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JUDICIAL CENTRE
OF CALGARY

FORM 10
[RULE 3.25]

COURT FILE NUMBER	1501 - 07708
COURT	COURT OF QUEEN'S BENCH OF ALBERTA
JUDICIAL CENTRE	CALGARY
PLAINTIFFS	LAVINA KARVONEN AND EINO KARVONEN
DEFENDANTS	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOERINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM (CANADA), LTD.
DOCUMENT	**Brought under the *Class Proceedings Act*** **STATEMENT OF CLAIM**
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NOTICE TO DEFENDANTS	You are being sued. You are a defendant. Go to the end of this document to see what you can do and when you must do it.

STATEMENT OF FACTS RELIED UPON:

DEFINED TERMS

1. In this Statement of Claim, in addition to the terms that are defined elsewhere herein, the following terms have the following meanings:

(a) "***AJIA***" means the Alberta *Judgment Interest Act*, RSA 2000, c J-1, as amended;

(b) "**Class Members**" means all people in Canada who were prescribed the pharmaceutical drug Pradaxa (dabigatran etexilate), and/or their assigns and heirs;

(c) "***Class Proceedings Act***" means the Alberta *Class Proceedings Act,* SA 2003, c C-16.5;

(d) **"Defendants"** means Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International, GmbH, and/or Boehringer Ingelheim (Canada), Ltd.

(e) **"Family Claimants"** means those who bring their claims on the basis of their relationship to a person who consumed Pradaxa.

(f) **"FDA"** means the Food and Drug Administration in the United States;

(g) **"Lavina"** means Lavina Karvonen, a Plaintiff in the within proceeding;

(h) **"Plaintiffs"** means Lavina and Eino, the Plaintiffs in the within proceeding;

(i) "**Eino**" means Eino Karvonen, Lavina's husband, a Plaintiff in the within proceeding; and

(j) "**Pradaxa**" means the anticoagulant drug, dabigatran etexilate;

PARTIES

The Plaintiffs

2. The Plaintiffs, Lavina and Eino, are individuals who reside on a farm north of the town of Waskatenau, Alberta.

3. Lavina was prescribed Pradaxa in January 2013, to treat atrial fibrillation. Lavina took Pradaxa regularly until March 11, 2015. On March 11, 2015, she started having pain in her abdomen, with subsequent vomiting and intestinal hemorraging. Lavina attended at the University of Alberta Hospital in Edmonton on March 13, 2015, and was hospitalized. She was subsequently discharged, but hospitalized again several days later. In total, Lavina was hospitalized for 10 days.

4. Lavina had no prior bleeding or hemorrhagic conditions prior to her use of Pradaxa.In the time period before and during Lavina's use of Pradaxa, she received no or inadequate warnings about the increased risk of uncontrollable bleeding and lack of a reversal agent.

5. The Plaintiff, Eino, is Lavina's husband and is pursuing his claim in that capacity. Eino and other Class Members have suffered and continue to suffer damages including loss of care, guidance and companionship, as well as financial expenses and special damages due to the wrongful conduct of the Defendants.

The Defendants

6. The Defendant, Boehringer Ingelheim Pharmaceuticals Inc., is a corporation organized pursuant to the laws of the State of Delaware in the United States. Its head offices are

situated in Ridgefield, Connecticut. Boehringer Ingelheim Pharmaceuticals Inc. carries on business in Canada through Boehringer Ingelheim (Canada), Ltd. Throughout Canada and the United States, Boehringer Ingelheim Pharmaceuticals, *inter alia,* designs, manufactures, labels, markets, sells and distributes pharmaceutical drugs through its own operations and certain of its subsidiaries.

7. The Defendant, Boehringer Ingelheim International, GmbH, is a corporation with its principal place of business in Germany.

8. The Defendant, Boehringer Ingelheim (Canada), Ltd., is a corporation incorporated under the *Canada Business Corporations Act,* RSC 1985, c C-44 with its head office located in Burlington, Ontario. Throughout Canada, Boehringer Ingelheim, *inter alia,* designs, manufactures, labels, markets, sells and distributes pharmaceutical drugs through its own operations and certain of its subsidiaries.

9. The business of each of Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International, GmbH and Boehringer Ingelheim (Canada), Ltd., (collectively, the "**Defendants**") is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the design, manufacture, labelling, marketing, sale and/or distribution of Pradaxa in Canada.

10. At all material times, the Defendants were carrying on business as, *inter alia,* the manufacturer and distributor of Pradaxa in Canada.

11. In bringing this action on behalf of a class of people in Alberta who were prescribed Pradaxa, and their family members, to be further defined at the motion for certification,

the Plaintiffs plead and rely upon the provisions of the *Class Proceedings Act,* SA 2003, c C-16.5.

THE NATURE OF THE CLAIM

12. This claim relates to Pradaxa, an anticoagulant pharmaceutical drug. This claim arises out of the Defendants' unlawful, negligent, inadequate, improper, unfair and deceptive practices and misrepresentations related to, *inter alia*, the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution and sale of Pradaxa.

13. The Defendants misrepresented that Pradaxa is a safe and effective treatment for the prevention of strokes and blood clots. In reality, the drug causes uncontrollable, life-threatening bleeds that are irreversible due to the lack of an antidote or reversal agent.

14. Consumers of Pradaxa were misled as to the drug's safety and efficacy and, as a result, have suffered serious, life-threatening, or even fatal bleeds.

THE DEFENDANTS' ANTI-COAGULANT THERAPY

BACKGROUND

15. Pradaxa is an oral anticoagulant pharmaceutical drug approved for the prevention of blood clots in patients who have undergone hip replacement or total knee replacement

surgery, and for the prevention of strokes and blood clots in the body of patients with atrial fibrillation ("**AF**")[1].

16. Pradaxa was first marketed in Canada in 2008, under the name "Pradax", for the prevention of venous thromboembolic events ("**VTE**")[2] in patients following hip or knee replacement surgery.

17. In October 2010, Pradax received a new indication for the prevention of strokes and systemic embolic events in AF patients who require anticoagulation medications.

18. On November 8, 2011, Health Canada posted a "Dear Health Care Professional" letter from Boehringer Ingelheim (Canada) Ltd. and Sanofi-Aventis Canada Inc. regarding mix-ups between Pradax and Plavix. The drug was subsequently marketed in Canada under the name "Pradaxa."

19. According to a press release issued by the Defendants in August 2011, AF affects up to 350,000 Canadians, and is a common yet serious heart condition that can lead to severe and debilitating strokes. Canadians with AF are at least five times more at risk of having a stroke and are twice as likely to die from one. In Canada, strokes are a leading cause of adult disability and the third leading cause of death with up to 15 per cent of strokes being caused by AF.

20. Prior to Health Canada's approval of Pradax in 2010, warfarin was the only oral anticoagulant available in Canada for reducing stroke and systemic embolism in patients

[1] Atrial fibrillation ("AF") is a condition where the heart beats irregularly, increasing the chance of clots forming in the body and possibly causing strokes.

[2] Venous thromboembolic events ("VTE") occur when a blood clot breaks loose and travels through the blood causing risk of stroke and other serious events.

with AF. Users of warfarin must follow dietary restrictions and regularly monitor their level of anticoagulation through periodic blood testing. However, if a patient is using warfarin and experiences an overdose or unexpected bleed, a highly effective antidote is available. In contrast, there is no antidote for patients using Pradaxa who experience an overdose or unexpected bleed, and no requirement that patients on Pradaxa receive regular monitoring of the anticoagulation level.

21. On June 26, 2014, Health Canada approved Pradaxa for the treatment of VTE, including deep vein thrombosis ("**DVT**")[3] and pulmonary embolism ("**PE**")[4], and for the prevention of recurrent DVT and PE.

DOSAGE

22. Originally, Pradax was approved with a recommended dosage of 220 mg once daily, taken orally as 2 capsules of 110 mg and a lower dosage of 150 mg once daily, taken orally as 2 capsules of 75 mg, for those age 80 years and older, as well as for those at a high risk of bleeding.

23. Pradaxa is currently approved by Health Canada in three capsule forms: 75 mg, 110 mg, and 150 mg. For VTE prevention after elective hip or knee replacement surgery, a dose of 220 mg is recommended in the form of two 110 mg capsules taken once daily. For treatment and prevention of DVT and PE, a dose of 300 mg is recommended in the form of one 150 mg capsules taken twice daily. Likewise, for prevention of stroke and

[3] Deep vein thrombosis ("DVT") occurs when a blood clot forms within a deep vein, predominantly in the legs.
[4] Pulmonary embolism ("PE") is a blockage of the main artery of the lung or one its branches by a substance, such as a blood clot, that has travelled from elsewhere in the body.

systemic embolism in patients with AF, a dose of 300 mg is recommended in the form of one 150 mg capsule taken twice daily.

THE RISKS

24. Pradaxa carries the risk of uncontrollable and irreversible bleeds in patients who use the drug.

25. Notwithstanding the link between Pradaxa and uncontrollable, life-threatening, irreversible bleeds, the Defendants concealed their knowledge that Pradaxa caused life-threatening bleeds and failed to draw attention to the lack of an effective reversal agent.

26. Pradaxa's product monograph in Canada does not provide any tangible precaution against the risk of uncontrollable and irreversible bleeds. The "Warning" section merely outlines that "[a]s with all anticoagulants, PRADAXA (diabigatran etexilate) should be used with caution in circumstances associated with an increased risk of bleeding". The only indication that such bleeds could be life-threatening is found not in the "Warning" section, but rather under the heading "Adverse Reactions":

> Although rare in frequency in clinical trials, major or severe bleeding may occur and, regardless of location, may lead to disabling, life-threatening or even fatal outcomes.

27. The only part of Pradaxa's product monograph that references the fact that Pradaxa has no known reversal agent is not located in the "Warning" section, but rather in a section that discusses "Overdosage". It states simply: "[t]here is no antidote". There is no corresponding recommendation that patients receive regular monitoring – in fact

marketing materials for Pradaxa emphasize that regular monitoring is *not* required,[5] suggesting that the drug is more convenient for patients than other anticoagulant therapies.

28. Further, although Pradaxa had been indicated for the prevention of stroke and systemic embolism in patients with AF since October 2010, there was not proper dosage information in the product monograph until 2012.

RIGHTS OF ACTION

NEGLIGENCE

29. The Defendants, at all material times, owed a duty of care to the Plaintiffs to:

(a) ensure that Pradaxa was fit for its intended or reasonably foreseeable use; and

(b) conduct appropriate research and testing to determine whether and to what extent the use of Pradaxa posed serious health risks, including the risk of uncontrollable and irreversible bleeding.

30. The Defendants negligently breached their duty of care.

31. The Plaintiffs state that their damages and the damages of other putative Class Members were caused by the negligence of the Defendants. Such negligence includes, but is not limited to, the following:

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5 Marketing materials for "New Pradax 150 mg BID" for example, clearly state "No INR monitoring or dose titration" and reference to Pradax Product Monograph, Boehringer Ingelheim (Canada), Ltd., 11/08/10. INR (international normalized ratio) is a measure of the extrinsic pathway of coagulation to determine the effects of an oral anticoagulant.

(a) the Defendants failed to ensure that Pradaxa was not dangerous to recipients during the course of its use and that the drug was fit for its intended purpose;

(b) the Defendants failed to adequately test Pradaxa in a manner that would fully disclose the magnitude of the risks associated with its use, including, but not limited to, the increased risk of uncontrollable and irreversible bleeding;

(c) the Defendants failed to properly label Pradaxa with adequate directions for use, and/or adequate warnings against use where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, or to recommend regular monitoring when they knew or ought to have known that no antidote existed for the drug;

(d) the Defendants failed to maintain and manage an adverse incident reporting system for Pradaxa;

(e) the Defendants failed to give Health Canada complete and accurate information as that information became available;

(f) the Defendants failed to conduct adequate follow-up studies on the efficacy and safety of Pradaxa;

(g) the Defendants failed to conduct any studies, long-term or otherwise, of the increased risk of continued use of Pradaxa;

(h) the Defendants failed to properly supervise their employees, their subsidiaries and their affiliated corporations;

(i) in all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of persons using Pradaxa; and

(j) the Defendants breached other duties of care to persons using Pradaxa, details of which breaches are known only to the Defendants.

FAILURE TO WARN

32. The Defendants, at all material times, owed the Plaintiffs a duty to properly, adequately, and fairly warn the Plaintiffs and their physicians of the magnitude of the risk associated with Pradaxa, compared to alternative treatments. The Defendants negligently breached their duty of care.

33. The damages of the Plaintiffs and the damages of other putative Class Members were caused by the Defendants' failure to warn, which includes, but is not limited to, the following:

(a) the Defendants failed to provide persons using Pradaxa, their physicians or other health care providers, and Health Canada, with proper, adequate, and/or fair warning of the increased risks associated with the use of Pradaxa, including but not limited to the increased risk of uncontrollable and irreversible bleeding;

(b) the Defendants failed to provide persons using Pradaxa, their physicians or other health care providers, and Health Canada, with proper, adequate, and/or fair warning of the lack of reversal agent, in cases of unexpected, uncontrollable and irreversible bleeding;

(c) the Defendants failed to warn persons using Pradaxa, their physicians or other health care providers and Health Canada about the need for comprehensive regular monitoring to ensure the early discovery of side effects related to using Pradaxa;

(d) the Defendants failed to adequately monitor, evaluate and act upon reports of adverse reactions to Pradaxa in Canada and elsewhere;

(e) the Defendants failed to provide adequate updated and/or current information to persons using Pradaxa, their physicians or other health care providers and Health Canada respecting the increased risks of Pradaxa as such information became available from time to time;

(f) the Defendants failed to provide adequate warnings of the potential increased risks associated with Pradaxa on package labels;

(g) the Defendants failed to provide adequate warnings of the increased risks associated with Pradaxa, including the increased risk of uncontrollable and irreversible bleeding in persons using Pradaxa, on the customer information pamphlets in Canada;

(h) the Defendants, after noticing problems with Pradaxa, failed to issue adequate warnings, timely recall of the drug, publicize the problem and otherwise act properly and in a timely manner to alert the public, including adequately warning persons using Pradaxa and their physicians or other health care providers of the

drug's inherent dangers, including, but not limited to, the danger of developing uncontrollable and irreversible bleeding in persons using Pradaxa;

(i) the Defendants failed to establish any adequate procedures to educate their sales representatives and prescribing physicians or other health care providers about the increased risks associated with using Pradaxa; and

(j) the Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act,* RSC 1985, c F-27 and its associated regulations.

NEGLIGENT DESIGN

34. The Defendants, at all material times, owed the Plaintiffs a duty to design Pradaxa in a way that is fit for its intended and/or reasonably foreseeable use. The Defendants negligently breached their duty of care.

35. The damages of the Plaintiffs and the damages of other putative Class Members were caused by the Defendants' breach which includes but is not limited to, the following:

(a) any benefit from using Pradaxa was outweighed by the serious and undisclosed risks, when used in its intended and reasonably foreseeable manner;

(b) there are no individuals for whom the benefits of Pradaxa outweigh the risks, given that there are alternative products that are at least as efficacious as Pradaxa, that have an antidote, and carry far less and/or less serious risks than Pradaxa;

(c) the Defendants knew, or ought to have known, that the foreseeable risks of using Pradaxa exceeded the benefits associated with its design;

(d) the Defendants failed to warn persons using Pradaxa and their physicians or other health care providers that Pradaxa, as designed, could result in adverse health or medical conditions, including uncontrollable and irreversible bleeding;

(e) the Defendants failed to conduct adequate follow-up studies on the efficacy and safety of Pradaxa, as designed;

(f) the Defendants failed to conduct adequate long-term studies of the increased risk of Pradaxa, as designed; and

(g) the Defendants, throughout the events described herein, had the economic and technical means to provide a safer alternative design that would have prevented the health and medical conditions described herein and prevented the injuries and damages suffered by persons using Pradaxa.

NEGLIGENT DISTRIBUTION, MARKETING AND SALE

36. The Defendants, at all material times, owed the Plaintiffs a duty to ensure that the plaintiffs, their physicians, other healthcare providers and health Canada were kept fully and completely warned and informed regarding all risks associated with Pradaxa as part of the Defendants' distribution, marketing, and sale activities. The Defendants negligently breached this duty.

37. The Plaintiffs state that their damages and the damages of other putative Class Members were caused by the Defendants' negligent distribution, marketing and sale of Pradaxa, which includes, but is not limited to, the following:

(a) Pradaxa was either defective in its design or, although non-defective, still had significant propensity to injure under its intended and ordinary use;

(b) any benefit from using Pradaxa was outweighed by the serious and undisclosed risks of its intended and ordinary use;

(c) there are no individuals for whom the benefits of Pradaxa outweigh the risks, given that there are several alternative products that are at least as efficacious as Pradaxa and carry far fewer and/or less serious risks than Pradaxa;

(d) the Defendants knew, or ought to have known, that Pradaxa was either defective in its design or, although non-defective, had significant propensity to injure under its intended and ordinary use;

(e) the Defendants sought to increase the usage of Pradaxa despite the significant known safety concerns;

(f) the Defendants actively promoted Pradaxa as not requiring INR monitoring or dose titration when they knew or ought to have known that there was no available means for treating a serious uncontrollable and irreversible bleeding event and, therefore, early detection and prevention was of paramount concern;

(g) the Defendants, when distributing the drug, failed to provide persons using Pradaxa, their physicians or other health care providers, and Health Canada with proper, adequate, and/or fair warning of Pradaxa's design defects or propensity to injure when used as intended; and

(h) the Defendants failed to cease the sale, marketing and/or distribution of Pradaxa when they knew, or ought to have known, that Pradaxa was either defective in its design, or although non-defective, still had significant propensity to injure under its intended and ordinary use.

WAIVER OF TORT

38. The Plaintiffs and other putative Class Members are entitled to elect, at the end of the trial of the common issues, to waive the tort and require the Defendants to account for all or part of the revenue they received from the sale of Pradaxa in Canada.

39. The Plaintiffs plead that such an election may be appropriate for the following reasons, among others:

(a) such revenue was acquired in such circumstances that the Defendants may not, in good conscience, retain it;

(b) the integrity of the pharmaceutical regulations and marketplace would be undermined if the Court did not require an accounting;

(c) The Defendants would not have received any or part of the revenue from the sale of Pradaxa in Alberta, absent the Defendants' tortious conduct; and

(d) the Defendants engaged in wrongful conduct by putting into the stream of commerce a pharmaceutical product that causes or has the potential to cause serious risks of injury.

DAMAGES AND SUBROGATED CLAIMS

40. The risks associated with the use of Pradaxa, including the risk of uncontrollable and irreversible bleeding, were in the exclusive knowledge and control of the Defendants.

41. The extent of the risks was not, and could not have been known to, the Plaintiffs and other putative Class Members.

42. The injuries of the Plaintiffs and other putative Class Members would not have occurred but for the negligence of the Defendants in failing to ensure that Pradaxa was safe for use or, in the alternative, in failing to provide adequate warning of the risks associated with using Pradaxa to persons using Pradaxa, their physicians and other health care providers and Health Canada.

43. As a result of the Defendants' conduct, the Plaintiffs and putative Class Members have suffered and will continue to suffer damages and loss, including but not limited to:

(a) personal injury;

(b) out-of-pocket expenses incurred, including those connected with hospital stays, medical treatment, medication and the cost of Pradaxa or, alternatively, the incremental cost of Pradaxa as paid for by the putative Class Members;

(c) loss of guidance, care and companionship;

(d) costs of future care and future services; and

(e) loss of income and loss of future income.

44. As a result of the Defendants' conduct, the Plaintiffs and putative Class Members suffered, and will continue to suffer, expenses and special damages of a nature and amount to be particularized prior to trial.

45. As a result of the Defendants' negligence, putative Class Members are entitled to damages pursuant to the *Tort-feasors Act*, RSA 2000, c T-5 and the regulations thereunder and amendments thereto.

PUNITIVE DAMAGES

46. The Plaintiffs plead that the Defendants' conduct, as particularized above, in the design, development, testing, manufacturing, licensing, distribution, marketing, sale and promotion of Pradaxa and the delayed withdrawal or recall and/or the failure to withdraw or recall was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, willful, an intentional disregard of the rights and safety of Lavina and Eino and the rights and safety of the other putative Class Members, and indifferent to the consequences and motivated by economic considerations, such as the maintenance of profits and market share. Such conduct renders the Defendants liable to pay punitive damages to the putative Class Members.

47. Claims are made for the Plaintiffs, and on behalf of other putative Class Members, for punitive, aggravated and exemplary damages for the Defendants' reckless and unlawful conduct.

PLACE OF TRIAL

48. The Plaintiffs propose that this action be tried in Calgary, Alberta.

REMEDY SOUGHT:

49. The Plaintiffs, Lavina and Eino, personally and on behalf of all Class Members, claim:

(a) an order pursuant to the *Class Proceedings Act,* SA 2003, c C-16.5 certifying this action as a class proceeding and appointing her as representative plaintiff;

(b) a declaration that the Defendants were negligent in the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution and sale of Pradaxa;

(c) a declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees and representatives;

(d) general damages in the amount of $30,000,000 or such other sum as this Honourable Court deems just and appropriate having regard to the circumstances;

(e) special damages in the amount of $15,000,000 or such other sum as this Honourable Court deems just and appropriate having regard to the circumstances;

(f) alternatively, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from the sale of Pradaxa in Alberta;

(g) damages in the amount of $100,000 for each Plaintiff family member;

(h) punitive, aggravated and exemplary damages in the amount of $5,000,000;

(i) bereavement damages pursuant to the *Fatal Accidents Act*, RSA 2000, c F-8;

(j) prejudgment interest and postjudgment interest, compounded pursuant to the *AJIA*;

(k) costs of this action on a substantial indemnity basis and, pursuant to s. 27(1) of the *Class Proceedings Act,* the costs of notice and of administering the plan of distribution of the recovery in this action, plus applicable taxes; and

(l) such further and other relief as to Honourable Court may deem just and appropriate having regard to the circumstances.

NOTICE TO THE DEFENDANTS

You only have a short time to do something to defend yourself against this claim:

20 days if you are served in Alberta

1 month if you are served outside Alberta but in Canada

2 months if you are served outside Canada.

You can respond by filing a statement of defence or a demand for notice in the office of the clerk of the Court of Queen's Bench at CALGARY, Alberta, AND serving your statement of defence or a demand for notice on the plaintiffs' address for service.

WARNING

If you do not file and serve a statement of defence or a demand for notice within your time period, you risk losing the law suit automatically. If you do not file, or do not serve, or are late in doing either of these things, a court may give a judgment to the plaintiffs against you.