File No.: CI 14-01-87568

The Queen's Bench
Winnipeg Centre

BETWEEN:

THE ESTATE OF SUSAN DARLENE GAREAU, and BRIGITTE PICHON
Plaintiffs

- and -

BOEHRINGER INGELHEIM (CANADA) LTD./LTEE,
BOEHRINGER INGELHEIM AUSLANDSBETEILIGUNGS GMBH,
BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and
C. H. BOEHRINGER SOHN AG & CO. KG
Defendants

Proceedings under the *Class Proceedings Act,* C.C.S.M. c. C130

Statement of Claim

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JAN 23 2014

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Brought Under the *Class Proceedings Act,* CCSM c C130

TO THE DEFENDANTS:

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

IF YOU WISH TO DEFEND THIS PROCEEDING, you or a Manitoba lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Queen's Bench Rules, serve it on the plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, and file it in this court office, WITHIN 20 DAYS after this statement of claim is served on you, if you are served in Manitoba.

If you are served in another province or territory of Canada or in the United States if America, the period for serving and filing your statement of defence is 40 days. If you are served outside Canada and the United States of America, the period is 60 days.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

January 23, 2014 Issued by: B. ROBINSON DEPUTY REGISTRAR COURT OF QUEEN'S BENCH FOR MANITOBA

Deputy Registrar
Court of Queen's Bench
100c - 408 York Avenue
Winnipeg, Manitoba R3C 3L6

TO: **BOEHRINGER INGELHEIM (CANADA) LTD./LTEE,**
5180 South Service Road
Burlington, Ontario
Canada L7L 5H4

AND TO: **BOEHRINGER INGELHEIM AUSLANDSBETEILIGUNGS GMBH**
900 Ridgebury Road,
Ridgefield, Connecticut
United States 06877

AND TO: **BOEHRINGER INGELHEIM INTERNATIONAL GMBH**
Binger Strasse 173, 55216 Ingelheim am Rhein,
Germany

AND TO: **C. H. BOEHRINGER SOHN AG & CO. KG**
Binger Strasse 173, 55216 Ingelheim am Rhein,
Germany

I. RELIEF SOUGHT

1. The Plaintiff, on behalf of her mother's estate, on her own behalf, and on behalf of other similarly situated individuals (to be defined by the Court at certification and referred to herein as the "**Class**" or as "**Class Members**"), claims:

   a) general and special damages in an amount to be determined at trial for:

      (i) personal injury or death;

      (ii) economic loss;

      (iii) pain and suffering;

      (iv) loss of income and earning capacity;

      (v) loss of amenities and enjoyment of life;

      (vi) loss of guidance, care and companionship;

      (vii) costs of future care and related expenses;

   b) an accounting and disgorgement of all benefit and amounts accruing to the Defendants, as a result of their wrongful, unlawful or improper conduct;

   c) aggravated, exemplary, and punitive damages;

   d) pre- and post-judgment interest on the foregoing sums in the accordance with ss. 78-88 of the *Courts of Queen's Bench Act*, C.C.S.M. c. C280;

   e) such further and other relief as counsel may advise and this Honourable Court may allow.

II. THE PARTIES

The Plaintiffs

2. The Plaintiff, Brigitte Pichon ("**Brigitte**"), resides in Lockport, Manitoba.

3. Susan Darlene Gareau ("**Susan**"), is the Plaintiff's late mother, and was born on April 13, 1951. At all material times, Susan was a resident of Manitoba.

4. Brigitte brings this claim as executrix of her mother's estate, on her own behalf, and on behalf of the Class.

5. Susan was first prescribed and began taking the prescription drug Pradaxa (also known as *dabigatran, dabigatran etexilate*, Pradax, and Prazaza) in or around September of 2012 following the installation of a pacemaker. Hereinafter, all references to "**Pradaxa**" are intended to include any product sold as Pradaxa, Pradax, Prazaza, *dabigatran,* or *dabigatran etexilate*.

The Defendants

6. The Defendants are all directly connected as related, parent or wholly-owned subsidiary companies.

7. The Defendants research, develop, design, test, manufacture, label, package, supply, market, sell, advertise, and distribute various pharmaceutical products, including Pradaxa, worldwide and in Canada. The Boehringer Ingelheim brand is borne by dozens of parent, subsidiary, and related companies in over forty countries worldwide.

8. The Defendants at all material times carried on business as a partnership, joint venture or other common enterprise inextricably interwoven with each other, making each Defendant vicariously liable for the acts and omissions of the others.

9. The Plaintiff, and no member of the public, could know what individual actions were taken by any of the individual Defendants because they act in concert and secretively.

10. All the Defendants collectively will be referred to as "**Boehringer**" and individually as follows:

    a) Boehringer Ingelheim (Canada) Ltd. /Ltée as "**Boehringer Canada**";

b) Boehringer Ingelheim Auslandsbeteiligungs GmbH as "**Boehringer Holdings**";

c) Boehringer Ingelheim International GmbH as "**Boehringer International**"; and

d) C. H. Boehringer Sohn AG & Co. KG as "**Boehringer Sohn**".

11. The corporate structure of Boehringer includes:

a) Boehringer Canada as a wholly-owned subsidiary of Boehringer Holdings;

b) Boehringer Holdings as a wholly-owned subsidiary of Boehringer International; and

c) Boehringer International as a wholly-owned subsidiary of Boehringer Sohn.

12. At all material times, Boehringer intended that its business be operated as a global enterprise carrying out business worldwide, including in Manitoba and elsewhere in Canada.

13. Boehringer Canada is a private company incorporated pursuant to the laws of Ontario, with its head office located at 5180 South Service Road, Burlington, Ontario. Boehringer Canada is a wholly-owned subsidiary of Boehringer Holdings. Boehringer Canada is directly responsible for research, development, and distribution of pharmaceutical drugs such as Pradaxa. Production of pharmaceutical drugs such as Pradaxa is conducted by related companies of Boehringer Canada that are also wholly-owned subsidiaries of Boehringer International.

14. Boehringer Holdings is a privately-held German holding company with its principal place of business and address for service located at Binger Str. 173, 55216 Ingelheim, Germany. Boehringer Holdings is the parent company of Boehringer Canada as well as dozens of other foreign subsidiaries bearing the Boehringer Ingelheim brand. Boehringer Holdings is also a wholly-owned subsidiary of Boehringer International. Boehringer Holdings directly and through its agents, subsidiaries, and related

companies, has conducted business and derived substantial revenue from within the province of Manitoba, including through the sale of Pradaxa.

15. Boehringer International is a privately-held German company with its principal place of business and address for service located at Binger Str. 173, 55216 Ingelheim, Germany. Boehringer International is the parent company of Boehringer Holdings and a subsidiary of Boehringer Sohn. Through its agents and subsidiaries Boehringer International has conducted business and derived substantial revenue from within the province of Manitoba, including through the sale of Pradaxa.

16. Boehringer Sohn is a privately-held German company with its principal place of business and address for service located at Binger Str. 173, 55216 Ingelheim, Germany. Boehringer Sohn is the parent company of Boehringer International. Through its agents and subsidiaries Boehringer Sohn has conducted business and derived substantial revenue from within the province of Manitoba, including through the sale of Pradaxa.

III. REAL AND SUBSTANTIAL CONNECTION TO MANITOBA

17. This action has a real and substantial connection to Manitoba. The Plaintiffs will serve this claim outside of Manitoba and pursuant to Rule 17.04 of the *Rules of Court*, pleads that the within proceeding relates to, *inter alia*:

    a) torts committed at least in part in Manitoba;
    b) breaches of statutory, legal, and equitable duties in Manitoba;
    c) loss and damage incurred in Manitoba; and,
    d) matters that necessarily require that these parties, located outside of Manitoba, be a party to this proceeding.

IV. THE PROPOSED CLASS

18. This action is brought on behalf of persons (referred to herein as the "**Class**" or "**Class Members**") who have acquired or ingested Pradaxa, including their estates, executors, personal representatives, corporations, other entities, and third parties who have a right to make a claim in relation to said acquisition or ingestion of Pradaxa, including:

a) those who have ingested Pradaxa and as a result have suffered death, internal bleeding or other injuries ("**Injury Subclass**");

b) those who have ingested Pradaxa and in so doing have been exposed to a material and otherwise avoidable risk to their health ("**Ingestion Subclass**");

c) those who have purchased or otherwise acquired Pradaxa ("**Purchaser Subclass**");

d) those who, by reason of their relationship to a member of Injury Subclass, Ingestion Subclass, or Purchaser Subclass, are entitled to make claims in respect of the harm to the said member(s) of the other subclasses ("**Family Subclass**");

e) those who are entitled to make claims in respect of expenses, costs, or losses incurred resulting from the harm of the said member(s) of the other subclasses, including but not limited to:

   i. provincial and federal governments and health departments;

   ii. provincial health insurance plans (including the Manitoba Health Care Insurance Plan) and other public health entities;

   iii. various employers and employee health insurance plans;

   iv. any other subrogated claims of members of the Class; and

   v. all other persons and entities that have and will suffer losses as a result of the acts and omissions of the Defendants ("**Resulting Losses Subclass**"); and

f) any other subclasses that this Court finds appropriate.

V. FACTS

Pradaxa

19. Pradaxa is a prescription anticoagulant (or so-called "blood-thinner") researched, developed, designed, tested, manufactured, labeled, packaged, supplied, marketed, sold, advertised, and distributed by Boehringer since at least 2008. Pradaxa is indicated in its Product Monograph for the prevention of:
    a) venous thromboembolic events ("VTE"—commonly known as blood clots) in patients who have undergone elective total hip replacement or total knee replacement surgery; and
    b) stroke and systemic embolism in patients with atrial fibrillation ("**AF**"; also commonly known as cardiac arrhythmia), in whom anticoagulation is appropriate.

20. Pradaxa has been marketed by Boehringer under several different brand names (including Pradax and Prazaza) worldwide since 2010.

21. Boehringer Canada received Health Canada approval for the sale of Pradaxa in Canada in July of 2008. Pradaxa has since been prescribed to thousands of patients across Canada, including in Manitoba.

22. Boehringer's worldwide annual revenues from the sale of Pradaxa, under all of its various brand names, are estimated to exceed $1 billion. The exact amount of revenue generated by Boehringer from Pradaxa sales in Canada is information in the possession of Boehringer, and can only be determined from Boehringer voluntarily or upon examination for discovery.

23. Before Pradaxa was introduced into Canada, the only oral anticoagulant available in Canada to patients with AF was a drug known as Coumadin ("**Warfarin**"). Boehringer stated in numerous publications, advertisements, and representations to the Canadian public that Pradaxa was more effective than Warfarin and safe and fit for its intended use.

24. One of the safety features of Warfarin is the existence of an "antidote" to its anticoagulant effects. When Warfarin is too effective in thinning a patient's blood such that the patient's health is endangered, the antidote can be administered to reduce or reverse these effects, a fact that is well known in the industry.

25. No drug, agent or means exists to reduce or reverse the anticoagulant effects of Pradaxa. When Pradaxa causes a patient's blood to be excessively thinned, such that the patient's health is endangered, these effects are essentially irreversible. This can lead to severe hemorrhaging and death. Pradaxa is therefore a much more dangerous drug in comparison to its main alternative, Warfarin.

26. Unlike Warfarin, there is no antidote to Pradaxa. Boehringer failed to include a warning of this important fact in advertisements and representation to the public, the medical community, or on Pradaxa labeling or packaging.

27. Approval of Pradaxa in the United States and in Canada was based on a clinical trial known as the Randomized Evaluation of Long-Term Anticoagulation Therapy study ("**RE-LY**"). The study's findings showed that ingesting 150mg doses of Pradaxa twice daily reduced the risk of stroke and systemic embolism more effectively than Warfarin. On the other hand, the study also showed a similar rate of major hemorrhaging and a significantly higher rate of major life threatening bleeding and increased risk of heart attack for Pradaxa (150 mg dose) as compared with Warfarin.

28. The Defendants were at all material times aware because of research and testing that Pradaxa presented a significantly higher rate of major life threatening bleeding and increased risk of heart attack, and that no antidote existed to reduce the potentially harmful effects of Pradaxa. The Defendants collectively withheld and suppressed this

information worldwide, including in Canada and Manitoba, preventing the Plaintiff and Class Members from making an informed decision as potential consumers of Pradaxa.

29. The Defendants used the results of RE-LY to promote Pradaxa, and all of the Defendants stated on their various websites that in clinical trials Pradaxa was 35% more effective at reducing stroke as compared to Warfarin. However, all of the Defendants failed to similarly highlight the increased risk of gastrointestinal bleeding associated with Pradaxa, as well as the aforementioned lack of an effective antidote.

30. To date in the United States, at least 500 patient deaths and over 2,000 reports of hemorrhaging have been linked to use of Pradaxa. As of June 2012, Health Canada's Adverse Drug Reaction Database contained nearly 900 reports of adverse reactions to Pradaxa, including serious hemorrhage events and deaths.

31. The Defendants' labeling and prescribing information for Pradaxa:
    a) failed to disclose that there is no drug, agent, or means to reverse the anticoagulation effects of Pradaxa; and
    b) failed to advise prescribing physicians, such as the Plaintiff's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Pradaxa.

32. The Defendants:
    a) failed to investigate, research, study and consider, fully and adequately, patient age, weight and kidney function as variable factors in establishing recommended dosages of Pradaxa;
    b) failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa;
    c) failed to provide adequate warnings to the Plaintiff and Class Members about the true safety risks associated with the use of Pradaxa;

d) failed to warn the Plaintiff and Class Members that it is difficult or impossible to assess the degree or extent of anticoagulation in patients taking Pradaxa;

e) failed to provide adequate instructions to healthcare professionals on how to intervene to stabilize a patient who suffers a bleeding event while taking Pradaxa;

f) failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Pradaxa and to continue testing and monitoring of renal functioning periodically while the patient is on Pradaxa;

g) failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Pradaxa users;

h) failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeding in those taking Pradaxa, especially in those patients with a prior history of gastrointestinal issues; and

i) failed to include an adequate warning on the face of or inside the drug's packaging about serious bleeding events associated with Pradaxa.

Pradaxa Worldwide

33. Since Boehringer launched Pradaxa worldwide beginning as early as 2008, international health authorities have conducted their own investigations and evaluations in order to assess the increased risk of serious side effects, such as life-threatening bleeding, associated with use of the drug.

34. On July 1, 2011, Pradaxa was approved for sale in New Zealand with lower dosing required (110mg down from 150mg) for patients over 80 years of age and lower dosing recommended for patients with moderate renal impairment.

35. In September 2011, the New Zealand pharmaceutical regulatory authority issued a "Prescriber Update" that alerted physicians that Pradaxa users had a higher incidence

of gastrointestinal bleeds than users of Warfarin and that there was no reversal agent to slow the anticoagulant effects of Pradaxa.

36. A follow-up report issued in December 2011 indicated that among 10,000 New Zealanders who had begun taking Pradaxa through the end of September 2011, there were 295 adverse event reports associated with Pradaxa, including 51 serious bleeding events, and 60 reports of gastrointestinal and rectal bleeding. Among 78 serious reported events, there 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 expressed concern that the risks of Pradaxa were not generally appreciated. The letter stressed that the serious consequences of a lack of an effective reversal agent were not to be underestimated.

37. On January 21, 2011, Pradaxa (under the brand name Prazaza®), in 75mg and 110 mg doses only, was approved for sale in Japan to treat non-valvular atrial fibrillation. In August of 2011, the Japan Ministry of Health, Labor and Welfare issued a safety warning regarding the potential risk of adverse events with Pradaxa, and announced that it was requiring a "BOXED WARNING" be added to Pradaxa to call attention to reports of severe hemorrhages in patients treated with the drug. The announcement reported 81 cases of serious events, including gastrointestinal bleeding, in approximately 64,000 users since the January 2011 release of Pradaxa in Japan. The ministry also requested that the foreign Defendants issue letters informing healthcare professionals of the increased risk of major bleeding events and urging physicians to assess a patient's renal function prior to initiating Pradaxa treatment.

38. The European Medicine Agency (hereinafter referred to as "EMA") announced on November 18, 2011 that between March 2008 and November 6, 2011 there were a total of 256 spontaneous case reports of fatal bleeding events associated with

Pradaxa use worldwide. The EMA associated the increased reporting rate of serious bleeding events with the increased use of Pradaxa. Based on these reports, EMA recommended a label change regarding bleeding risk, including suggesting a renal assessment prior to beginning Pradaxa and cautioning the use of Pradaxa in high dosage with elderly and renal impaired patient populations. The Defendants have confirmed in their own statements that nearly 260 reports of fatal bleeding events were linked to Pradaxa usage.

39. The Australian Government Department of Health and Ageing Therapeutic Goods Administration (hereinafter referred to as "TGA") also released a safety advisory on November 3, 2011 regarding the risk of bleeding related to Pradaxa use. TGA granted an additional indication for Pradaxa in April 2011 for prevention of stroke and other blood clots in people with atrial fibrillation, but would later comment that an increase in serious bleeding-related adverse event reports followed the increase in Pradaxa use.

40. In addition, TGA criticized the RE-LY study in its May 2011 Public Assessment Report, calling into question the study's open-label design and lack of placebo control. Within the same report, TGA also discussed the reanalysis of the RE-LY study performed by the Defendants after the United States Food and Drug Administration (hereinafter "FDA") found inconsistencies in the original data, which resulted in an additional 81 outcome events related to safety and efficacy. The 2011 TGA Report voiced concern over the reliability of the RE-LY, alarmed that such a large number of major bleeds were not initially identified in the original study.

41. In December of 2012, Boehringher discontinued a phase–II study of Pradaxa (known as RE-ALIGN) after discovering that more thromboembolic events (mainly strokes) and more bleeding events were observed with Pradaxa than with Warfarin in patients with prosthetic heart valves. As a result, on December 21st, 2012, the Pradaxa Product

Monograph was updated to contraindicate the use of Pradaxa in patients with artificial heart valves.

Use of Pradaxa

42. Susan was implanted with a pacemaker in or around October 2011 to treat an irregular heart rate.

43. In or around December 2011 Susan was diagnosed with AF.

44. Had Susan been warned of the potentially serious and fatal side effect of excessive bleeding, and the absence of an antidote to treat the anticoagulant effects of Pradaxa, Susan would have taken note of these warnings.

45. Prior to being prescribed Pradaxa, Susan had not been on any other prescription drugs.

46. On January 16th, 2013, Susan came down with the flu; she experienced a sore throat, fever, chills, and nausea.

47. Over the course of the next day and a half, Susan's symptoms worsened and she also began to experience severe body pain.

48. By the morning of January 18th, Susan began to show signs of mental confusion, she became incoherent in her speech, and she began to bleed from the mouth. Brigitte called an ambulance that morning, which brought Susan to Seven Oaks General Hospital in Winnipeg, Manitoba.

49. When Susan was admitted to the hospital, she was bleeding uncontrollably and unexplainably from her mouth. The bleeding spread to her intestines and brain.

Further, Susan's lungs were filled with fluid and blood was being suctioned from Susan's mouth and stomach almost constantly.

50. By approximately 4pm on January 18th, 2013, Susan's condition worsened significantly and she was on a respirator in a coma. The bleeding continued from Susan's mouth and she was then also bleeding from the rectum.

51. The doctor working with Susan showed visible concern when he heard that Susan was on Pradaxa. The doctor said that had it been Warfarin, "we could stop the bleeding".

52. The doctor was not as sure how to deal with Pradaxa. The doctor administered vitamin K and took Susan off Pradaxa immediately, however, the bleeding could not be stopped.

53. Brigitte and other family members were told by the doctors at the hospital that the doctors had done everything to try and stop the bleeding, but that the effects of Pradaxa were irreversible. Susan was placed in ICU where she received round the clock care until her death shortly after midnight on January 20th.

54. The experience was witnessed by Brigitte and other family members, and was very traumatic.

55. Susan's autopsy listed her cause of death as brain hemorrhage (bleeding), caused by a strep virus. The infection triggered the bleeding and the bleeding itself continued to spread until it reached her brain, which in effect caused Susan's death.

56. The suffering of Susan and the traumatic shock suffered by Brigitte and other family members as a result of the manner of death of Susan, while not identical to the suffering experienced by other Class Members who have died or suffered physical damage and recovered, and while not identical to the traumatic effect upon the families of others in circumstances similar to Susan, it was suffering similar to the suffering of other class members.

Defendants' promotion of Pradaxa

57. From as early as 2009, and prior to receiving Health Canada approval to sell Pradaxa, Boehringer promoted Pradaxa as a novel medicine for patients with non-valvular atrial fibrillation. Boehringer's 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 it did not require blood monitoring or dose adjustments, and did not require any dietary restrictions.

58. As part of its marketing of Pradaxa, Boehringer widely disseminated direct-to-consumer advertising campaigns that were designed to influence Canadian patients, including Susan, to make inquiries to their prescribing physician about Pradaxa and to request prescriptions for Pradaxa.

59. In the course of its direct-to-consumer advertisements, Boehringer overstated the efficacy of Pradaxa with respect to preventing stroke and systemic embolism and failed to adequately disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa, and that such irreversibility could have permanently disabling, life-threatening, and fatal consequences.

60. Prior to Susan being prescribed Pradaxa, her prescribing physician, and similarly prescribing physicians of Pradaxa to other Class Members, received promotional materials and information from sales representatives of the Defendants.

61. The promotional materials and information from sales representatives of the Defendants stated that Pradaxa was more effective than Warfarin in reducing strokes and was more convenient to use. The promotional materials failed, however, to adequately inform prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Pradaxa.

62. At all times relevant hereto, Boehringer also failed to warn emergency room doctors, surgeons, and other critical care medical professionals in Canada that unlike generally-known measures taken to treat and stabilize bleeding in users of Warfarin, there is no effective agent to reverse the anticoagulation effects of Pradaxa, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Pradaxa.

63. The Defendants impliedly warranted that Pradaxa was a drug of merchantable quality and safe and fit for its intended use. The Defendants have breached this implied warranty, because Pradaxa is neither of merchantable quality nor safe and fit for its intended use.

64. At all material times, the Defendants failed to provide the medical community and the general public with a clear, complete, and current warning of the risks associated with Pradaxa use. This negligent behaviour was a direct cause of the injuries to Susan and Class Members.

VI. CAUSES OF ACTION

Negligence

65. At all material times, the Defendants owed a duty of care to Susan and Class Members to exercise reasonable diligence in the design, research, development, testing, manufacturing and placement of Pradaxa into the stream of commerce,

including a duty to ensure that Pradaxa did not pose a significantly increased risk of injury, bodily harm, and adverse events.

66. The Defendants breached this duty in producing and marketing a drug that was capable of causing serious personal injuries such as those suffered by Susan and Class Members. The Defendants knew or should have known that Pradaxa caused such significant injury, bodily harm, or death, was not safe for use by consumers, and was less safe than Warfarin.

67. The Defendants collectively conducted negligent design, research, development, and testing of Pradaxa. The result was a drug that was unsafe and unfit for its intended use. This negligent behaviour was a direct cause of the injuries to Susan and Class Members.

68. The Defendants each owed a further duty to disclose to Susan and Class Members:
    a) an accurate description of the effectiveness of Pradaxa;
    b) the full extent of the risks associated with taking Pradaxa; and
    c) the fact that no drug, agent, or means exists to reverse the anticoagulation effects of Pradaxa.

69. The Defendants breached these duties by over-promoting the effectiveness of Pradaxa, failing to provide a clear, current, and complete warning of the dangers associated with taking Pradaxa as described above, and failing to disclose that there is no antidote to the anticoagulant effects of Pradaxa. This negligent failure to disclose relevant information was a direct cause of the injuries to the Plaintiff and Class Members.

70. As a direct and proximate result of the Defendants' negligence, Susan and Class Members suffered serious injury or death and economic loss for which the Defendants are liable.

71. The Defendants failed to exercise ordinary care in the design, formulation, manufacture, promotion, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Pradaxa into the stream of commerce in Manitoba and in Canada, in that the Defendants knew or should have known that the product caused such significant injury, bodily harm, or death, and was not safe for use by consumers.

72. Despite the fact that the Defendants knew or should have known that Pradaxa posed a serious increased risk of injury, bodily harm, or death to consumers, the Defendants continued to manufacture, promote, and market Pradaxa for use by consumers.

73. The Defendants knew or should have known that consumers, such as Susan and Class Members, would suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.

74. As a direct and proximate result of the Defendants' negligence, Susan and Class Members suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

75. The Defendants acted willfully or with gross negligence indicating a wanton disregard for the safety of Susan and Class Members.

Negligent Misrepresentation

76. The Defendants are the manufacturers, designers, distributors, sellers, and suppliers of Pradaxa and, while engaged in the course of such business, made

misrepresentations to physicians in Manitoba and Canada and other health care providers regarding the character and quality of Pradaxa, which misrepresentation may be judged objectively and on a class wide basis.

77. The Defendants misrepresented that their product was just as safe, and just as effective or more effective, than other anticoagulants on the market.

78. The Defendants had knowledge based upon research, studies, published reports and clinical experience that Pradaxa created an unreasonable increased risk of serious bodily injury and death to the Class, or should have known such information.

79. The Defendants negligently and intentionally misrepresented or omitted information on a Class wide basis in their product labeling, promotions, and advertisements and instead labeled, promoted, and advertised Pradaxa as safe and effective in order to avoid losses and sustain profits in their sales to the Class of the drug.

80. In supplying such false information, the Defendants failed to exercise reasonable care or competence in obtaining or communicating information to their intended recipients, including Susan and her physicians.

81. As a direct and proximate result of the Defendants' negligent and intentional misrepresentations or omissions, Susan and others suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

Products Liability: Defect in Design or Formulation

82. The risks of Pradaxa exceeded the benefits associated with its design or formulation, and Pradaxa was more dangerous than Susan and members would objectively be held to expect.

83. The risks associated with the design or formulation of Pradaxa include but are not limited to the fact that the design or formulation of Pradaxa was more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

84. As a direct and proximate result of Susan's use of Pradaxa as manufactured, designed, sold, supplied, and introduced into the stream of commerce by the Defendants, Susan and others suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

Products Liability: Defective Manufacturing

85. Pradaxa was manufactured, designed, promoted, sold, distributed, supplied and placed in the stream of commerce by the Defendants; Pradaxa was expected to and did reach Susan and others without any alterations or changes.

86. The Pradaxa produced, manufactured, designed, promoted, sold, distributed, supplied, and placed in the stream of commerce by the Defendants was defective in its manufacture when it left the possession of the Defendants in that it was unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

87. As a direct and proximate result of their use of Pradaxa as manufactured, designed, sold, supplied, and introduced into the stream of commerce by the Defendants, Susan and others suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

Products Liability: Inadequate Warnings or Instructions

88. Pradaxa products manufactured, promoted, and supplied by the Defendants provided inadequate warning or instruction because at the time the product left their control the Defendants knew or should have known that the product was unreasonably dangerous in that it created a substantially increased risk of serious bodily harm and death to consumers such as Susan, and the Defendants failed to adequately warn consumers and their health care providers of such increased risks.

89. The Pradaxa manufactured, promoted, and supplied by the Defendants was also defective due to inadequate post-marketing warning or instruction because after the product left their control, the Defendants became further aware, or in the exercise of ordinary care should have known, that the product posed a substantial increased risk of serious bodily harm and death to reasonably foreseeable consumers such as the Plaintiff and failed to take reasonable steps to provide adequate warnings or instructions to consumers and their health care providers of such increased risks.

90. As a direct and proximate result of the Plaintiffs' use of Pradaxa as manufactured, designed, promoted, sold, supplied and introduced into the stream of commerce by the Defendants, the Plaintiff and others suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

Breach of Express Warranty

91. The Defendants expressly warranted that Pradaxa was a safe and effective drug.

92. Pradaxa manufactured, promoted, and sold by the Defendants did not conform to these express representations because it caused serious injury to consumers who used the product.

93. As a direct and proximate result of the Defendants' breach of warranty, the Plaintiff and others suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

Breach of Implied Warranty

94. The Defendants manufactured, marketed, promoted, sold, and distributed Pradaxa as an anticoagulant, and impliedly warranted that Pradaxa was of merchantable quality, fitness, and safe for such use.

95. Brigitte, Susan, the Class, and their health care providers, relied on an objective Class wide basis upon the skill and judgment of the Defendants as to whether Pradaxa was of merchantable quality and safe for its intended use, and relied upon the Defendants' express and implied warranty as to such matters.

96. Contrary to the implied warranty, the Defendants' product Pradaxa was not of merchantable quality or safe for its intended use because it was unreasonably dangerous as described herein.

97. As a direct and proximate result of the Defendants' breach of warranty, Susan and others suffered personal injury, economic, and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

98. The Defendants acted willfully or with gross negligence indicating a wanton disregard for the safety of Susan and the Class.

Statutory Contraventions and Claims

99. Brigitte brings this action relying upon the following statutes and, where applicable, the Defendants' violations thereof:

Canada

(i) *Competition Act*, RSC 1985, c C-34 ss 52, 74.01;

(ii) *Food and Drugs Act*, RSC 1985, c F-27, s 9;

Manitoba

(c) *Consumer Protection Act*, CCSM c C200, s 58;

(d) *Sale of Goods Act,* CCSM c S 10, ss 16, 54;

(e) *The Health Services Insurance Act*, RSM 1987, c H35, s 97;

(f) *The Tortfeasors and Contributory Negligence Act*, CCSM c T90, ss 2, 5;

(g) *Trustee Act,* CCSM c T160, s 53;

(h) *The Fatal Accidents Act*, C.C.S.M. c. F50, ss. 2, 3;

British Columbia

(i) *Business Practices and Consumer Protection Act*, SBC 2004, c 2, ss 4, 5

(j) *Family Compensation Act*, RSBC 1996, c 126, ss 2, 3(8)-(9);

(k) *Health Care Costs Recovery Act*, SBC 2008, c 27, ss 2, 3, 6-8

(l) *Negligence Act*, RSBC 1996, c 333, ss 1-4

(m) *Sale of Goods Act*, RSBC 1996, c 410, ss 18, 56

Alberta

(n) *Crown's Right of Recovery Act*, SA 2009, c C-35, ss 2-6

(o) *Fatal Accidents Act*, RSA 2000, c F-8 ss 2, 3

(p) *Sale of Goods Act*, S-2 RSA 2000, ss 16, 52

(q) *Survival of Actions Act*, R.S.A. 2000, c S-27, ss 2, 5(1), 5(2)

(r) *Tort-feasors Act*, RSA 2000, c T-5, ss 2.1, 3

New Brunswick

(s) *Consumer Product Warranty and Liability Act*, c C-18.1, ss 4, 10, 11, 15, 23, 27

(t) *Fatal Accidents Act*, RSNB 1973, c F-7, ss 1-3

(u) *Hospital Services Act*, RSNB 1973, c H-9, s 10

(v) *Sale of Goods Act*, RSNB 1973, c S-1, ss 15, 50

(w) *Survival of Actions Act*, RSNB 1973, c. S-18, ss 2, 5(1)-(2)

Newfoundland & Labrador

(x) *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1, ss 7, 9, 10

(y) *Fatal Accidents Act*, RSNL 1990, c F-6, ss 2-4

(z) *Hospital Insurance Agreement Act*, RSNL 1990, c H-7, s 5

(aa) *Medical Care Insurance Act*, 1999, SNL 1999, c M-5.1, s 19

(bb) *Sale of Goods Act*, RSNL 1990, c S-6, ss 16, 54

(cc) *Survival of Actions Act*, RSNL 1990, c S-32, ss 2, 4

Northwest Territories

(dd) *Consumer Protection Act*, RSNWT 1988, c C-17, s 70

(ee) *Hospital Insurance and Health and Social Services Administration Act*, RSNWT1988, c T-3, s 20

(ff) *Sale of Goods Act*, RSNWT 1988, c S-2, ss 18, 60

Nova Scotia

(gg) *Health Services and Insurance Act*, RSNS 1989, c 197, s18

(hh) *Fatal Injuries Act*, RSNS 1989, c 163, ss 2-3, 5

(ii) *Sale of Goods Act*, RSNS 1989, c 408, ss 17, 54

(jj) *Survival of Actions Act*, RSNS 1989, c 453, ss 2(1)-(2), 4

Nunavut

(kk) *Consumer Protection Act*, RSNWT (Nu) 1988, c C-17, s 70

(ll) *Hospital Insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c T-3, s 20

(mm) *Sale of Goods Act*, RSNWT (Nu) 1988, c S-2,, ss 18, 60

Ontario

(nn) *Consumer Protection Act*, 2002 SO 2002, c 30, Sched. A, ss 14, 17

(oo) *Family Law Act*, RSO 1990, c F.3, s 61

(pp) *Health Insurance Act*, RSO 1990, c H.6, s 36.0.1

(qq) *Negligence Act*, RSO 1990, c N.1, s1

(rr) *Sale of Goods Act*, RSO 1990, c S.1, s 15

(ss) *Trustee Act*, RSO 1990, c T.23, s 38(1)

Prince Edward Island

(tt) *Hospital and Diagnostic Services Insurance Act*, RSPEI 1988, c H-8, s 14

(uu) *Fatal Accidents Act*, R.S.P.E.I. 1988, c. F-5, ss 1-2, 6

(vv) *Sale of Goods Act*, RSPEI 1988, c S-1, ss 15, 53

(ww) *Survival of Actions Act*, RSPEI 1988, c S-11, ss 2, 5

Quebec

(xx) *Civil Code of Quebec*, Book 5

(yy) *Consumer Protection Act*, RSQ c P-40.1, ss 37, 40-43, 219, 221

Saskatchewan

(zz) *Department of Health Act*, RSS 1978, c D-17, s 19

(aaa) *The Consumer Protection Act*, RSS 1996, c C-30.1, ss 5-8, 14, 16, 45-48, 55, 57, 64-66

(bbb) *The Fatal Accidents Act*, RSS 1978, c F-11, ss 2, 3(1), 4(1)-(3)

(ccc) *The Sale of Goods Act*, RSS 1978, c S-1, ss 16, 52, 53, 56

(ddd) *The Survival of Actions Act*, SS 1990, c S-66.1, ss 3, 6(1)-(3)

Yukon

(eee) *Consumers Protection Act*, RSY 2002, c 40, s 58

(fff) *Hospital Insurance Services Act*, RSY 2002, c 112, ss 10, 11

(ggg) *Sale of Goods Act*, RSY 2002, c 198, ss 15, 50, 51

Consumer Protection

100. The Defendants engaged in: unfair practices; deceptive acts or practices, unconscionable acts or practices, unfair business practices, unfair consumer practices; prohibited practices; false, misleading or deceptive representations; unfair trade practices, and breached statutory, express, or implied conditions or warranties by marketing Pradaxa in Canada and failing to include an adequate warning in the Pradaxa product monograph.

101. The Defendants deliberately withheld information from the public about the risk of excessive bleeding, and the absence of an antidote for Pradaxa's anticoagulant effects, associated with Pradaxa use.

102. Pradaxa was not of acceptable quality, state, or condition; particular standard, quality, grade, style, model, origin, or method of manufacture; or merchantable quality. The serious and life-threatening side effects of the drug Pradaxa far outweigh its benefits. This is especially true considering Pradaxa's alternative (Warfarin) is far safer because there is an antidote to Warfarin's anticoagulant effects.

103. On behalf of Class Members, Brigitte pleads the consumer protection and trade practice legislation in Canada, Manitoba, and other provinces, including:

(a) *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2, as am., including ss. 4-5 & 8-10;

(b) *Fair Trading Act,* R.S.A. 2000, c. F-2, as am., including ss. 6, 7 & 13;

(c) *The Consumer Protection Act*, S.S. 1996, c. C-30.1, as am., including ss. 5- 8, 14, 16, 48, 64 & 65;

(d) *The Business Practices Act*, S.M. 1990-91, c. 6, as am., including ss. 2 & 23;

(e) *Consumer Protection Act*, 2002, S.O. 2002, c. 30, Sched. A, as am., including ss. 8, 11 & 14;

(f) *Consumer Protection Act,* R.S.Q. c. P-40.1, as am., including ss. 219 & 272;

(g) *Consumer Product Warranty and Liability Act*, S.N.B. 1978, c. C-18.1, including ss. 4, 10, 12, 15-18, 23 & 27;

(h) *Consumer Protection Act,* R.S.N.S. 1989, c. 92, including ss. 26 & 28A;

(i) *Business Practices Act,* R.S.P.E.I. 1988, c. B-7, as am., including ss. 2-4;

(j) *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1, including ss. 7, 8 & 10; and

(k) *The Competition Act,* R.S.C. 1985, c. C-34, including ss. 36, 52 and 74.01.

Competition Act

104. Section 52 of the *Competition Act,* RSC 1985, c C-34 prohibits the use of false and misleading representations or omissions of material fact in connection with the marketing, promotion, and sale of products such as Pradaxa.

105. At material times, the Defendants violated, inter alia, section 52 of the *Competition Act* by the use of false and misleading representations or omissions of material fact in connection with the marketing, promotion, and sale of Pradaxa. The Defendants communicated the purported benefits of Pradaxa while failing to properly identify the serious and dangerous side effects related to the use of Pradaxa with the intent that consumers, like Susan and the Class, purchase and ingest Pradaxa.

106. As a result of violating the *Competition Act*, the Defendants caused Susan and the Class to be prescribed and to use Pradaxa, thereby causing severe injuries and damages, as previously described herein.

Subrogated Medical Claims

107. The Plaintiff claims on behalf of the:

(a) Minister of Health of Saskatchewan, for the cost of health services received by class members under *The Department of Health Act*, SS 1978, c D-17, s. 19(5);

(b) Minister of Health of British Columbia, for the cost of health services received by class members pursuant to s. 2 of the *Health Care Costs Recovery Act*, S.B.C. 2008, c. 27, including necessary operating and care room facilities, diagnostic or therapeutic X-ray and laboratory procedures, anesthetics, prescriptions and drugs;

(c) Minister of Health of Alberta, for the cost of health services received by class members pursuant to Part 5, Division 1, of the *Hospital Act*, R.S.A. 2000, c. H-12, as am., including in-patient and out-patient services, transportation services, public health services, mental health services and drug services;

(d) Minister of Health of Manitoba, for the cost of health services received by class members under s. 106(1) of *The Health Services Insurance Act,* C.C.S.M. c. H35.

(e) Ontario Health Insurance Plan, for the cost of insured services received by class members pursuant to *Health Insurance Act*, R.S.O. 1990, c. H.6, as am., s. 31(1), including, prescribed services of hospitals and health facilities, prescribed medically necessary services rendered by physicians, and prescribed health care services rendered by prescribed practitioners;

(f) Minister of Health and Social Services of Quebec, for the cost of all insured services furnished or to be furnished pursuant to the *Hospital Insurance Act*, R.S.Q. c. A-28, s. 10;

(g) Her Majesty the Queen in right of New Brunswick, for the cost of entitled services received by class members pursuant to *Health Services Act*, R.S.N.B. 1973, c. H-9, as am., s.10, including accommodation and meals, nursing

services, laboratory, radiological and other diagnostic procedures, drugs, use of operating rooms, case rooms and anaesthetic facilities, and routine surgical supplies;

(h) Her Majesty the Queen in right of Nova Scotia, for the cost of insured hospital services received by class members pursuant to the *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197, as am., s. 18, including benefits under the Insured Prescription Drug Plan, ambulance services, and insured professional services; and

(i) Minister of Health of Newfoundland and Labrador, for the cost of insured services received by class members pursuant to s. 5 of the *Hospital Insurance Agreement Act*, R.S.N. 1990, c. H-7, s. 5, as am.

Estates and Derivative Claims

108. On behalf of the estates and families of class members, the Plaintiff pleads:

(a) *Survival of Actions Act*, R.S.A. 2000, c. S-27, ss. 2, 5(1), 5(2); *The Survival of Actions Act*, S.S. 1990, c. S-66.1, ss. 3 and 6(1)-(3); *Trustee Act*, R.S.O. 1990, c. T.23, s. 38(1); *Survival of Actions Act*, R.S.N.S. 1989, c. 453, ss. 2(1)-(2) and 5; *Survival of Actions Act*, R.S.N.B. 2011, c. 227, ss. 3(1)-(2) and 6(1)-(2); *Survival of Actions Act*, R.S.P.E.I. 1988, c. S-11, ss. 2 and 5; *Survival of Actions Act*, R.S.N.L. 1990, c. S-32, ss. 2 and 4.

(b) *Family Compensation Act*, R.S.B.C. 1996, c. 126, ss. 2 and 3(8)-(9); ss. 1, 2, and 3(1) of the *Fatal Accidents Act*, R.S.A. 2000, c. F-8; *The Fatal Accidents Act*, R.S.S. 1978, c. F-11, ss. 2, 3(1), and 4(1)-(3); *Family Law Act*, R.S.O. 1990, c. F. 3, ss. 61(1)-(2); *Fatal Accidents Act*, S.N.B. 2012, c. 104, ss. 3, 4, 7; *Fatal Injuries Act*, R.S.N.S. 1989, c. 163, ss. 2-3 and 5; *Fatal Accidents Act*, R.S.P.E.I. 1988, c. F-5, ss. 1-2, 6; *Fatal Accidents Act*, R.S.N.L. 1990, c. F-6, ss. 2-4.

Unjust Enrichment and Waiver of Tort

109. The Defendants collectively owed the Plaintiff and Class Members a duty of care to ensure through research and testing that Pradaxa was safe and fit for its intended purpose; alternatively, the Defendants were obligated Class wide to warn Susan and Class Members of the full extent of the dangers associated with use of Pradaxa and that no antidote existed to reverse or reduce its anticoagulant effects.

110. The Defendants' collective decisions to breach these duties give rise, in addition or in the alternative to the causes of action listed above, to the equitable doctrine of waiver of tort. Brigitte, Susan, and Class Members suffered harm as a direct, proximate, and foreseeable result of the Defendants' wrongful conduct. Brigitte and Class may waive the tort and demand disgorgement of all revenue received by the Defendants from the sale of Pradaxa.

111. To allow the Defendants to retain revenue from the sale of Pradaxa would constitute an unjust enrichment, whereby the Defendants would profit from their own wrongdoing.

112. Brigitte and Class Members therefore rely on the equitable doctrine of waiver of tort to seek an accounting and disgorgement of the revenue generated by the Defendants as a result of their wrongful conduct as stated herein.

113. Susan and Class Members were deprived and the Defendants unjustly enriched.

114. The exact amount of revenue generated from the sale of Pradaxa in Canada is information in the sole possession of the Defendants and is provable upon examination for discovery.

Punitive and Exemplary Damages

115. The Defendants prioritized corporate profits over patient safety. They made a calculated decision not to appropriately change the product monograph, because they knew that providing proper warnings would adversely impact the number of prescriptions and volume of sales of Pradaxa. The Defendants made a calculated decision to market and notwithstanding mounting evidence of profound danger, to continue to market Pradaxa, a drug which had the significant potential to cause uncontrollable bleeding and death. Punitive and exemplary damages should be awarded against the Defendants for the entire Class period with an even higher level of punitive and exemplary damages being awarded for the later years of the Class period at a time when the Defendants knew from mounting evidence that the risks of taking Pradaxa outweighed the benefits, that alternative products were safer, that the marketing of Pradaxa was false, and that the product monograph did not provide clear cogent warnings as to the risks and unusual risks of Pradaxa.

IV. GENERAL ISSUES, PUNITIVE AND EXEMPLARY DAMAGES

116. The acts, omissions, wrongdoings, and breaches of legal duties and obligations of the Defendants have caused or materially contributed to the Plaintiff and others suffering injury, economic loss, and damages.

117. The Defendants have demonstrated and taken a cavalier and arbitrary approach with respect to their obligations to Susan and the Class.

118. At all material times, the conduct of the Defendants as set forth above was malicious, deliberate and oppressive towards their customers, the general public, and the Class, and the Defendants conducted themselves in a willful, wonton, and reckless manner, as set forth above.

119. The Defendants' aforesaid acts, omissions, wrongdoings, and breaches of legal duties and obligations constitute a wonton and outrageous disrespect for fair business practices and dealings with consumers and the public.

120. As a result of the aforesaid acts, omissions, wrongdoings, and breaches of legal duties and obligations by the Defendants, Susan and the Class have sustained substantial injury, economic loss and damages, and are entitled to awards of aggravated, punitive, and exemplary damages.

121. By engaging in the acts and conduct described herein, the Defendants unjustly enriched themselves and deprived Susan of a fair marketplace, as well as financially depriving members of the Class and causing the Plaintiff class to suffer economic harm.

122. The Plaintiff therefore claims against the Defendants as described in paragraph 1.

Date: January 23, 2014

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