to Pradaxa subsequent to its approval for sale in Canada; and

f. They advertised Pradaxa in a manner that failed to adhere with the standards set out in the Pharmaceutical Advertising Advisory Board Code of Advertising Acceptance.

68. In January and then again in April of 2012, the Defendants modified the U.S. labeling and prescribing information for Pradaxa. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa; (ii) a July 25, 2011 article in the Archives of Internal Medicine concluding that the risk of harm in elderly populations is much increased and that there exists no antidote to excessive bleeding; (iii) the addition of a boxed warning to Pradaxa in Japan; (iv) questions being raised by physicians and the regulator in New Zealand about serious bleeding events associated with Pradaxa; and (v) a Drug Safety Communication published by the FDA in December, 2011 announcing that it was undertaking a "Drug Safety Review" of post-marketing reports of serious bleeding events with Pradaxa, the Defendants nonetheless failed to provide adequate disclosures or warnings in their label regarding the risks associated with Pradaxa as detailed above.

69. At all times, the Defendants' warnings to Canadians with respect to Pradaxa lagged behind the Defendants' state of knowledge regarding the drug's risks, and lagged both in their timing and comprehensiveness behind the Defendants' warnings in relation to Pradaxa abroad.

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

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

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

a. It was as a result of the Defendants' claims regarding the effectiveness, safety, and benefits of Pradaxa, and the Defendants' failure to warn about the risks of serious injury associated with Pradaxa, that Marion, other class members, and Marion's physicians healthcare professionals, and Health Canada, were unaware, and could not reasonably have known or have learned through reasonable diligence that Marion would be exposed to the risk of excessive and/or uncontrollable bleeding and the other risks and injuries described herein;

b. It was as a result of the Defendants' failure to warn about the risks of serious injury associated with Pradaxa, as aforesaid, that Marion and class members were unaware of the increased risk for developing life-threatening injuries as compared to warfarin. Had Marion, the other and class members, healthcare providers, and Health Canada known of the risks and dangers associated with Pradaxa, as well as the lack of additional benefits, and had the Defendants provided adequate

warnings that there is no agent to reverse the anticoagulation effects of Pradaxa, Marion and class members would not have used Pradaxa; and

c. As a direct and proximate result of using Pradaxa, Marion and class members have suffered severe personal injuries, physical pain and mental anguish.

c. Breach of Express Warranty

73. The Defendants expressly warranted, through their direct-to-consumer marketing, reminder marketing, labeling, product monographs, and sales representatives, that Pradaxa was a safe and effective prescription blood thinner. The safety and efficacy of Pradaxa constitute material facts in connection with the marketing, promotion, and sale of Pradaxa.

74. Pradaxa manufactured and sold by the Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

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

d. Breach of Implied Warranty

76. At the time the Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released Pradaxa

into the stream of commerce, the Defendants knew of the use for which Pradaxa was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

77. The Defendants breached their implied warranties of the Pradaxa product sold to Marion and other class members because this product was not fit for its common, ordinary, and intended use.

78. As a direct, foreseeable and proximate result of the Defendants' breaches of implied warranties, Marion and other class members suffered bodily injury and consequential economic and other losses, as described above, when Marion and other class members ingested Pradaxa, in reasonable reliance upon the implied warranties.

e. Waiver of Tort

79. The Plaintiff and the other class members are entitled to waive the tort and require the Defendants to account for all the revenue they received from the sale of Pradaxa in Canada.

80. The Plaintiff pleads 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. Pradaxa 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;

e. The Defendants engaged in wrongful conduct by misrepresenting the safety and efficacy of Pradaxa in scientific literature; and

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

f. Unjust enrichment

81. The Defendants voluntarily accepted and retained profits and benefits, derived from Marion and other class members, with full knowledge and awareness that, as a result of the Defendants' conscious and intentional wrongdoings, Marion and other class members did not receive a product of the quality, nature or fitness that had been represented by the Defendants or reasonably expected by Marion and other class members.

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

83. There is no juristic reason for the Defendants' enrichment.

g. Conspiracy

84. 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.

85. 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.

86. The Defendants conspired with one another for an illegal purpose, *i.e.* to conceal the fact that Pradaxa had a propensity to cause severe and irreversible bleeding, the fact that there was no antidote for Pradaxa, and the fact Pradaxa was dangerous as a result.

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

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

89. Marion pleads that the Defendants' conspiracy involved unlawful means with the predominant purpose of causing Marion and putative class members to use Pradaxa instead of older, more well-established and reversible anticoagulants. In conspiring unlawfully to develop, design, license, manufacture, distribute, sell, and market this unsafe product, the Defendants knew or ought reasonably to have known that such use would cause harm to Marion and other class members.

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

a. causing Marion and other class members to use Pradaxa.

b. maximizing profit from the sale of Pradaxa;

c. increasing or maintaining their market share in the anticoagulant pharmaceutical drug market;

d. avoiding adverse publicity;

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

f. maintaining their brand and corporate image; and

g. keeping Marion and other class members, their physicians, and Health Canada in the dark regarding the dangerous properties of Pradaxa and the lack of a reversal agent.

91. 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 Pradaxa in Canada;

b. They concealed and disguised information about the dangerous properties and effect of Pradaxa, as well as the lack of a reversal agent, from Health Canada, from health practitioners and from Marion and other class members;

c. They misled Marion and other class members, health practitioners and others about the efficacy, safety and effect of Pradaxa and the lack of a reversal agent;

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

e. They developed and used marketing and promotional strategies that covered up the truth about Pradaxa's dangerous properties and side effects, as well as the dangers arising from the lack of a reversal agent.

92. As a result of the said conspiracy, Marion and other class members used Pradaxa and thereby have suffered damage and loss.

h. Breach of Section 52 of the *Competition Act*, R.S. 1985, c. C-34

93. The Plaintiff relies on, and pleads a breach of, the *Competition Act*, R.S. 1985, c. C-34. The Defendants' claims regarding Pradaxa's safety, effectiveness, and effectiveness compared with other comparable drugs were representations made for the purpose of promoting the business interests of the Defendants and promoting these drugs. These representations were made to the public, including Marion and other class members. They were false and misleading in a material respect, and they were made by the Defendants knowingly or recklessly.

94. The Defendants have breached s.52 of the *Competition Act* in knowingly or recklessly making such false and/or misleading representations to the public. By reason of such breach, the Defendants are liable under s.36 of the *Competition Act* in damages, and for the costs of investigating and pursuing this action.

i. Breach of the *Consumer Protection Act*, R.S. c. 92

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

j. Breach of the *Sale of Goods Act*, R.S., c. 408

96. The Plaintiff pleads and relies upon the *Sale of Goods Act*, R.S. c. 408, ss. 2 and 17 and equivalent legislation in other provinces. Pradaxa was purchased by Marion and other class members pursuant to contracts of sale within the meaning of the *Sale of Goods Act*. The Defendants represented that Pradaxa was safe and effective for its indications. These representations were in fact false, misleading or deceptive.

97. The Plaintiff pleads that Pradaxa was not fit for its intended purpose nor of merchantable quality as an effective treatment for their approved indications, or as a more effective treatment for those indications than older, reversible anticoagulants or other comparable drugs. In making contrary representations, the Defendants acted in breach of section 17 of the *Sale of Goods Act*.

k. Breach of the *Food and Drugs Act*, R.S.C., 1985 c. F-27

98. The plaintiff pleads and relies upon the *Food and Drugs Act*. Contrary to s.9 of the *Food and Drugs Act*, the Defendants labelled, packaged, treated, processes, sold or advertised Pradaxa as aforesaid in a manner that was false, misleading or deceptive or was likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

DISCOVERABILITY

99. For the reasons stated about as regards Marion discovering that Pradaxa was the cause of her bleeding, neither Marion nor her estate were able to commence the herein action before this time.

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

DAMAGES AND OTHER SUBROGATED CLAIMS

a. General and Special Damages

101. As a result of the Defendants' negligence and other actionable conduct as set out above, Marion 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 Pradaxa as paid for by Marion, class members and by the Nova Scotia's Health Insurance Programs, and other provincial health insurers and drug benefit plans, and private third party payors as set out above;

c. Cost of past care and services;

d. Cost of future care and services; and

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

102. As a result of the Defendants' negligence and other actionable conduct as set out above, and the consequent injuries to Marion and other class members, Dawn and similarly situated members of the Family Class have suffered loss and damage. They have incurred out-of-pocket expenses for the benefit of Marion 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 Marion and other class members had not occurred.

b. Subrogated Claims

103. The Nova Scotia Department of Health and Wellness provides coverage for healthcare services to Nova Scotia residents through the Nova Scotia's Health Insurance Programs. Similar programs are available in other provinces.

104. Marion and other class members required hospitalization and other medical services as a result of the conduct of the Defendants as aforesaid. These medical services were paid for by the Nova Scotia's Health Insurance Programs and other provincial health insurers.

105. The Nova Scotia's Health Insurance Programs and other provincial health insurers will continue to provide treatment in the future to Marion and other class members.

106. The subrogated interest of the Nova Scotia's Health Insurance Programs and all other provincial health insurers includes the cost of all past and future insured services for the benefit of Marion and all other class members.

107. The cost of the purchase of Pradaxa by Marion 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.

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

109. The Plaintiff states that Marion and the other class members would not have used Pradaxa if the Defendants had acted reasonably and responsibly.

110. The Plaintiff and the other class members are entitled to recover from the Defendants as special damages the cost of purchasing Pradaxa. But for the Defendants' wrongdoing as particularized above, Marion and other class members would not have incurred the expense of purchasing Pradaxa.

c. Punitive and Aggravated Damages

111. At all material times, the Defendants knew or should have known that Pradaxa was inherently dangerous because of its propensity to cause irreversible bleeding.

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

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

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

115. 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 Pradaxa as being safe and efficacious in the scientific literature, and their continued manufacture, sale, and marketing or their products when they knew or should have known of the serious health risks created, evidences a flagrant disregard of human health as to warrant

the imposition of punitive damages as the acts or omissions were committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Marion and other class members.

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

117. For the reasons stated about as regards Marion discovering that Pradaxa was the cause of her bleeding, neither Marion nor the estate were able to commence the herein action before this time.

STATUTES

118. The Plaintiff pleads and relies upon section 43(9) of the *Judicature Act,* R.S.N.S. 1989, c. 240, Rules 41 and 68 of the *Nova Scotia Civil Procedure Rules* and, *inter alia,* upon the following legislation:

Nova Scotia

- *Class Proceedings Act*, S.N.S 2007, c. 28
- *Consumer Protection Act,* R.S.N.S. 1989, c.92
- *Contributory Negligence Act*, R.S.N.S. 1989, c 95
- *Fatal Injuries Act,* R.S.N.S. 1989, c. 163, amended 2000, c. 29, ss 9-12
- *Health Services Insurance Act*, R.S.N.S. 1989, c. 197
- *Hospitals Act*, R.S.N.S. 1989, c. 208

- *Sale of Goods Act*, R.S., c.408
- *Tortfeasors Act*, R.S.N.S. 1989, c. 471
- *Trustee Act*, RSNS 1989, c 479

Alberta

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

British Columbia

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

Manitoba

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

New Brunswick

- *Class Proceedings Act*, S.N.B. 2006, c.C-5.15
- *Consumer Product Warranty and Liability Act*, c. C-18.1
- *Contributory Negligence Act*, R.S.N.B. 2011, c 131
- *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7
- *Family Services Act*, S.N.B. 1980, c F-2.2
- *Hospital Services Act*, R.S.N.B. 1973, c. H-9
- *Prescription and Catastrophic Drug Insurance Act*, S.N.B. 2014, c 4
- *Sale of Goods Act*, R.S.N.B. 1973, c.S-1
- *Tortfeasors Act*, R.S.N.B. 2011, c 231

Newfoundland

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

Northwest Territories

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

Nunavut

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

- *Medical Care Act*, R.S.N.W.T. (Nu) 1988, c M-8
- *Sale of Goods Act*, R.S.N.W.T. (Nu) 1988, c S-2

Ontario

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

Prince Edward Island

- *Consumer Protection Act*, R.S.P.E.I. 1988, c. C-19
- *Contributory Negligence Act*, RSPEI 1988, c C-21
- *Family Law Act*, R.S.P.E.I 1988, c F-2.1
- *Fatal Accidents Act*, R.S.P.E.I. 1988, c. F-5, as amended
- *Health Services Act*, R.S.P.E.I. 1988, c H-1.6
- *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c H-8
- *Sale of Goods Act*, R.S.P.E.I. 1988, c. S-1

Quebec

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

Saskatchewan

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

Yukon

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

Canada

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

and all relevant amendments thereto.

JURISDICTION

119. The Plaintiff pleads and relies upon the *Court Jurisdiction and Proceedings Transfer Act* NS 2003 (2d Sess), c 2 ("*CJPTA*") and equivalent legislation in other Provinces.

120. The Plaintiff pleads that the Nova Scotia Courts have territorial competence over the foreign Defendants because there is a real and substantial connection between Nova Scotia and the facts on which this proposed class action is based.

121. There is a real and substantial connection between Nova Scotia and this proposed class proceeding pursuant to s.11 of the *CJPTA* because this action:

a. concerns contractual obligations that, to a substantial extent, were to be performed in Nova Scotia;

b. concerns restitutionary obligations that, to a substantial extent, arose in Nova Scotia;

c. concerns a tort committed in Nova Scotia; and

d. concerns a business carried on in Nova Scotia.

122. There is no mechanism to pursue class proceedings in the Federal Republic of Germany. In the United States, the Pradaxa multi-district litigation relating to Pradaxa has settled, such that proceedings by Canadian putative class members in that jurisdiction would be *res judicata*.

RELIEF SOUGHT

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

a. an Order certifying this proceeding as a class proceeding and appointing the Plaintiff as Representative Plaintiff for the Class;

b. general damages, including aggravated damages for personal injuries;

c. special damages for medical expenses and other expenses related to the use of Pradaxa;

d. aggravated, punitive and exemplary damages;

e. further or alternatively the Plaintiff claims, on Marion's estate behalf and on behalf of the other class members:

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

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

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

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

g. damages for the funding of a "Medical Monitoring Program", supervised by the Court, for the purpose of retaining appropriate health and other experts to review

and monitor the health of the class members, and to make recommendations about their treatment;

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

i. interest pursuant to the *Judicature Act*;

j. costs; and

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

PLACE OF TRIAL: Halifax, Nova Scotia

DATED at Toronto, Ontario this 27th day of June, 2014.

Signature
Signed this 27th day of June, 2014.

per

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