CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000732-152

(Class Action)
SUPERIOR COURT

D. GAGNON

Petitioner

-vs.-

JANSSEN INC., legal person duly constituted, having its head office at 19 Green Belt Drive, City North York, Province of Ontario, M3C 1L9

and

JANSSEN RESEARCH & DEVELOPMENT, LLC, legal person duly constituted, having its head office at One Johnson & Johnson Plaza, City of New Brunswick, County of Middlesex, State of New Jersey, 08933, U.S.A.

and

JOHNSON & JOHNSON, legal person duly constituted, having its head office at One Johnson & Johnson Plaza, City of New Brunswick, County of Middlesex, State of New Jersey, 08933, U.S.A.

and

JOHNSON & JOHNSON INC., legal person duly constituted, having its head office at 88 McNabb Street, City of Markham, Province of Ontario, L3R 5L2

and

JANSSEN ORTHO, LLC, legal person duly constituted, having its head office at Stateroad 933 Km 0 1, Street Statero,

Municipality of Gurabo, United States Territory of Puerto Rico, 00778

and

JANSSEN PHARMACEUTICALS, INC., legal person duly constituted, having its head office at 1125 Trenton-Harbourton Road, City of Titusville, State of New Jersey, 08560, U.S.A.

and

BAYER INC., legal person duly constituted, having its head office at 77 Belfield Road, City of Toronto, Province of Ontario, M9W 1G6

and

BAYER CANADIAN HOLDINGS INC., legal person duly constituted, having its head office at 77 Belfield Road, City of Toronto, Province of Ontario, M9W 1G6

and

BAYER CORPORATION, legal person duly constituted, having its head office at 100 Bayer Road, Building 4, City of Pittsburgh, State of Pennsylvania, 15205, U.S.A.

and

BAYER HEALTHCARE AG, legal person duly constituted, having its head office at D-51368 Leverkusen, Germany

and

BAYER PHARMA AG, legal person duly constituted, having its head office at D-51368 Leverkusen, Germany

and

BAYER AG, legal person duly constituted, having its head office at D-51368 Leverkusen, Germany

and

BAYER HEALTHCARE LLC, legal person duly constituted, having its head office at 100 Bayer Boulevard, P.O. Box 915, City of Whippany, State of New Jersey, 07981-0915, U.S.A.

and

BAYER HEALTHCARE PHARMACEUTICALS, INC., legal person duly constituted, having its head office at 340 Changebridge Road, City of Pine Brook, State of New Jersey, 07058-9714, U.S.A.

Respondents

MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION
&
TO ASCRIBE THE STATUS OF REPRESENTATIVE
(Art. 1002 C.C.P. and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR PETITIONER STATES AS FOLLOWS:

I. GENERAL PRESENTATION

A) The Action

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

    - all persons residing in Canada who have taken and/or purchased the drug, RIVAROXABAN (sold under the brand name XARELTO®) since 2008, and their successors, assigns,

family members, and dependants, or any other group to be determined by the Court;

Alternately (or as a subclass)

- all persons residing in Quebec who have taken and/or purchased the drug, RIVAROXABAN (sold under the brand name XARELTO®) since 2008, and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

2. "XARELTO" is the brand name of the anticoagulant[1] drug, Rivaroxaban, which is prescribed to patients in order to reduce the ability of the blood to clot in the arteries, veins and/or heart or to prevent existing blood clots from increasing in size. Specifically, XARELTO is used to:

   (i) Reduce the risk of stroke in patients with non-valvular atrial fibrillation (AF)[2],

   (ii) Treat deep vein thrombosis (DVT)[3] and pulmonary embolism (PE)[4] and to reduce the risk of reoccurrence, and

   (iii) Prevent or reduce venous thromboembolism (VTE)[5] after knee and hip replacement surgery;

3. Petitioner contends that Respondents represented to the medical and healthcare community, to Health Canada and the United States Food and Drug Administration ("USFDA") and to the Class Members that they researched, designed, developed, manufactured, and tested XARELTO and that it had been found to be safe and/or effective for its intended use. In addition, the Respondents concealed their knowledge of XARELTO's defects from the medical and healthcare community, Health Canada and the USFDA, and from Class Members;

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[1] Anticoagulant medicines are used to prevent the formation of blood clots.

[2] Atrial fibrillation (AF) is a common heart rhythm disorder (a cardiac arrhythmia) associated with deadly and debilitating consequences including heart failure, stroke, poor mental health, reduced quality of life and death.

[3] Deep vein thrombosis, or deep venous thrombosis, (DVT) is the formation of a blood clot (thrombus) within a deep vein, predominantly in the legs.

[4] Pulmonary embolism (PE) is a blockage of the main artery of the lung or one of its branches by a substance that has travelled from elsewhere in the body through the bloodstream (embolism). PE most commonly results from deep vein thrombosis (a blood clot in the deep veins of the legs or pelvis) that breaks off and migrates to the lung, a process termed venous thromboembolism (VTE).

[5] Venous thromboembolism (VTE) comprises both deep vein thrombosis (DVT) and pulmonary embolism (PE). The most serious complication of DVT occurs when the blood clot dislodges and travels to the lungs, becoming a PE.

4. The Respondents marketed, packaged, promoted, advertised, distributed, labelled and/or sold XARELTO as a new, safe, effective, and more convenient oral treatment that was more effective than Warfarin (also known by the brand names Coumadin, Jantoven, Marevan, and Uniwarfin), a long-established safe treatment for the prevention of heart attacks, strokes, and blood clots in the veins and arteries despite a wealth of existing knowledge that the drug had dangerous side effects including, an increased risk of major life-threatening internal bleeding, among other serious and severe bleeding complications;

5. Importantly, there is no antidote to XARELTO, unlike Warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent and the Respondents gave inadequate warnings and/or information on the topic;

6. In addition, while the Respondents were labelling XARELTO as a drug that prevents heart attacks, strokes, and blood clots, its side effect of major internal bleeding has the potential to cause heart attacks and death. Thus, the Respondents researched, designed, developed, manufactured, tested, marketed, packaged, promoted, advertised, distributed, labelled and/or sold XARELTO as a preventative drug, without so much as mentioning that it was also a catalyst;

7. Respondents continue to market, package, promote, advertise, distribute, label and/or sell XARELTO throughout Canada, including within the province of Quebec, with inadequate warnings as to its serious and adverse side effect of the increased risk of major life-threatening internal bleeding and the lack of an antidote which has severe and life-threatening complications which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences which are described in more detail below;

B) <u>The Respondents</u>

8. Respondent Janssen Inc. (“Janssen Canada”) is a Canadian pharmaceutical corporation, with its head office in North York, Ontario. Janssen Canada is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO. It is a wholly-owned subsidiary of Respondent Johnson & Johnson (“J&J”) that does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises*, produced herein as **Exhibit R-1**;

9. Respondent Janssen Research & Development, LLC[6] ("Janssen R&D") is an American pharmaceutical research and development corporation with its head office in New Brunswick, New Jersey. Janssen R&D is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO. In 2005, Respondent Janssen R&D entered into an agreement with Respondent Bayer HealthCare AG to jointly develop XARELTO. Janssen R&D is the holder of the approved United States New Drug Application ("NDA'') for XARELTO, as well as the supplemental NDAs, the whole as appears more fully from a copy of the Press Release entitled "Johnson & Johnson Pharmaceutical Research & Development, L.L.C. submits New Drug Application to FDA for Rivaroxaban" dated July 30, 2008, from a copy of the New Release entitled "FDA Approves XARELTO® (rivaroxaban tablets) to Help Prevent Deep Vein Thrombosis in Patients Undergoing Knee or Hip Replacement Surgery" dated July 1, 2011, from a copy of the Press Release entitled "New Drug Application Submitted to FDA for Rivaroxaban for Prevention of Stroke in Patients with Atrial Fibrillation" dated January 5, 2011, and from a copy of the News Release entitled "FDA Approves XARELTO® (rivaroxaban) to Reduce the Risk of Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation" dated November 4, 2011, produced herein *en liasse* as **Exhibit R-2**;

10. Respondent J&J is an American pharmaceutical corporation with its head office in New Brunswick, New Jersey. It is the parent company of Janssen Canada and a parent company of Respondent Janssen Ortho, LLC. J&J manufactures, markets and sells a wide range of pharmaceutical products including XARELTO. J&J is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO;

11. Respondent Johnson & Johnson Inc. ("J&J Canada") is a Canadian pharmaceutical corporation with its head office in Markham, Ontario. It is a subsidiary of Respondent J&J that does business throughout Canada, including within the province of Quebec. J&J Canada is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO;

12. Respondent Janssen Ortho, LLC ("Janssen Ortho") is a Delaware pharmaceutical corporation with its head office in Gurabo, Puerto Rico. Janssen Ortho is a subsidiary of Respondent J&J. Janssen Ortho is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising,

[6] Janssen Research & Development, LLC was formerly known as Johnson and Johnson Pharmaceutical Research and Development LLC.

distribution, labelling and/or sale of pharmaceutical products including XARELTO;

13. Respondent Janssen Pharmaceuticals, Inc.[7] ("Janssen Pharma") is an American pharmaceutical corporation with its head office in Titusville, New Jersey. Janssen Pharma is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO;

14. Respondent Bayer Inc. ("Bayer Canada") is a Canadian pharmaceutical corporation with its head office in Toronto, Ontario. Bayer Canada is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO. It is a subsidiary of Respondent Bayer Canadian Holdings Inc. ("Bayer Canada Holdings") and non-party Bayer Global Investments B.V., that does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises*, produced herein as **Exhibit R-3**;

15. Respondent Bayer Canada is the Canadian manufacturer and the owner of the patent for XARELTO for the "• prevention of stroke and systemic embolism in patients with atrial fibrillation, in whom anticoagulation is appropriate. • treatment of venous thromboembolic events (deep vein thrombosis [DVT], pulmonary embolism [PE]) and prevention ofrecurrent *[sic]* DVT and PE" under three (3) Drug Identification Numbers ("DIN") according to its three (3) strengths being: 10 mg (DIN: 02316986[8]), 15 mg (DIN: 02378604[9]), and 20 mg (DIN: 02378612[10]), the whole as appear more fully from a copy of Health Canada's Patent Registers for the Medicinal Ingredient "rivaroxaban" and the Brand Name "XARELTO", produced herein *en liasse* as **Exhibit R-4**;

16. Respondent Bayer Canadian Holding Inc. ("Bayer Canada Holding") is a Canadian holding corporation with its head office in Toronto, Ontario. Bayer Canada Holding is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO. It is a parent company of Respondent Bayer Canada that also does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of the Government of

[7] Janssen Pharmaceuticals, Inc. was formerly known as Janssen Pharmaceutica Inc. and formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc.
[8] Associated patent numbers for DIN 2396561: 2547113, 2624310, and 2823159.
[9] Associated patent numbers for DIN 02378604: 2396561, 2547113, 2624310, and 2823159.
[10] Associated patent numbers for DIN 02378612: 2396561, 2547113, 2624310, and 2823159.

Canada Federal Corporation Information for corporation 3325903, produced herein as **Exhibit R-5**;

17. Respondent Bayer Corporation ("Bayer USA") is an American pharmaceutical corporation with its head office in Pittsburgh, Pennsylvania. It is a wholly-owned subsidiary of Respondent Bayer AG and it is the parent company of Respondents Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals, Inc[11]. Bayer USA is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO;

18. Respondent Bayer HealthCare AG is a German pharmaceutical corporation with its head office in Germany. In 2005, Respondent Bayer HealthCare AG entered into an agreement with Respondent Janssen R&D to jointly develop XARELTO (Exhibit R-2). It is the parent/holding company of Respondents Bayer Inc., Bayer Canadian Holdings Inc., Bayer USA, Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals, Inc., and Bayer Pharma AG. Bayer HealthCare AG is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO;

19. Respondent Bayer Pharma AG[12] is a German pharmaceutical corporation with its head office in Germany. It is a subsidiary of Respondent Bayer Healthcare Pharma AG and Bayer AG. Bayer Pharma AG is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO;

20. Respondent Bayer AG is a German chemical and pharmaceutical corporation with its head office in Germany. It is the parent company of Respondents Bayer Canada, Bayer, Bayer USA, Bayer HealthCare AG, Bayer Pharma AG, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals, Inc. It is the third largest pharmaceutical company in the world. Bayer AG is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO. It is the registrant of the trade-mark (word) XARELTO (TMA726283) which was filed on August 8, 2002, the whole as appears more fully from a copy of said trade-mark from the CIPO database, produced herein as **Exhibit R-6**;

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[11] Bayer USA is the parent company of Respondent Bayer HealthCare LLC, which owns 100% of non-party Schering Berlin, Inc., which owns 100% of Respondent Bayer HealthCare Pharmaceuticals, Inc. As such, Respondent Bayer USA is the parent company of Respondent Bayer HealthCare Pharmaceuticals, Inc.

[12] Bayer Pharma AG was formerly known as Bayer Schering Pharma AG (July 1, 2011) which was formerly known as Schering AG (December 29, 2006).

21. In addition, Respondent Bayer AG is the applicant and owner of the patent for XARELTO, which was filed on December 11, 2000 and issued on October 14, 2008, the whole as appears more fully from a copy of patent no. 2396561 from the CIPO database, produced herein as **Exhibit R-7**;

22. Respondent Bayer HealthCare LLC is an American pharmaceutical corporation with its head office in Whippany, New Jersey. It is a wholly-owned subsidiary of Respondent Bayer USA. Respondent Bayer Healthcare LLC is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO;

23. Respondent Bayer HealthCare Pharmaceuticals, Inc.[13] ("Bayer HealthCare Pharma") is an American corporation with its head office in Pine Brook, New Jersey. It is an indirectly wholly-owned subsidiary of Bayer USA (*supra* footnote 11). Bayer Healthcare Pharma is and was at all relevant times involved in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including XARELTO;

24. All Respondents have either directly or indirectly researched, designed, developed, manufactured, tested, marketed, packaged, promoted, advertised, distributed, labelled and/or sold XARELTO to distributors and retailers for resale to or, directly to physicians, hospitals, medical practitioners and to the general public throughout Canada, including within the Province of Quebec;

25. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other. Unless the context indicates otherwise, all Respondents will be referred to as "Bayer" for the purposes hereof;

C) <u>The Situation</u>

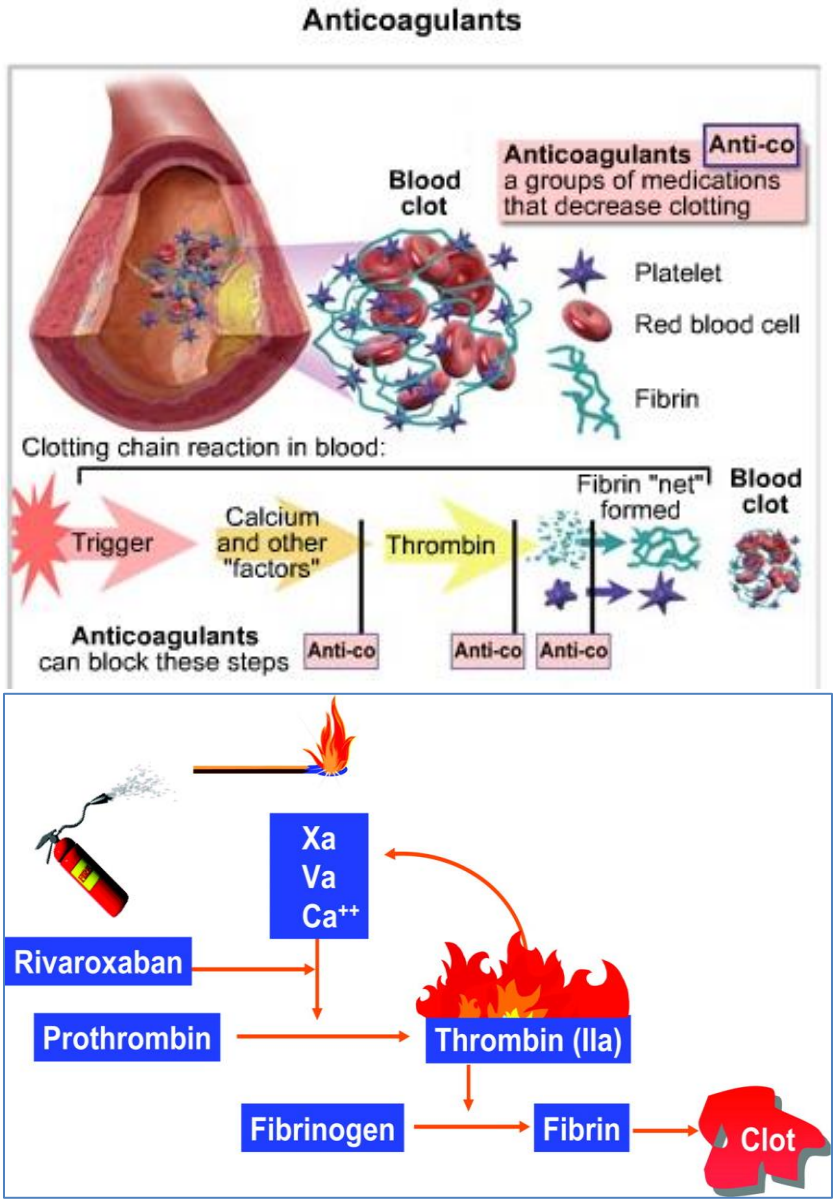
I. <u>What is XARELTO?</u>

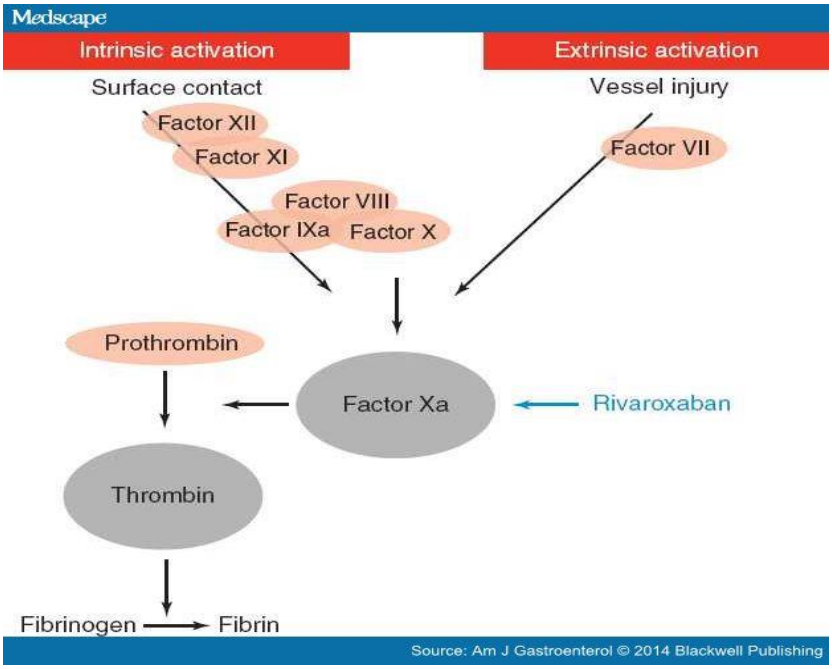
26. XARELTO belongs to a group of medicines called anticoagulants. It works by directly inhibiting the blood-clotting "Factor Xa"[14] and thereby reducing the tendency of the blood to form clots. Specifically, it is an oral anticoagulant

[13] Bayer HealthCare Pharmaceuticals, Inc. was formerly known as Berlex Laboratories, Inc.

[14] Simply put, Factor Xa, also known as Stuart-Prower factor and as prothrombinase, thrombokinase or thromboplastin, is an enzyme that participates in the coagulation or clotting of blood.

medication that is prescribed to patients to reduce the risk of stroke in patients with non-valvular atrial fibrillation (AF), to treat deep vein thrombosis (DVT) and pulmonary embolism (PE), and to reduce the risk of reoccurrence, and to prevent or reduce venous thromboembolism (VTE) after knee and hip replacement surgery;





27. On September 15, 2008, Respondent Bayer Canada obtained approval for XARELTO from Health Canada in the 10 mg strength for the "prevention of venous thromboembolic events (VTE) in patients who have undergone elective total hip replacement or total knee replacement surgery". On March 19, 2009 this approval was supplemented due to "[t]he addition of new physician sample labelling". On January 16, 2012, Respondent Bayer Canada obtained approval from Health Canada to market XARELTO in Canada in the 10, 15, and 20 mg strengths as a "prevention of stroke and systemic embolism in patients with arterial fibrillation". On February 15, 2012 this approval was supplemented with the "treatment of deep vein thrombosis (DVT) without symptomatic pulmonary emoblism *[sic]* (PE)" for the 15 and 20 mg strengths. Lastly, on April 18, 2013, Respondent Bayer Inc. obtained approval from Health Canada to market XARELTO as a "[t]reatment of pulmonary embolism (PE) and prevention of recurrent deep vein thrombosis (DVT) and PE" in the 10, 15, and 20 mg strengths, the whole as appears more fully from a copy of the five (5) Notices of Compliance obtained from Respondent Bayer Canada from Health Canada and from a copy of the Health Canada Summary Basis of Decision (SBD) for Xarelto dated February 13, 2009, produced herein *en liasse* as **Exhibit R-8**;

28. Accordingly, the Respondents launched XARELTO in Canada in 2008 in the 10mg strength as a prescription medication to prevent VTE in patients undergoing total hip replacement or total knee replacement surgery and in 2012, the Respondents launched XARELTO in all three (3) strengths, namely 10, 15, and 20 mg as a prescription medication to prevent stroke and systemic embolism in patients with atrial fibrillation. These uses increased to the present day classification as an anticoagulant medication to reduce the risk of

stroke in patients with non-valvular atrial fibrillation (AF), to treat deep vein thrombosis (DVT) and pulmonary embolism (PE) and to reduce the risk of reoccurrence, and to prevent or reduce venous thromboembolism (VTE) after knee and hip replacement surgery;

29. On July 1, 2011, Respondent Janssen R&D obtained approval from the USFDA to market XARELTO in the United States as a "prevention (prophylaxis) of deep vein thrombosis (DVT), which may lead to a pulmonary embolism (PE) in people undergoing knee or hip replacement surgery" and on November 4, 2011, Respondent Janssen R&D obtained approval from the USFDA to market XARELTO in the United States as having the ability to "reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation" (Exhibit R-2);

30. A one-year supply of XARELTO costs approximately $3,000 as compared to warfarin which costs approximately $200 per year;

II. The Scientific Studies Behind the Drug

31. The studies that follow demonstrate that ingesting XARELTO has an increased risk of serious bleeding events and/or the severity thereof;

32. Approval of XARELTO for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (the "RECORD" studies) (Exhibit R-8). The findings of the RECORD studies showed that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (based on the Respondents' definition), accompanied by similar rates of bleeding. However, the studies also showed a greater incidence with XARELTO of bleeding leading to decreased hemoglobin levels and transfusion of blood, the whole as appears more fully from a copy of the New England Journal of Medicine article entitled "Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty" dated June 26, 2008, from a copy of the Lancet journal article entitled "Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomised controlled trial" dated June 28, 2009, and from a copy of the New England Journal of Medicine article entitled "Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty" dated June 26, 2008, produced herein *en liasse* as **Exhibit R-9**;

33. Approval of XARELTO for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation was based on a clinical trial known as the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism

Trial in Atrial Fibrillation study ("ROCKET AF") - which set out to prove, and in fact did prove, that rivaroxaban was non-inferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, "bleeding from gastrointestinal sites, including upper, lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion". Interestingly, the ROCKET AF study was sponsored by Respondents Janssen R&D (then Johnson & Johnson Pharmaceutical Research and Development) and Bayer HealthCare Pharma, the whole as appears more fully from a copy of the New England Journal of Medicine article entitled "Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation" dated September 8, 2011, from a copy of the Supplementary Appendix, from a copy of the Disclosure Forms, and from a copy of the Protocol, produced herein *en liasse* as **Exhibit R-10**;

34. The ROCKET AF study was controversial as reviewers had noted that warfarin had not been optimally used in the study and that this flaw prevented the study results from definitively proving that rivaroxaban was no worse than warfarin. This is dangerous territory as the flawed results could lead to use of a drug that could increase death and injury, the whole as appears more fully from a copy of the Institute for Safe Medication Practices' QuarterWatch entitled "Monitoring FDA MedWatch Reports - Why Reports of Serious Adverse Drug Events Continue to Grow" dated October 3, 2012, produced herein as **Exhibit R-11**;

35. Approval of XARELTO for the treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE was based on the clinical trials known as the EINSTEIN-DVT, EINSTEIN-PE, and EINSTEIN-Extension studies. The EINSTEIN-DVT study tested XARELTO versus a placebo, and merely determined that XARELTO offered an option for treatment of DVT, with obvious increased risk of bleeding events as compared to a placebo. The EINSTEIN-Extension study confirmed that result. The EINSTEIN-PE study's findings showed that a rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events in users of XARELTO, including those that resulted in permanent discontinuation of XARELTO or prolonged hospitalization, the whole as appears more fully from a copy of the New England Journal of Medicine article entitled "Oral Rivaroxaban for Symptomatic Venous Thromboembolism" dated December 23, 2010, from a copy of the Expert Review of Cardiovascular Therapy Clinical Trial Report entitled "Oral rivaroxaban after symptomatic venous thromboembolism: the continued treatment study (EINSTEIN-Extension study)" dated July 2011, and from a copy of New England Journal of Medicine article entitled "Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism" dated April 5, 2012, produced herein *en liasse* as **Exhibit R-12**;

36. The Respondents have used the results of the RECORD studies, the ROCKET AF study, and the EINSTEIN studies to promote XARELTO in their promotional materials, including, the XARELTO website, which tout the positive results of those studies. However, the Respondents' promotional materials fail to similarly highlight the increased risk of gastrointestinal bleeding and bleeding that required transfusion, among other serious bleeding concerns;

37. In addition, the Respondents designed their studies to under-represent the true risk of adverse bleeding events and they failed to conduct proper studies that they knew or should have known would have disclosed the true risks;

38. These studies serve to indicate the importance of informing both patients and healthcare professionals of these adverse side-effects so that they may make informed decisions regarding this medication. In addition, should the patient make an informed decision to take XARELTO in spite of the serious risks, knowledge of these risks would have led to regular blood monitoring and/or doctor follow-up to ensure proper dosage if at all;

39. The Respondents, in failing to advise doctors and patients of the increased risks associated with XARELTO, effectively usurped their ability to make informed decisions regarding its use and removed their ability to limit and/or control the risk through engaging in precautionary monitoring measures;

40. In August of 2014, the Journal of Neurosurgery published an study that showed that the use of XARELTO and other newer anticoagulant medications could lead to irreversible intracerebral hemorrhage or bleeding inside the brain, the whole as appears more fully from a copy of the Journal of Neurosurgery article entitled "Race against the clock: Overcoming challenges in the management of anticoagulant-associated intracerebral hemorrhage" dated August 2014, produced herein as **Exhibit R-13**;

III. <u>The Respondents' Marketing Practices</u>

41. The Respondents marketed XARELTO as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism. The Respondents sharply emphasized the supposed benefits of treatment with XARELTO over warfarin, which they refer to as the Xarelto Difference – namely, that XARELTO does not require regular monitoring with blood tests and that it does not limit a patient's diet;

42. For example, in advertising XARELTO on the Respondents' websites, they state:

> With XARELTO®, blood tests aren't typically necessary to set your starting dose, and you don't need to schedule regular blood tests throughout your treatment to have your dosage adjusted. So instead of spending time monitoring your blood, you can do more of the things you enjoy. (emphasis added)

The whole as appears more fully from a copy of Respondent Janssen Pharma's website at www.xarelto.com and from a copy of the Respondent-sponsored WebMD webpage for XARELTO available at www.webmd.com, produced herein *en liasse* as **Exhibit R-14**;

43. This emphasis on convenience is dangerously misleading and it negated the already inadequate language in XARELTO's labelling concerning the serious risk of severe and irreversible bleeding;

44. However, in its QuarterWatch publication for the first quarter of the 2012 fiscal year (Exhibit R-11), the Institute for Safe Medication Practices ("ISMP") noted that, even during the approval process, FDA "[r]eviewers also questioned the convenient once-a-day dosing scheme [of XARELTO], saying blood level studies had shown peaks and troughs that could be eliminated by twice-a-day dosing";

45. Importantly, there is no antidote to XARELTO, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent;

46. This important information hardly present in the Product Monograph at present as it is only mentioned once in the "Overdosage" section and is unclear. The excerpt is as follows:

> A specific antidote for XARELTO is not available. The use of activated charcoal to reduce absorption in case of XARELTO overdose may be considered. Administration of activated charcoal up to 8 hours after overdose may reduce the absorption of XARELTO.

The whole as appears more fully from a copy of the Product Monograph for XARELTO last revised on July 10, 2014, produced herein as **Exhibit R-15**;

47. There are feasible alternatives to XARELTO in the form of anticoagulants for which there is an established antidote, i.e., reversal agent, and for which there is an established blood monitoring protocol. The lack of these attributes in XARELTO rendered its design defective, which was a substantial factor in causing the Plaintiff's and Class Members' injuries. Today, the Respondents are frantically searching for an antidote that they should have developed before making the business decision to release XARELTO into the marketplace;

48. Clinical collaboration agreements were entered into by the Respondents with Portola Pharmaceuticals Inc. a pharmaceutical corporation based in San Francisco, California for the development of an antidote for XARELTO. On January 9, 2015, Portola Pharmaceuticals Inc. announced positive results for the safety and efficacy of Andexanet Alfa as a suitable antidote therapy for a major bleeding episode from XARELTO in the ANNEXA-R[15] study and that it would present its findings to the American College of Cardiology on March 16, 2015, the whole as appears more fully from a copy of the Globe Newswire News Release entitled "Portola Announces Phase 3 ANNEXA-R Study of Andexanet Alfa and Factor Xa Inhibitor XARELTO(R) (rivaroxaban) Met Primary Endpoint With High Statistical Significance" dated January 9, 2015 and from a copy of the non-yet-registered trade-mark "ANNEXA" (Application Number: 1707663) which was filed on December 17, 2014, produced herein *en liasse* as **Exhibit R-16**;

49. The Respondents have spent significant money in their promotion of XARELTO, which included at least $11,000,000.00 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of the 2013 fiscal year, XARELTO was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent, the whole as appears more fully from a copy of the Drugs.com article entitled "Janssen, Forest Labs dominate top five in spent advertising" dated September 2013, produced herein as **Exhibit R-1**7;

50. As a result of the Respondents' aggressive marketing efforts, XARELTO garnered approximately $122 million in global sales in 2011, $457 million in 2012 (a 274.4% increase), and $1.3455 billion in 2013 (a 194.7 % increase)[16]. Thus, in 2013, XARELTO cleared the $1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry. Thus, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales, the whole as appears more fully from a copies of three (3) Bayer Annual Reports for the years 2008, 2012, and 2013, produced herein *en liasse* as **Exhibit R-18**;

51. The Respondents' website for XARELTO claims that over nine (9) million people worldwide have been prescribed XARELTO, the whole as appears more fully from a copy of an extract from the Respondents' website at www.xarelto.com, produced herein as **Exhibit R-19**;

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[15] Andexanet Alfa a Novel Antidote to the Anticoagulant Effects of FXa Inhibitors – Rivaroxaban.

[16] € 86 million is approximately $122 million Canadian, € 322 million is approximately $457 million Canadian, and € 949 million is approximately $1.3455 billion Canadian not adjusting for currency fluctuations at the time.

52. As part of their marketing of XARELTO, the Respondents employed a "pull marketing" technique[17] whereby direct-to-consumer advertising campaigns were disseminated that were designed to influence patients, including the Petitioner, to make inquiries to their prescribing physician about XARELTO and/or request prescriptions for XARELTO;

53. In the course of these direct-to-consumer advertisements, the Respondents overstated the efficacy of XARELTO, misleadingly suggested that no blood monitoring was required, failed to adequately disclose to patients that there is no antidote for XARELTO, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences;

54. It is this manner that sales of XARELTO have been steadily rising as can be clearly seen from the Bayer Annual Reports (Exhibit R-16) despite the number of serious and life-threatening side effects related to the medication. In fact, the Respondents are actually looking to expand their market size to include its use for patients with acute coronary syndrome (ACS), peripheral artery disease and embolic stroke of indeterminate source, the whole as appears more fully from a copy of the Drugwatch article entitled "Xarelto Report: Prescriptions Rise despite Hike in Bleeding Events" dated November 13, 2014 and from a copy of the Associated Press article entitled "FDA Rejects Wider Use of J&J's Xarelto for 3rd Time" dated February 14, 2014, produced herein *en liasse* as **Exhibit R-20**;

55. On June 6, 2013, the Respondents received a letter from the USFDA's Office of Prescription Drug Promotion regarding its promotional material for the atrial fibrillation indication, stating that, "the print ad is false or misleading because it minimizes the risks associated with Xarelto and makes a misleading claim" regarding dose adjustments, which was in violation of USFDA regulations. The USFDA Office of Prescription Drug Promotion thus requested that the Respondents immediately cease distribution of such promotional material[18], the whole as appears more fully from a copy of the letter sent from the USFDA's Office of Prescription Drug Promotion to Johnson & Johnson dated June 6, 2013, produced herein as **Exhibit R-21**;

56. On the Respondents' website it is rather difficult to find information on the side effects of XARELTO, but when the most intrepid consumer does in fact find this information, in addition to the run-on sentence of possible "undesirable effects" all that is provided is the following:

> Contraindications:

[17] A "pull marketing" technique primarily targets patients by urging them to "pull" or request certain drugs from their physicians whereas a "push marketing" technique primarily targets physicians by urging them to "push" certain drugs onto their patients.

[18] This letter (Exhibit R-19) indicates that the Respondents were in violation of the *Food and Drugs Act*, RSC 1985, c. F-27, namely s. 9

> Hypersensitivity to the active substance or any of the excipients; active clinically significant bleeding; lesion or condition if considered a significant risk for major bleeding; concomitant treatment with any other anticoagulants except under specific the circumstances of switching anticoagulant therapy to or from rivaroxaban or when unfractionated heparin is given at doses necessary to maintain an open central venous or arterial catheter; hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C; pregnancy and breast feeding.
>
> Warnings and Precautions:
> Clinical surveillance in line with anticoagulation practice is recommended throughout treatment. Xarelto should be discontinued if severe haemorrhage occurs. Increasing age may increase haemorrhagic risk."

The whole as appears more fully from a copy of an extract from the Respondents' website at www.xarelto.com, produced herein as **Exhibit R-22**;

57. On the Respondents' Canadian website, the following is provided in terms of warning:

> Contraindications: clinically significant active bleeding including gastrointestinal bleeding; lesions or conditions at increased risk of clinically significant bleeding, e.g., recent cerebral infarction (hemorrhagic or ischemic), active peptic ulcer disease with recent bleeding, patients with spontaneous or acquired impairment of hemostasis; concomitant systemic treatment with strong inhibitors of both CYP 3A4 and P-glycoprotein (P-gp); concomitant treatment with any other anticoagulant (including unfractionated heparin [UFH] except at doses used to maintain a patent central venous or arterial catheter; low molecular weight heparins [LMWH]; heparin derivatives; and oral anticoagulants except under circumstances of switching therapy to or from Xarelto®); hepatic disease associated with coagulopathy and having clinically relevant bleeding risk; pregnancy; nursing women; hypersensitivity to Xarelto® (rivaroxaban) or to any ingredient in the formulation.

The whole as appears more fully from a copy on an extract from the Respondents' website at www.xarelto.ca, produced herein as **Exhibit R-23**;

58. Nowhere on their websites do the Respondents indicate the crucial fact that there is no antidote for XARELTO such that in the event of hemorrhagic complications, there is no available reversal agent as there is for warfarin;

59. Despite various warning changes, the Respondents' marketing of XARELTO continues to fail to warn consumers, healthcare professionals and the public:

    a. Of the serious and significant risk of serious, severe and irreversible bleeding complications;

    b. That in the event of a bleeding complication, there is no antidote to reverse it; and

    c. That people taking XARELTO should closely and frequently monitor their blood;

IV. The Respondents' Liability

60. Although XARELTO is marketed, packaged, promoted, advertised, distributed, labelled and/or sold as a safe and effective prescription drug to reduce the risk of stroke in patients with non-valvular atrial fibrillation (AF), to treat deep vein thrombosis (DVT) and pulmonary embolism (PE), and to reduce the risk of reoccurrence, and to prevent or reduce venous thromboembolism (VTE) after knee and hip replacement surgery, it has the serious side effect of the increased risk for severe and irreversible bleeding and/or hemorrhagic complications, which has no available antidote;

61. A reasonably prudent drug researcher, designer, developer, manufacturer, tester, marketer, packager, promotor, advertiser, distributer, labeller and/or seller in the Respondents' position would have adequately warned both doctors and patients of the risks associated with the use of XARELTO;

62. There have been thousands of reports of severe hemorrhagic events and death reported with federal regulators in the United States and in Europe. On a global scale, in the first eight (8) months of 2013, German regulators received XARELTO-related averse event reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012;

63. Despite a clear signal, the Respondents failed to either alert the public and the scientific and medical community or to perform further investigation into the safety of XARELTO;

64. The Respondents were negligent in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of XARELTO in one or more of the following respects:

a. They knew of should have known that XARELTO increased the risk of the adverse side effect of severe and irreversible bleeding and/or hemorrhagic complications, which has no available antidote and which has sever and life-threatening complications;

b. They failed to ensure that XARELTO was not dangerous to consumers;

c. They failed to conduct appropriate testing to determine whether and to what extent the ingestion of XARELTO poses serious health risks, including the bleeding complications;

d. They failed to adequately test the product prior to placing it on the market;

e. They failed to adequately test XARELTO in a manner that would fully disclose the side effect of severe and irreversible bleeding and/or hemorrhagic complications;

f. They failed to use care in designing, developing and manufacturing their products so as to avoid posing unnecessary health risks to users of such products;

g. They failed to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine the safety of the drug;

h. They failed to advise that the consumption of XARELTO could result in severe and disabling side effects, including but not limited to, severe and irreversible bleeding and/or hemorrhagic complications;

i. They failed to advise the medical and scientific communities of the potential to increase the risk of severe and irreversible bleeding and/or hemorrhagic complications;

j. They failed to provide adequate and timely warnings or sufficient indications about the increased potential health risks associated with the use of XARELTO;

k. They failed to adequately warn emergency room doctors, surgeons, and other critical care medical professionals as well as Class Members and the medical and health community in general, that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation effects of Xarelto, and therefore no effective

means to treat and stabilize patients who experience uncontrolled bleeding while taking XARELTO;

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

m. They failed to provide Class Members and their physicians with adequate warnings or sufficient indications of inherent risks associated with XARELTO;

n. They failed to adequately warn Class Members and their physicians about the need to undergo regular medical monitoring to prevent the severe and irreversible bleeding and/or hemorrhagic complications;

o. They failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on XARELTO and to continue testing and monitoring of renal functioning periodically while the patient is on XARELTO;

p. They failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on XARELTO and to continue testing and monitoring of hepatic functioning periodically while the patient is on XARELTO;

q. They failed to instruct prescribing physicians and patients on how to determine proper dosing;

r. They failed to provide adequate updated and current information to class members and their physicians respecting the risks of XARELTO as such information became available;

s. They failed to provide prompt warnings of potential hazards of XARELTO in the products' monograph and in the products' labelling;

t. They failed to warn that class members and their physicians that the risks associated XARELTO would exceed the risks of other available anticoagulant medications;

u. After receiving actual or constructive notice of problems XARELTO, they failed to issue adequate warnings, to publicize the problem and otherwise act properly and in a timely manner to alert the public, the Class Members and their physicians, of the drugs' inherent dangers;

v. They failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the risks associated with the drug;

w. They falsely stated and/or implied that XARELTO was safe when they knew or ought to have known that this representation was false;

x. They disregarded reports of severe and irreversible bleeding and/or hemorrhagic complications among patients;

y. They failed to accurately and promptly disclose to Health Canada information relating severe and irreversible bleeding and/or hemorrhagic complications associated with XARELTO and to modify XARELTO product monograph and product labelling accordingly in a timely manner;

z. They failed to monitor and to initiate a timely review, evaluation and investigation of reports of severe and irreversible bleeding and/or hemorrhagic complications associated with XARELTO in Canada and around the world;

aa. They failed to properly investigate cases of severe and irreversible bleeding and/or hemorrhagic complications caused by XARELTO;

bb. They deprived patients of a chance for safe, effective and/or successful alternative treatments; and

cc. In all circumstances of this case, they applied callous and reckless disregard for the health and safety of their consumers;

65. Despite the vast availability of knowledge clearly indicating that XARELTO use is causally-related to severe and irreversible bleeding and/or hemorrhagic complications, Respondents not only failed to provide adequate labelling to warn Class Members of the risks associated with the use of XARELTO, but instead incongruously promoted and marketed XARELTO as a safe and effective drug, effectively appropriating the ability of doctors and patients to make informed decisions regarding their health;

66. The Respondents concealed and failed to completely disclose their knowledge that XARELTO was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk;

67. The Respondents ignored the association between the use of XARELTO and the risk of developing life-threatening bleeding;

68. The Respondents' failure to disclose information that they possessed regarding the failure to adequately test and study XARELTO for life-threatening bleeding risk further rendered warnings for this medication inadequate;

II. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

69. On or about October 10, 2012, the Petitioner underwent knee replacement surgery on her left knee at the Hôpital Notre-Dame at 1560 Sherbrooke Street East, in Montreal, Quebec;

70. Immediately thereafter, the Petitioner was prescribed XARELTO by her orthopedic surgeon to prevent deep venous thrombosis (DVT) and venous thromboembolism (VTE) and she took the medication as directed;

71. Within days, the Petitioner suffered a massive hemorrhage in her left knee whereby she was given blood and plasma for several hours until the bleeding abated;

72. The Petitioner stopped taking XARELTO immediately upon suffering the bleeding event;

73. After three (3) to four (4) days, the Petitioner was sent directly to a CSSS physiotherapy centre located on René Lévesque where she remained to undergo physical therapy for her knee until the end of November 2012;

74. The Petitioner agreed to initiate XARELTO treatment in an effort to prevent DVT and VTE and she relied on claims made by the Respondents that XARELTO has been clinically shown to reduce the risk of DTV and VTE;

75. At no time was the Petitioner made aware of the risks of suffering hemorrhagic complications associated with taking XARELTO;

76. Had the Respondents properly disclosed the risks associated with XARELTO, the Petitioner would have avoided the risk of suffering hemorrhagic complications by not using XARELTO at all or by having her blood closely monitored;

77. The Petitioner has recently discovered, while researching online, that several lawsuits were filed in the United States due to the defects associated with XARELTO and due to the Respondents' conduct related thereto, the whole as appears more fully from a copy of the Complaints, produced herein *en liasse* as **Exhibit R-24**;

78. As a result of the Respondents' conduct, the Petitioner suffered damages including, but not limited to physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increase risk of health problems, and the apportioned cost of the XARELTO;

79. Petitioner's damages are a direct and proximate result of her use of the drug XARELTO, Respondent's negligence and/or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug XARELTO;

80. In consequence of the foregoing, Petitioner is justified in claiming damages;

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

81. Every member of the class has purchased and/or ingested the drug, XARELTO or is the successor, family member, assign, and/or dependant of a person who purchased and/or ingested XARELTO;

82. The class members' damages would not have occurred, but for the acts, omissions and/or negligence of the Respondents in failing to ensure that XARELTO was safe to use, for failing to provide adequate warning of the unreasonable risks associated with using the drug, for false or misleading representations and for omitting to disclose important information to Class Members and to their physicians;

83. In consequence of the foregoing, each member of the class is justified in claiming at least one or more of the following as damages:

    a. Physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increase risk of health problems;

    b. Out-of-pocket expenses incurred or to be incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, and the diagnosis and treatment of XARELTO side effect services;

    c. Loss of income and loss of future income;

    d. Refund of the purchase price of XARELTO or alternatively, the incremental costs of XARELTO as paid for by the class members and/or by the *Régie de l'assurance maladie du Québec*, the Ontario Health Insurance Plan, and other provincial health insurers; AND

    e. Punitive damages;

84. As a direct result of the Respondents' conduct, the users' family members and dependants have, had, and/or will suffer damages and loss including:

    a. Out-of-pocket expenses, including paying or providing nursing, housekeeping and other services;

    b. Loss of income and loss of future income; AND

    c. Loss of support, guidance, care, consortium, and companionship that they might reasonably have expected to receive if the injuries had not occurred;

85. All of these damages to the class members are a direct and proximate result of the use of XARELTO and Respondents' conduct, negligence and reckless failure to adequately disclose necessary information and the risks associated with the drug;

IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

A) The composition of the class renders the application of articles 59 or 67 C.C.P. difficult or impractical

86. Petitioner is unaware of the specific number of persons who ingested and/or purchased XARELTO, which information is confidential, however, it is safe to estimate that it is in the tens of thousands;

87. Class members are numerous and are scattered across the entire province and country;

88. 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 class members themselves could afford such individual litigation, it would place an unjustifiable burden on the courts. Further, individual litigation of the factual and legal issues raised by the conduct of the Respondents would increase delay and expense to all parties and to the court system;

89. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having contradictory judgments on questions of fact and law that are similar or related to all members of the class;

90. 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;

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

B) <u>The questions of fact and law which are identical, similar, or related with respect to each of the class members with regard to the Respondents and that which the Petitioner wishes to have adjudicated upon by this class action</u>

92. Individual questions, if any, pale by comparison to the numerous common questions that are significant to the outcome of the litigation;

93. The damages sustained by the class members flow, in each instance, from a common nucleus of operative facts, namely, Respondent's misconduct;

94. The recourses of the members raise identical, similar or related questions of fact or law, namely:

    a) Does XARELTO cause, exacerbate or contribute to an increased risk severe and irreversible bleeding and/or hemorrhagic complications?

    b) Were the Respondents negligent and/or did they fail in their duty of safety and/or duty to inform imposed upon them as researchers, designers, developers, manufacturers, testers, marketers, packagers, promotors, advertisers, distributers, labellers and/or sellers of XARELTO?

    c) Was XARELTO researched, designed, developed, manufactured, tested, marketed, packaged, promoted, advertised, distributed, labelled, and sold with defects that increase a patient's risk of severe and irreversible bleeding and/or hemorrhagic complications?

    d) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for XARELTO?

    e) Did the Respondents fail to adequately and properly test XARELTO before and/or after placing it on the market?

    f) Did the Respondents know or should have known about the risks associated with the use of XARELTO?

    g) Did the Respondents knowingly, recklessly or negligently breach a duty to warn class members and/or their physicians of the risks of harm from the use/ingestion of XARELTO?

h) Did the Respondents knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks of harm from the use/ingestion of XARELTO?

i) Did the Respondents knowingly fail to disclose and warn of XARELTO's defects?

j) Did the Respondents adequately and sufficiently warn the members and/or their physicians of the class about the risks associated with the use of XARELTO?

k) Should XARELTO have been sold with more appropriate warnings?

l) Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that XARELTO was safe or omitted to disclose material facts regarding XARELTO's safety?

m) Did the Respondents fail in their duty to inform class members and/or their physicians about the importance of frequently monitoring blood for patients taking XARELTO so as to prevent the consequences that could result?

n) Were the members of the class prejudiced by taking XARELTO instead of other anticoagulant medications, which have similar benefits, but do not pose such an increased risk of severe and irreversible bleeding and/or hemorrhagic complications and/or have an antidote in case thereof?

o) In the affirmative to any of the above questions, did Respondents conduct engage their solidary liability toward the members of the class?

p) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the class can claim from the Respondents?

q) Are members of the class entitled to bodily, moral, and material damages?

r) Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking XARELTO?

s) Are the members of the class entitled to recover as damages an amount equal to the purchase price of XARELTO or any part of the purchase price?

t) Are members of the class entitled to aggravated or punitive damages?

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

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

96. The action that the Petitioner wishes to institute on behalf of the members of the class is an action in damages, injunctive relief, and declaratory judgment;

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

GRANT the class action of the Petitioner and each of the members of the class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of XARELTO;

RESERVE the right of each of the members of the class to claim future damages related to the use of XARELTO;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the Class;

CONDEMN the Defendants to pay to each member of the class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual class members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

A) <u>The Petitioner requests that she be attributed the status of representative of the Class</u>

98. Petitioner is a member of the class;

99. Petitioner is ready and available to manage and direct the present action in the interest of the members of the class that she wish to represent and is determined to lead the present dossier until a final resolution of the matter, the whole for the benefit of the class, as well as, to dedicate the time necessary for the present action before the Courts of Quebec and the *Fonds d'aide aux recours collectifs*, as the case may be, and to collaborate with her attorneys;

100. Petitioner has the capacity and interest to fairly and adequately protect and represent the interest of the members of the class;

101. Petitioner has given the mandate to her attorneys to obtain all relevant information with respect to the present action and intends to keep informed of all developments;

102. Petitioner, with the assistance of her attorneys, is ready and available to dedicate the time necessary for this action and to collaborate with other members of the class and to keep them informed;

103. Petitioner has given instructions to her attorneys to put information about this class action on its website and to collect the coordinates of those class members that wish to be kept informed and participate in any resolution of the present matter, the whole as will be shown at the hearing;

104. Petitioner is in good faith and has instituted this action for the sole goal of having her rights, as well as the rights of other class members, recognized and protected so that they may be compensated for the damages that they have suffered as a consequence of the Respondents' conduct;

105. Petitioner understands the nature of the action;

106. Petitioner's interests are not antagonistic to those of other members of the class;

B) <u>The Petitioner suggests that this class action be exercised before the Superior Court of Justice in the district of Montreal</u>

107. A great number of the members of the class reside in the judicial district of Montreal and in the appeal district of Montreal;

108. The Petitioner's attorneys practice their profession in the judicial district of Montreal;

109. 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, injunctive relief, and declaratory relief;

ASCRIBE the Petitioner the status of representative of the persons included in the class herein described as:

- all persons residing in Canada who have taken and/or purchased the drug, RIVAROXABAN (sold under the brand name XARELTO®) since 2008, and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

Alternately (or as a subclass)

- all persons residing in Quebec who have taken and/or purchased the drug, RIVAROXABAN (sold under the brand name XARELTO®) since 2008, and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

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

a) Does XARELTO cause, exacerbate or contribute to an increased risk severe and irreversible bleeding and/or hemorrhagic complications?

b) Were the Respondents negligent and/or did they fail in their duty of safety and/or duty to inform imposed upon them as researchers, designers, developers, manufacturers, testers, marketers, packagers, promotors, advertisers, distributers, labellers and/or sellers of XARELTO?

c) Was XARELTO researched, designed, developed, manufactured, tested, marketed, packaged, promoted, advertised, distributed, labelled, and sold with defects that increase a patient's risk of severe and irreversible bleeding and/or hemorrhagic complications?

d) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for XARELTO?

e) Did the Respondents fail to adequately and properly test XARELTO before and/or after placing it on the market?

f) Did the Respondents know or should have known about the risks associated with the use of XARELTO?

g) Did the Respondents knowingly, recklessly or negligently breach a duty to warn class members and/or their physicians of the risks of harm from the use/ingestion of XARELTO?

h) Did the Respondents knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks of harm from the use/ingestion of XARELTO?

i) Did the Respondents knowingly fail to disclose and warn of XARELTO's defects?

j) Did the Respondents adequately and sufficiently warn the members and/or their physicians of the class about the risks associated with the use of XARELTO?

k) Should XARELTO have been sold with more appropriate warnings?

l) Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that XARELTO was safe or omitted to disclose material facts regarding XARELTO's safety?

m) Did the Respondents fail in their duty to inform class members and/or their physicians about the importance of frequently monitoring blood for patients taking XARELTO so as to prevent the consequences that could result?

n) Were the members of the class prejudiced by taking XARELTO instead of other anticoagulant medications, which have similar benefits, but do not pose such an increased risk of severe and irreversible bleeding and/or hemorrhagic complications and/or have an antidote in case thereof?

o) In the affirmative to any of the above questions, did Respondents conduct engage their solidary liability toward the members of the class?

p) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the class can claim from the Respondents?

q) Are members of the class entitled to bodily, moral, and material damages?

r) Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking XARELTO?

s) Are the members of the class entitled to recover as damages an amount equal to the purchase price of XARELTO or any part of the purchase price?

t) Are members of the class entitled to aggravated or punitive damages?

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

GRANT the class action of the Petitioner and each of the members of the class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of XARELTO;

RESERVE the right of each of the members of the class to claim future damages related to the use of XARELTO;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the class;

CONDEMN the Defendants to pay to each member of the class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual class members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

DECLARE that all members of the class that have not requested their exclusion, be bound by any judgment to be rendered on the class action to be instituted in the manner provided for by the law;

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the members, date upon which the members of the class that have not exercised their means of exclusion will be bound by any judgment to be rendered herein;

ORDER the publication of a notice to the members of the group in accordance with article 1006 C.C.P. within sixty (60) days from the judgment to be rendered herein in LA PRESSE and the NATIONAL POST;

ORDER that said notice be available on the Respondents' websites, Facebook page(s), and twitter accounts with a link stating "Notice to XARELTO prescribers and users";

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

THE WHOLE with costs, including all publications fees.

Montreal, February 16, 2015

(S) Andrea Grass

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CONSUMER LAW GROUP INC.
Per: Me Andrea Grass
Attorneys for the Petitioner