**CANADA**
**PROVINCE OF QUEBEC**
**DISTRICT OF MONTREAL**
**NO: 500-06-000741-153**

**(Class Action)**
**SUPERIOR COURT**

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**Lionel Whiteduck,** [redacted]

Petitioner

v.

**Boehringer Ingelheim (Canada) Ltd.,** [redacted]

and

**Boehringer Ingelheim Pharmaceuticals, Inc.,** [redacted]

and

**Boehringer Ingelheim International GMbH,** [redacted]

Defendants

**MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVE**
**(Articles 1002 and seq. C.C.P.)**

**TO ONE OF THE HONOURABLE JUDGES OF THE SUPERIOR COURT, SITTING IN PRACTICE DIVISION, IN AND FOR THE DISTRICT OF MONTREAL, PETITIONER RESPECTFULLY SUBMITS THE FOLLOWING:**

**THE PETITIONER WISHES TO INSTITUTE A CLASS ACTION ON BEHALF THE CLASS OF PERSONS HEREINAFTER DESCRIBED, NAMELY:**

1. The Petitioner intends to institute a class action on behalf of the persons forming the class hereinafter described and of which the Petitioner is a member ("the Class"), namely:

> "All natural persons residing in Quebec who were prescribed the pharmaceutical Pradaxa (dabigatran etexilate) and who have suffered damages as a result of the use of this prescription drug, and/or their family members, assigns and heirs.
>
> or such other group definition as may be approved by the Court."

**THE PETITIONER'S PERSONAL CLAIM AGAINST THE DEFENDANTS IS BASED ON THE FOLLOWING FACTS:**

**THE PETITIONER**

2. On January 21, 2014, the Petitioner had a knee operation on his left knee, which took place at the Hull Hospital in Gatineau, Quebec;

3. Following the operation, the Petitioner began taking Pradaxa which was prescribed by his physician;

4. The Petitioner used Pradaxa in accordance with the package label and consumer information pamphlet and in the manner in which it was intended to be used;

5. In September of 2014, the Petitioner suffered a bleed in his left eye and shortly after lost complete sight. He was operated forthwith at Riverside Hospital in Ottawa;

6. Progressively, the Petitioner's eyesight returned to his left eye;

7. Subsequently, the Petitioner noticed that his right-hand index finger had turned green and black and was causing him throbbing pain;

8. The Petitioner admitted himself to the Maniwaki Hospital and was immediately referred to the Hull Hospital in Gatineau;

9. Testing was done on the Petitioner's right index finger which showed a lack of circulation in that area;

10. The Petitioner did not have any bleeding or blood circulation issues or problems prior to his use of Pradaxa;

11. Physicians at the Hull Hospital examined the Petitioner's finger and immediately recommended amputation;

12. The Petitioner was terrified at the possibility of having his finger amputated, and refused the amputation. He was subsequently given treatment and was advised to immediately stop taking Pradaxa;

13. The Petitioner has been advised by his treating physicians that the problems with his left eye and right index finger, including the resultant injuries and impairments, were caused by the use of Pradaxa;

14. Moreover, the Petitioner suffered from regular and lengthy nosebleeds during the time he was using Pradaxa;

15. The Petitioner's nosebleeds were a frequent occurrence until he stopped using Pradaxa;

16. The Petitioner also suffered from recurrent nightmares and night sweats during that period;

17. To this day, the Petitioner's right index finger remains sensitive and he cannot write for long periods of time without pain;

18. Had the Petitioner been aware of the risks associated with the use of Pradaxa, he would never have used Pradaxa. But for the Defendants' wrongful conduct, the Petitioner would not have suffered and continue to suffer damages, inconveniences and loss as alleged;

**THE DEFENDANTS**

19. 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, the whole as appears from the Organization Chart, a copy of which is produced herewith as **Exhibit P-1**;

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

21. The Defendant, Boehringer Ingelheim (Canada), Ltd., is a corporation incorporated under the *Canada Business Corporations Act* 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, the whole as appears from the Information sheet on the Registraire des entreprises du Québec, a copy of which is produced herewith as **Exhibit P-2**;

22. The business of each of Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International, GmbH and Boehringer Ingelheim (Canada), Ltd., (collectively, "Boehringer Ingelheim") are 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 Quebec;

23. At all material times, the Defendants were carrying on business as, inter alia the manufacturer and distributor of Pradaxa in Quebec;

## THE FACTS

- **Overview**

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

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

26. Members of the Class 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**

27. Pradaxa is an oral anticoagulant therapy 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] in whom a medication to prevent blood clotting is considered appropriate, the whole as appears from an excerpt from the database of the Canadian Intellectual Property Office, a copy of which is produced herewith as **Exhibit P-3**;

28. 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;

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

30. 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", the whole as appears from the "Dear Health Care Professional" letter posted on November 8, 2011, a copy of which is produced herewith as **Exhibit P-4**;

31. 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, the whole as appears from a press release issued by the Defendants on September 4, 2014, a copy of which is produced herewith as **Exhibit P-5**;

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[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.

[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.

32. According to a press release issued by the Defendants in August 2011, AF affects up to 350,000 Canadians, and is a serious yet common 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, stroke is 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, the whole as appears from the press release issued on August 29, 2011, a copy of which is produced herewith as **Exhibit P-6**;

33. 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 with AF. Unlike patients who use Pradaxa, 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 readily available and highly effective antidote is available. 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, the whole as appears from the product monograph, a copy of which is produced herewith as **Exhibit P-7**;

**Dosage**

34. 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;

35. 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 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**

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

37. On July 25, 2011, the Archives of Internal Medicine published *The Use of Dabigatran* [Pradaxa] *in Elderly Patients*. [Vol 171, No. 14] which concluded that "The 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.", the whole as appears from the article of the Archives of Internal Medicine dated July 25, 2011, a copy of which is produced herewith as **Exhibit P-8**;

38. On August 12, 2011, Japan's pharmaceutical regulatory authority announced that it was requiring a "BOXED WARNING" be added to Pradaxa (marketed as Prazaxa in Japan) to call attention to reports of severe hemorrhages in patients treated with Pradaxa (Prazaxa), the whole as appears from the press release issued on August 12, 2011, a copy of which is produced herewith as **Exhibit P-9**;

39. 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 Pradaxa. 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.", the whole as appears from the "Prescriber Update" published in September 2011, a copy of which is produced herewith as **Exhibit P-10**;

40. In November 2011, the Defendants confirmed at least 260 fatal bleeding events were reported in patients taking Pradaxa worldwide between March 2008 and October 2011, the whole as appears from the Medscape article dated November 17, 2011, a copy of which is produced herewith as **Exhibit P-11**. Moreover, The Institute for Safe Medication Practices reported that:

> "In the first quarter of 2011 [Pradaxa] produced two different kinds of signals of major drug risk: a large volume of total serious reports, and large numbers of reports for a specific adverse event, hemorrhage. Overall [the study] identified 932 serious adverse drug events of all types in which [Pradaxa] was the primary suspect drug, including 120 patient deaths, 25 cases of permanent disability, and 543 cases requiring hospitalization."
>
> the whole as appears from the Institute for Safe Medication Practices Report dated January 12, 2012, a copy of which is produced herewith as **Exhibit P-12.**

41. In 2011, an FDA analysis showed that with Pradaxa treatment, life threatening bleeds (a drug adverse effect) occurred at a higher rate than the strokes or systemic embolisms Pradaxa is intended to prevent (1.5% per year versus 1.1% a year), suggesting that Pradaxa creates an extreme risk for patients and provides no benefit whatsoever (Exhibit P-12);

42. 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;

43. Pradaxa's product monograph in Quebec does not provide any real precaution against the risk of uncontrollable and irreversible bleeds. In the "Warning" section, it merely outlines that "[a]s with all anticoagulants, PRADAXA (dabigatran 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 not even found under the "Warning" section, but rather under "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."

44. 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" on the medication, where it says 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 the drug is more convenient for patients than other anticoagulant therapies;

45. 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;

**THE DEFENDANTS' FAULTS**

46. The Defendants, at all material times, owed a duty of care to the Petitioner 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 use of Pradaxa posed serious health risks, including the risk of uncontrollable and irreversible bleeding.

- **Negligence and Fault**

47. The Defendants negligently breached their duty of care which constitutes a fault;

48. The Petitioner states that his damages and the damages of Class members were caused by the negligence and faults of the Defendants. Such negligence and faults include but are not limited to, the following:

(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

[5] Marketing materials for "New Pradax 150mg BID" for example, clearly state "No INR monitoring or dose titration" and footnote 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.

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, or a sufficient, 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 any or any adequate follow-up studies on the efficacy and safety of Pradaxa;

(g) the Defendants failed to conduct any or any long-term or adequate studies 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**

49. The Defendants failed to warn of the risks associated with Pradaxa which constitutes an omission to provide information;

50. The damages of the Petitioner and the damages of 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 should unexpected, uncontrollable and irreversible bleeding occur;

(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 Quebec and elsewhere;

(e) the Defendants failed to provide any or any 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 Quebec;

(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 respecting 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**

51. The Defendants were negligent in designing Pradaxa which constitutes a fault;

52. The damages of the Petitioner and the damages of Class members were caused by the Defendants' negligent design of Pradaxa, which includes but is not limited to, the following:

    (a) any benefit from using Pradaxa was outweighed by the serious and undisclosed risks of its use when used as intended;

    (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 Pradaxa exceeded the benefits associated with its design;

    (d) the Defendants knew, or ought to have known, that Pradaxa was more dangerous than persons using Pradaxa and their physicians or other health care providers, as reasonably prudent consumers and health care providers, would expect when used in an intended or reasonably foreseeable manner;

    (e) 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;

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

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

    (h) 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**

53. The Defendants were negligent in the distribution, marketing and sale of Pradaxa in violation of their duty of safety;

54. The Petitioner states that his damages and the damages of 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 is 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 use, when used as intended;

(c) there are no individuals for whom the benefits of Pradaxa outweigh the risks, given that there are many alternative products that are at least as efficacious as Pradaxa and carry far less 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, still 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 suitable for use in general without regard for severe health risks;

(g) 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;

(h) 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

(i) the Defendants failed to timely cease the manufacture, 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.

**DAMAGES**

55. 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;

56. The extent of the risks were not known to, and could not have been known by, the Petitioner and Class members;

57. The injuries of the Petitioner and Class members would not have occurred but for the negligence and fault of the Defendants in failing to ensure that Pradaxa was safe for use or, in the alternative, providing adequate warning of the risks associated with using Pradaxa to persons using Pradaxa and their physicians or other health care providers;

58. As a result of the Defendants' conduct, the Petitioner and Class members have suffered and will continue to suffer damages, inconveniences 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.

59. As a result of the Defendants' conduct, the Petitioner and Class members suffered and will continue to suffer expenses and damages, of a nature and amount to be particularized prior to trial;

60. As a result of the Defendants' negligence and fault, Class members are entitled to damages;

**PUNITIVE DAMAGES**

61. The Petitioner 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 reckless, entirely without care and deliberate. Such conduct renders the Defendants liable to pay punitive damages to the Class members;

62. Claims are made for the Petitioner, and on behalf of Class members, for punitive, aggravated and exemplary damages for the Defendants' reckless and unlawful conduct;

**LIABILITY OF THE DEFENDANTS**

63. The Defendants are liable for the acts and/or omissions of each of the individual Defendants and its other officers, directors, agents, employees and representatives;

**THE PERSONAL CLAIMS OF EACH OF THE MEMBERS OF THE CLASS AGAINST DEFENDANTS ARE BASED ON THE FOLLOWING FACTS:**

64. The claims of each of the members of the Class are based on the same facts as those upon which the claim of the Petitioner is based;

65. Class members have either ingested and/or purchased Pradaxa or are the successor, family member, assign, and/or dependant of a person who purchased and/or ingested Pradaxa;

66. The Class members' damages would not have occurred but for the acts and/or omissions and/or negligence and/or fault of the Defendants in failing to ensure that Pradaxa was safe for use, for failing to provide adequate warning of the risks associated with using it, and for over-promoting and misrepresenting its efficacy;

67. In light of the faults alleged, each member of the Class is entitled to the alleged damages in addition to damages for inconveniences and punitive damages;

**THE COMPOSITION OF THE MEMBERS OF THE CLASS MAKES THE APPLICATION OF ARTICLES 59 AND 67 OF THE *C.C.P.* DIFFICULT AND/OR IMPRACTICAL FOR THE FOLLOWING REASONS:**

68. The size of the Class consists of thousands of persons geographically dispersed throughout Quebec;

69. Thus, it is impossible for the Petitioner to identify all such potential class members and/or obtain a mandate from each of them;

70. A class action will ensure the most efficient use of judicial resources;

**THE IDENTICAL, SIMILAR OR RELATED QUESTIONS OF LAW OR OF FACT BETWEEN EACH MEMBER OF THE CLASS AND THE DEFENDANTS, WHICH PETITIONER WISHES TO HAVE DECIDED BY THIS CLASS ACTION ARE:**

71. The identical, similar or related questions of fact and law between each Class Member and the Defendants which the Petitioner wishes to have settled by the class action are as follows:

(a) Does Pradaxa cause a materially increased risk of serious, life-threatening, or even fatal bleeds, hemorrhages, blood clots, embolisms and/or strokes?

(b) Did the Defendants breach a duty of care owed to the Petitioner and the Class in violation of the *Civil Code of Quebec* and/or the *Consumer Protection Act*?

(c) Were the Defendants negligent and/or did they commit a fault and/or did they fail in their duty of safety, and/or duty to inform imposed upon them as manufacturer, distributer and/or seller of Pradaxa in violation of the *Civil Code of Quebec* and/or the *Consumer Protection Act*?

(d) Are the members of the Class entitled to claim material, bodily and/or moral damages in compensation for injury arising from the use of Pradaxa?

(e) Are members of the Class entitled to claim punitive damages?

**THE QUESTIONS OF LAW OR OF FACT WHICH ARE PARTICULAR TO EACH OF THE MEMBERS OF THE CLASS ARE:**

72. Out of the damages recovered by the Class, collectively, from the Defendants, what amount of damages is each member of the Class entitled to?

**IT IS EXPEDIENT THAT THE INSTITUTION OF A CLASS ACTION FOR THE BENEFIT OF THE MEMBERS OF THE CLASS BE AUTHORIZED FOR THE FOLLOWING REASONS:**

73. The class action is an efficient procedural vehicle that allows members of the Class to have access to justice;

74. The legal and factual issues surrounding the Defendants conduct and their liability are identical for each member of the Class;

75. It is in the interests of justice that members of the Class be given the opportunity to participate in the institution of a Class action that would benefit all those who have sustained damages as a result of the Defendants conduct;

**THE NATURE OF THE RECOURSE WHICH THE PETITIONER WISHES TO EXERCISE ON BEHALF OF THE MEMBERS OF THE CLASS IS:**

76. The nature of the recourse which the Petitioner wishes to exercise on behalf of the members of the Class is an action in civil liability and damages;

**THE CONCLUSIONS SOUGHT BY PETITIONER AGAINST THE DEFENDANTS ARE AS FOLLOWS:**

77. The conclusions sought by the Petitioner are:

**GRANT** the Petitioner's action against the Defendants;

**CONDEMN** the Defendants to pay to the Petitioner and the Class members compensation for all damages suffered in an amount to be determined by the Court;

**CONDEMN** the Defendants to pay to the Petitioners and the Class members punitive damages in an amount to be determined by the Court;

**GRANT** the class action of the Petitioner on behalf of all the Class members;

**ORDER** collective recovery of the claims of the Class members for damages if the Court is of the view that the evidence produced enables the establishment with sufficient accuracy of the total amount of the claims of the members; OR

**ALTERNATELY, ORDER** individual recovery of the claims of the Class members for damages, the whole in accordance with articles 1037 to 1040 CPC;

**ORDER** collective recovery of the claims of the Class members for punitive damages;

**THE WHOLE** with interest and additional indemnity provided for in the *Civil Code of Quebec* and with full costs and expenses, including expert fees, notice fees and fees relating to administering the plan of distribution of the recovery in this action.

**PETITIONER REQUESTS THAT HE BE ASCRIBED THE STATUS OF REPRESENTATIVE**

**PETITIONER IS IN A POSITION TO REPRESENT THE MEMBERS OF THE CLASS ADEQUATELY FOR THE FOLLOWING REASONS:**

78. The Petitioner, who requests that he be ascribed the status of representative, will fairly and adequately protect and represent the interests of the Class members for the following reasons:

(a) The Petitioner understands the nature of the action;

(b) The Petitioner is well-informed of the facts alleged in this motion;

(c) The Petitioner is available to dedicate the time necessary for an action to collaborate with members of the Class;

(d) The Petitioner has retained an established Quebec law firm with experience in class actions;

(e) The Petitioner does not have any interests in conflict with other members of the Class;

**THE PETITIONER PROPOSES THAT THE CLASS ACTION BE BROUGHT BEFORE THE SUPERIOR COURT OF THE DISTRICT OF MONTREAL FOR THE FOLLOWING REASONS:**

79. Due to demographics, the largest portion of members of the Class resides in the judicial District of Montreal;

80. The legal counsel for Petitioner has an office and practices in the judicial District of Montreal;

81. The present motion is well founded in law and in fact;

**FOR THESE REASONS, MAY IT PLEASE THE COURT:**

**GRANT** the present motion;

**AUTHORIZE** the bringing of a class action in the form of a motion to institute proceedings in damages;

**ASCRIBE** the Petitioner the status of representatives of the persons included in the Class herein described as:

> "All natural persons residing in Quebec who were prescribed the pharmaceutical Pradaxa (dabigatran etexilate) and who have suffered damages as a result of the use of this prescription drug, and/or their family members, assigns and heirs.
>
> or such other group definition as may be approved by the Court."

**IDENTIFY** the principle questions of fact and law to be treated collectively as the following:

(a) Does Pradaxa cause a materially increased risk of serious, life-threatening, or even fatal bleeds, hemorrhages, blood clots, embolisms and/or strokes?

(b) Did the Defendants breach a duty of care owed to the Petitioner and the Class in violation of the *Civil Code of Quebec* and/or the *Consumer Protection Act*?

(c) Were the Defendants negligent and/or did they commit a fault and/or did they fail in their duty of safety, and/or duty to inform imposed upon them as manufacturer, distributer and/or seller of Pradaxa in violation of the *Civil Code of Quebec* and/or the *Consumer Protection Act*?

(d) Are the members of the Class entitled to claim material, bodily and/or moral damages in compensation for injury arising from the use of Pradaxa?

(e) Are members of the Class entitled to claim punitive damages?

**IDENTIFY** the conclusions sought by the class action to be instituted as being the following:

> **GRANT** the Petitioner's action against the Defendants;

**CONDEMN** the Defendants to pay to the Petitioner and the Class members compensation for all damages suffered in an amount to be determined by the Court;

**CONDEMN** the Defendants to pay to the Petitioners and the Class members punitive damages in an amount to be determined by the Court;

**GRANT** the class action of the Petitioner on behalf of all the Class members;

**ORDER** collective recovery of the claims of the Class members for damages if the Court is of the view that the evidence produced enables the establishment with sufficient accuracy of the total amount of the claims of the members; OR

**ALTERNATELY, ORDER** individual recovery of the claims of the Class members for damages, the whole in accordance with articles 1037 to 1040 CPC;

**ORDER** collective recovery of the claims of the Class members for punitive damages;

**THE WHOLE** with interest and additional indemnity provided for in the *Civil Code of Quebec* and with full costs and expenses, including expert fees, notice fees and fees relating to administering the plan of distribution of the recovery in this action;

**DECLARE** that all Class Members that have not requested their exclusion from the Class in the prescribed delay to be bound by any judgement to be rendered on the class action to be instituted;

**FIX** the delay of exclusion at 30 days from the date of the publication of the notice to the Class Members;

**ORDER** the publication of a notice to the Class Members in accordance with article 1006 C.C.P.;

**REFER** the record to the Chief Justice so that he may determine the district wherein the class action is to be brought and the judge before whom it will be heard;

**THE WHOLE** with costs, including the costs of all publications of notices.

Montreal, May 6, 2015

Siskinds, Desmeules, Avocats, S.E.N.C.R.L.

**SISKINDS, DESMEULES, AVOCATS, S.E.N.C.R.L.**
Lawyers for the Petitioner

## SCHEDULE 1

## NOTICE TO DEFENDANT

Take notice that the Petitioner has filed this action or application in the office of the Superior Court of the judicial district of Montreal.

To file an answer to this action or application, you must first file an appearance, personally or by advocate, at the courthouse of Montreal located at 1, Notre-Dame East, Montreal, Quebec, H2Y 1B6 within 10 days of service of this motion.

If you fail to file an appearance within the time limit indicated, a judgment by default may be rendered against you without further notice upon the expiry of the 10 day period.

If you file an appearance, the action or application will be presented before the court on June 18th, 2015 at 9h00 a.m. On that date, the court may exercise such powers as are necessary to ensure the orderly progress of the proceeding or the court may hear the case, unless you have made a written agreement with the Petitioner or the Petitioner's advocate on a timetable for the orderly progress of the proceeding. The timetable must be filed in the office of the court.

These exhibits are available on request.

Montreal, May 6, 2015

Siskinds, Desmeules, avocats, S.E.N.C.R.L.

**SISKINDS, DESMEULES, AVOCATS, S.E.N.C.R.L.**
Lawyers for the Petitioner

**CANADA**
**PROVINCE OF QUEBEC**
**DISTRICT OF MONTREAL**
**NO:**

**(Class Action)**
**SUPERIOR COURT**

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**Lionel Whiteduck;**
Petitioner

v.

**Boehringer Ingelheim (Canada) Ltd.,**

and

**Boehringer Ingelheim Pharmaceuticals, Inc.,**

and

**Boehringer Ingelheim International GMbH**

Defendants

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LIST OF EXHIBITS

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**Exhibit P-1:** Organization Chart;

**Exhibit P-2:** Information sheet on the Registraire des entreprises du Québec;

**Exhibit P-3:** Excerpt from the database of the Canadian Intellectual Property Office;

**Exhibit P-4:** Letter entitled: "Dear Health Care Professional", posted on November 8, 2011;

**Exhibit P-5:** Defendants' Press Release issued on September 4, 2014;

**Exhibit P-6:** Defendants' Press Release issued on August 29, 2011;

**Exhibit P-7:** Product monograph;

**Exhibit P-8:** Article of the Archives of Internal Medicine, dated July 25, 2011;

**Exhibit P-9:** Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (Japan) - Press release issued on August 12, 2011;

**Exhibit P-10:** New Zealand Medicines and Medical Devices Safety Authority - "Prescriber Update", published in September 2011;

**Exhibit P-11:** Medscape article dated November 17, 2011;

**Exhibit P-12:** Institute for Safe Medication Practices Report, dated January 12, 2012.

Montreal, May 6, 2015

Siskinds, Desmeules, avocats, S.E.N.C.R.L.

**SISKINDS, DESMEULES, AVOCATS, S.E.N.C.R.L.**
Lawyers for the Petitioner

No: 500-06-000741-153

SUPERIOR COURT (Class Action)
DISTRICT OF MONTREAL

**Lionel Whiteduck**

Petitioner

v.

**Boehringer Ingelheim (Canada) Ltd.,**

and

**Boehringer Ingelheim Pharmaceuticals, Inc.**

and

**Boehringer Ingelheim International GMbH**

Defendants

**MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVE**
**(Articles 1002 and seq. C.C.P.)**

**Me Samy Elnemr** **BS2497**
**N/dossier: 67-159**

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