C A N A D A

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

Nº : 500-06-000692-141

S U P E R I O R C O U R T
(Class Action)

DENIS LEBEL, residing and domiciled at 1266 rue Beau-Harnois , in the city of St-Jean Chrysostone, Province of Québec, G6Z 3J4;

Applicant

-vs-

BOEHRINGER INGELHEIM (CANADA) LTD./LTEE, a legal person, having its principal place of business at 1908 Colonel Sam Dr., Oshawa, Ontario, L1H 8P7;

-and-

BOEHRINGER INGELHEIM AUSLANDSBETEILIGUNGS GMBH, a legal person, having its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany;

-and-

BOEHRINGER INGELHEIM INTERNATIONAL GMBH, a legal person, having its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany;

-and-

C. H. BOEHRINGER SOHN AG & CO. KG
, a legal person, having its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany;

Respondents

AMENDED APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT A REPRESENTATIVE PLAINTIFF
(Art. 574 C.C.P. and following)

TO THE HONOURABLE SUZANNE COURCHESNE, JUSTICE OF THE SUPERIOR COURT OF QUEBEC, SITTING IN AND FOR THE DISTRICT OF MONTREAL, THE APPLICANT STATES THE FOLLOWING:

GENERAL PRESENTATION

1. The Applicant wishes to institute a class action on behalf of the following group, of which he is a member, namely:

    - All estates, successors, assigns, family members, and dependants of persons deceased prior to April 29, 2016 who, at the time of death, resided in Quebec, had taken the drug Pradaxa, and whose death involved hemorrhage or exsanguination.

(hereinafter, referred to as "**Class Member(s)**", "**Group Member(s)**", the "**Group**", the "**Class**", the "**Member(s)**")

The Respondents

2. The Respondents 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**";

3. 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;

4. 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;

5. 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 Quebec, including through the sale of Pradaxa;

6. 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 Quebec, including through the sale of Pradaxa;

7. 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 Quebec, including through the sale of Pradaxa;

8. The Respondents are all directly connected as related, parent or wholly-owned subsidiary companies;

9. The Respondents 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;

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

General Facts**:**

11. 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;

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

13. Boehringer Canada received Health Canada's 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 Quebec;

14. Before Pradaxa was introduced into Canada, the only oral anticoagulant available in Canada 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;

15. 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;

16. Prior to April 29, 2016 when Health Canada conditionally approved Praxbind® for use in Canada, as shown in **Exhibit P-5**, no drug, agent or means existed to reduce or reverse the anticoagulant effects of Pradaxa. When Pradaxa caused a patient's blood to be excessively thinned, such that the patient's health is endangered, these effects were essentially irreversible potentially leading to severe hemorrhaging and death. Pradaxa was therefore a dangerous drug at the relevant times;

17. Unlike Warfarin, there was during the class period no antidote to Pradaxa. Boehringer failed to include an adequate warning of this important fact in advertisements and representation to the public, the medical community, or on Pradaxa labeling or packaging;

18. 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;

19. At all material times, the Respondents were aware 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 Respondents collectively withheld and suppressed this information worldwide, including in Canada and Quebec, preventing the *Applicant* and Class Members from making an informed decision as potential consumers of Pradaxa;

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

21. To date in the United States, at least 500 patient deaths and over 2,000 reports of hemorrhaging have been linked to the use of Pradaxa. By December 2013, Health Canada's Adverse Drug Reaction Database contained nearly 500 reports of adverse reactions to Pradaxa, including serious hemorrhage events and deaths, as it appears more fully in a copy of the Summary of Reported Adverse Reactions communicated herewith as **exhibit P-1**. A summary of the reported adverse reactions (limited to fatal outcomes prior to April 29, 2016) is communicated herewith as **Exhibit P-8;**

22. The Respondents' labeling and prescribing information for Pradaxa failed to disclose that there was no drug, agent, or means to reverse the anticoagulation effects of Pradaxa;

23. The Respondents knew or ought to have known that Pradaxa had been associated with greater mortality rates than alternative therapies when patients presented in emergency and trauma situations: see, for example, **Exhibit P-6** (40% mortality rate of dabigatran patients vs 0% mortality rate of warfarin patients presenting at a trauma centre with closed head injuries following ground-level falls) and **Exhibit P-7** (reporting

on the RE-LY study: 27% fatality rate from intracranial haemorrhage on dabigatran vs 11% on warfarin).

24. The Respondents failed to:

a) investigate, research, study and consider, fully and adequately, patient age, weight and kidney function as variable factors in establishing recommended dosages of Pradaxa;

b) investigate, research, study and define, fully and adequately, the safety profile of Pradaxa;

c) provide adequate warnings to the Applicant and Class Members about the true safety risks associated with the use of Pradaxa;

(…)

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

(…)

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

f) 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

g) include an adequate warning on the face of or inside the drug's packaging about serious bleeding events associated with Pradaxa;

Pradaxa Worldwide

25. 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;

26. 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;

27. 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;

28. 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;

29. 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 and that the serious consequences of a lack of an effective reversal agent were not to be underestimated, the whole as appears more fully from a copy of the letter published in the New England Journal of Medicine communicated herewith as **exhibit P-2**;

30. 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 Respondents 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;

31. 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 whole as appears more fully from a copy of the press release from the EMA communicated herewith as **exhibit P-3**. The Respondents have confirmed in their own statements that nearly 260 reports of fatal bleeding events were linked to Pradaxa usage;

32. 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;

33. 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 Respondents 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, the whole as appears more fully from a copy of the Australian Public Assessment Report, communicated herewith as **exhibit P-4**;

34. 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;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE APPLICANT

35. The Applicant, Denis Lebel, is a resident of St-Jean Chrysostone, Quebec;

36. On April 29, 2013, the Applicant's mother, Ms. Solange Lapointe, died at the age of 79, from a massive cerebral hemorrhage after taking Pradaxa;

37. Solange had previously undergone hip surgery and was prescribed Coumadin (warfarin) in order to prevent deep vein thrombosis;

38. On or around June 2011, on advice of her prescribing physician, Solange switched to Pradaxa, which she duly took until she passed away;

39. Solange had no previous health issues. She was independent and self-sufficient, and lived at her home;

40. On April 28th, 2013, the day before Solange's birthday, she was expecting company. Her daughter was the first to arrive but nobody answered the door. She proceeded to enter her mother's home with a spare key and found Solange on the floor but still breathing. Her daughter called an ambulance and Solange was transported to Hôpital Hôtel-Dieu de Lévis;

41. Solange suffered a massive cerebral hemorrhage and passed away within 24hrs of the incident;

42. As a result of the sudden death of his mother, the Applicant, who was very close to his mother, has suffered moral damages, including but not limited to pain, loss of guidance, care and companionship and other moral damages;

43. The damages suffered by the Applicant are a direct and proximate result of the Respondents' conduct;

44. As a consequence of the foregoing, the Applicant is justified in claiming damages;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP

45. Members of the Group consist of the successors, assigns, family members and dependants of individuals in Quebec who ingested Pradaxa and as a result suffered death;

46. Each Member of the Group is justified in claiming at least one or more of the following:

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

(i) personal injury and 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) exemplary and punitive damages;

47. All of these damages to the Group Members are a direct and proximate result of the Respondents' conduct;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

The composition of the group makes the application of Article 59 or 67 C.C.P. impractical or impossible for the reasons detailed below:

48. The number of persons included in the Group is estimated to be in the thousands. Global sales of Pradaxa reached €1.2 billion in 2013;

49. The names and addresses of all persons included in the Group are not known to the Applicant;

50. In addition, given the costs and risks inherent in an action before the Courts, many people will hesitate to institute an individual action against the Respondents. Even if the Group Members themselves could afford such individual litigation, the Court system could not as it would be overloaded. Furthermore, individual litigation of the factual, scientific, and legal issues raised by the conduct of Respondents would increase delay and expense to all parties and to the Court system;

51. These facts demonstrate that it would be impractical, if not impossible, to contact each and every Member of the Class to obtain mandates and to join them in one action;

52. In these circumstances, a class action is the only appropriate procedure for all of the Members of the Group to effectively pursue their respective rights and have access to justice;

The questions of fact and law which are identical, similar, or related with respect to each of the Class Members:

53. The recourses of the Group Members raise identical, similar or related questions of fact or law, namely:

a) Does Pradaxa cause, contribute to, or materially increase the risk of uncontrollable bleeding or hemorrhagic events?

(…)

b) Is Pradaxa a dangerous drug, unfit for its intended purpose, which should not have been marketed in the absence of an antidote?

c) Did the Respondents fail to adequately disclose the risks and dangers of Pradaxa to consumers?

d) Are the Respondents liable to pay compensatory damages to Group Members stemming from the dangerous drug, or the Respondents' failure to warn?

e) Does the conduct of the Respondents warrant an award of exemplary damages, and if so, what amount of exemplary damages should be awarded?

f) What are the categories of damages for which the Respondents are responsible to pay to Group Members, and in what amount?

g) Are Respondents liable to pay any other compensatory, moral, punitive or exemplary damages to Group Members, and if so in what amount?

54. The interests of justice favour that this motion be granted in accordance with its conclusions;

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

55. The action that the Applicant wishes to institute for the benefit of the members of the Class is an action in damages for product liability;

56. The conclusions that the Applicant wishes to introduce by way of a motion to institute proceedings are:

GRANT Applicant`s action against Respondents;

ORDER AND CONDEMN Respondents to pay compensatory damages to the Group Members for the personal injury or death, economic and moral losses stemming from the defective drug, or the Respondents' failure to warn.

CONDEMN Respondents to pay punitive and/or exemplary damages to the Group Members, to be determined by the Court;

GRANT the class action of Applicant on behalf of all the Members of the Group;

ORDER the treatment of individual claims of each Member of the Group in accordance with articles 599 to 601 C.C.P.;

RENDER any other order that this Honourable Court shall determine and that is in the interest of the Members of the Group;

THE WHOLE with interest and additional indemnity provided for in the Civil Code of Quebec and with full costs and expenses including expert's fees and publication fees to advise members;

57. Applicant suggests that this class action be exercised before the Superior Court in the district of Montreal for the following reasons:

a) Many Group Members are domiciled in the district of Montreal;

b) The Respondents sold Pradaxa in the district of Montreal;

c) The Applicant's counsel is domiciled in the District of Montreal;

58. The Applicant, who is requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the Members of the Group, since Applicant:

a) Is a member of the group, who lost his mother from the use of the drug Pradaxa;

b) understands the nature of the action and has the capacity and interest to fairly and adequately protect and represent the interests of the Members of the Group;

c) is available to dedicate the time necessary for the present action before the Courts of Quebec and to collaborate with Class attorneys in this regard;

d) is ready and available to manage and direct the present action in the interest of the Group Members that the Applicant wishes to represent, and is determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Class;

e) does not have interests that are antagonistic to those of other members of the Group;

f) has given the mandate to the undersigned attorneys to obtain all relevant information to the present action and intend to keep informed of all developments;

g) is, with the assistance of the undersigned attorneys, ready and available to dedicate the time necessary for this action and to collaborate with other Members of the Group and to keep them informed;

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

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 Applicant the status of representative of the persons included in the Group herein described as:

- All estates, successors, assigns, family members, and dependants of persons deceased prior to April 29, 2016 who, at the time of death, resided in Quebec, had taken the drug Pradaxa, and whose death involved hemorrhage or exsanguination.

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

a) Does Pradaxa cause, contribute to, or materially increase the risk of uncontrollable bleeding or hemorrhagic events?

(…)

b) Is Pradaxa a dangerous drug, unfit for its intended purpose, which should not have been marketed in the absence of an antidote?

c) Did the Respondents fail to adequately disclose the risks and dangers of Pradaxa to consumers?

d) Are the Respondents liable to pay compensatory damages to Group Members stemming from the dangerous drug, or the Respondents' failure to warn?

e) Does the conduct of the Respondents warrant an award of exemplary damages, and if so, what amount of exemplary damages should be awarded?

f) What are the categories of damages for which the Respondents are responsible to pay to Group Members, and in what amount?

g) Are Respondents liable to pay any other compensatory, moral, punitive or exemplary damages to Group Members, and if so in what amount?

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

GRANT Applicant`s action against Respondents;

ORDER and CONDEMN Respondents to pay damages to the Group Members to pay compensatory damages to Group Members stemming from the defective drug, or the Respondents' failure to warn;

CONDEMN Respondents to pay punitive and/or exemplary damages to the Group Members, to be determined by the Court;

GRANT the class action of Applicant on behalf of all the Members of the Group;

ORDER the treatment of individual claims of each Member of the Group in accordance with articles 599 to 601 C.C.P.;

RENDER any other order that this Honourable Court shall determine and that is in the interest of the Members of the Group;

THE WHOLE with interest and additional indemnity provided for in the Civil Code of Quebec and with full costs and expenses including expert's fees and publication fees to advise members;

DECLARE that all Members of the Group that have not requested their exclusion from the Group in the prescribed delay to be bound by any judgment 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 Members;

ORDER the publication of a notice (the content and distribution of which is to be determined after authorization has been ordered and all applicable appeal periods have expired) to the Members of the Group in accordance with Article 579 C.C.P.;

THE WHOLE with costs to follow.

MONTREAL, January 29, 2021

Merchant Law Group.

_____

MERCHANT LAW GROUP LLP

Attorneys for the Applicant

Nº.: 500-06-000692-141

S U P E R I O R C O U R T
DISTRICT OF MONTREAL

DENIS LEBEL

Applicant

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Defendants

AMENDED APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT A REPRESENTATIVE PLAINTIFF

(Art. 574 C.C.P. and following)

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