AMENDED this 16th day of NOV 2015 Pursuant to Rule 3.62 dated the 16 day of NOV 2015

FORM 10
[RULE 3.25]

CLERK OF THE COURT

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JUDICIAL CENTRE OF CALGARY

COURT FILE NUMBER	1501-09439
COURT	COURT OF QUEEN'S BENCH OF ALBERTA
JUDICIAL CENTRE	CALGARY
PLAINTIFFS	PAUL KARVONEN and HELI KARVONEN
DEFENDANTS	BAYER INC., BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER PHARMA AG, JANSSEN PHARMACEUTICALS, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, AND JANSSEN ORTHO LLC
DOCUMENT	**Brought under the *Class Proceedings Act*** **AMENDED STATEMENT OF CLAIM**
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NOTICE TO DEFENDANT(S)	You are being sued. You are a defendant. Go to the end of this document to see what you can do and when you must do it.

OVERVIEW

1. This is a proposed class action related to the pharmaceutical drug Xarelto, a product designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold by the Defendants, as defined below.

2. Xarelto is an anticoagulant prescribed to prevent blood clots from forming.

3. Xarelto is a dangerous drug. While excessive bleeding which can result in severe injury and death is a side-effect of any anticoagulant, antidotes are available for most other drugs, which can quickly stop the bleeding. In contrast, there is no substance that can be administered to stop or reverse excessive bleeding caused by Xarelto.

4. Due to the absence of a reversal agent, a patient experiencing bleeding while taking Xarelto is at risk of serious injury or death. Elderly patients, patients with impaired renal functions, and patients with a history of gastro-intestinal bleeding are particularly vulnerable to the risks of unstoppable, excessive bleeding caused by Xarelto. The Defendants failed to properly warn the Plaintiffs and other putative class members, or their healthcare providers, of the particular vulnerability of several population groups to Xarelto's adverse effects, despite knowing of it.

5. The Defendants owed a duty to the Plaintiffs and members of the putative class to clearly warn about the lack of a reversal agent for Xarelto and the vulnerability of particular population groups to the adverse effects of this drug. Putative class members were harmed by the Defendants' failure to warn. Among them is the Plaintiff, Paul Karvonen (**Paul**), who experienced extensive bleeding as a result of taking Xarelto, and

his wife, Heli Karvonen (**Heli**), who cared for Paul during the times he experienced and continues to experience adverse effects from taking Xarelto.

PARTIES

6. The Plaintiffs, Paul and Heli, are individuals residing on an acreage south of the Town of Spruce Grove, in the Province of Alberta.

7. Paul had been prescribed and started taking Xarelto, 15 mg daily, in January 2015. Paul's dose was increased to 20 mg daily on March 15, 2015. He continued taking Xarelto until April 16, 2015.

8. On April 16, 2015, Paul experienced severe gastrointestinal bleeding, requiring immediate medical attention. He ceased taking Xarelto on that date.

9. Currently, Paul continues to suffer from the effects of hemorrhaging caused by Xarelto, including having blood in his stool. His health and wellbeing are further affected by excessive bruising and acid reflux disease.

10. The Plaintiff, Heli, is Paul's wife and is pursuing her claim in that capacity. Heli and other Class Members have suffered and continue to suffer damages including loss of care, guidance and companionship, as well as financial expenses and special damages due to the wrongful conduct of the Defendants.

11. The Defendant, Bayer Inc., is a corporation incorporated pursuant to the laws of Canada, with its registered head office and principal place of business in the city of ^Mississauga, in the Province of Ontario. Bayer Inc. is the manufacturer and "sponsor" of Xarelto. As the "sponsor" of Xarelto in Canada, Bayer Inc. is responsible for the

Product Monographs for this device, which are documents intended for healthcare professionals and patients that set out the uses, dosage, and risks associated with a drug. Accordingly, Bayer Inc. is responsible for any deficiencies or omissions within the Product Monograph regarding the lack of a reversal agent for Xarelto. Bayer Inc. publishes several websites, such as www.bayer.ca and m.xarelto.ca, from which healthcare professionals and patients can learn about the risks associated with Xarelto.

12. The Defendant, Bayer Healthcare Pharmaceuticals, Inc. (**Bayer Health**), is a corporation incorporated under the laws of the State of Delaware, in the United States of America. Bayer Health is the entity that "discovered" Xarelto, according to the U.S. label. Bayer Health is also described in that label as having jointly developed Xarelto with JRD (as defined below). It is the entity that markets Xarelto outside of the U.S., also according to the U.S. label.

13. The Defendant, Bayer Pharma AG (**Bayer Pharma**), is a company incorporated under the laws of the Federal Republic of Germany, with a principal place of business in Berlin, Germany. Bayer Pharma is one of the two entities identified on the U.S. label for Xarelto as the manufacturers of the drug, along with Janssen Ortho (as defined below). Bayer Pharma AG hosts the www.xarelto.com website, a source of health and safety information regarding Xarelto that is accessible by Canadian healthcare professionals and patients.

14. The Defendant, Janssen Pharmaceuticals, Inc. (**JPI**), is a corporation incorporated pursuant to the laws of the State of New Jersey with its head office located in Titusville, New Jersey. JPI is identified in the U.S. label for Xarelto as being the entity for which

Xarelto is manufactured by other entities named in this action. JPI publishes the U.S. Xarelto website, a source of health and safety information regarding Xarelto that is accessible by Canadian healthcare professionals and patients. JPI markets Xarelto in the U.S., developing advertising that is also consumed by Canadian healthcare professionals and patients.

15. The Defendant, Janssen Research & Development, LLC. (**JRD**), is a corporation incorporated pursuant to the laws of the State of New Jersey, in the United States of America. JRD jointly developed Xarelto with Bayer Health.

16. The Defendant, Janssen Ortho LLC (**Janssen Ortho**), is a corporation incorporated pursuant to the laws of the State of Delaware with its head office located in Gurabo, Puerto Rico. Janssen Ortho is the second of the two entities identified on the U.S. label for Xarelto as the manufacturers of the drug, along with Bayer Pharma.

17. Bayer Inc., Bayer Health, Bayer Pharma, JPI, JRD, and Janssen Ortho are referred to collectively herein as the "**Defendants**".

18. At all material times, the Defendants, directly or through their agents, designed, researched, developed, tested, manufactured, marketed, packaged, labelled, promoted, distributed, licensed, and sold Xarelto for use by patients throughout the world, including in Alberta.

19. The Plaintiffs plead that, by virtue of the acts described herein, each of the Defendants is vicariously liable for the act and omissions of the others for the following reasons:

    (a) each was the agent of the other;

(b) each Defendant's business was operated so that it was inextricably interwoven with the business of the other;

(c) each Defendant entered into a common advertising and business plan with the other to distribute and sell Xarelto;

(d) each Defendant operated pursuant to a common business plan to distribute and sell Xarelto;

(e) each Defendant intended that the businesses be run as one business organization; and

(f) all or some of the Defendants are related, associated or affiliated.

XARELTO

20. Xarelto is an anti-coagulant used to prevent blood clotting in certain patients.

21. Xarelto is approved for use by patients who suffer from atrial fibrillation (**AF**), as well as patients who have had hip and knee surgery. AF is a condition in which the heart beats irregularly, increasing the chance of clots forming in the body and possibly causing strokes. AF accounts for approximately 15 to 20 per cent of all strokes in Canada. It mostly affects the elderly.

22. Xarelto is also indicated for the treatment of venous thromboembolic events (**VTE**) such as deep vein thrombosis and pulmonary embolism. Deep vein thrombosis refers to the formation of a blood clot within a deep vein, predominantly in the legs. Pulmonary embolism occurs when a blood clot detaches from a vein and travels with the bloodflow to the lungs.

23. On September 15, 2008, Xarelto was approved by Health Canada for the prevention of VTE in patients who have undergone elective total hip replacement or total knee replacement surgery, a relatively small population. It was approved in a single dosage, 10 mg. In January of 2012, it was approved for the prevention of stroke and embolism in the much larger population suffering from AF. Health Canada approved three dosages, 10, 15 and 20 mg.

24. Prior to Health Canada's relatively recent approval of new anticoagulants like Xarelto, the drug warfarin was a popular oral anticoagulation available in Canada for reducing stroke and systemic embolism in patients with AF.

25. Warfarin has been on the market for approximately 50 years. According to the Defendants, unlike patients who use Xarelto, users of warfarin must follow dietary restrictions and regularly monitor their internal normalization ratio (**INR**) levels. INR, determined through a blood test, measures the speed with which a patient's blood coagulates. Dose adjustments may be necessary on the basis of INR measurements.

26. The Defendants promoted Xarelto as an innovative medicine. The Defendants' marketing campaign claimed that Xarelto was more effective than warfarin in preventing stroke and systemic embolism, and that Xarelto provided a convenient alternative to warfarin therapy because: (i) Xarelto does not require INR monitoring or dose adjustments and (ii) it does not require dietary restrictions.

HARM CAUSED BY XARELTO

27. Shortly after Xarelto was first approved for sale in the United States and Canada, adverse events came to be reported to the U.S. Food and Drug Administration (**FDA**) and to Health Canada.

28. A September 2013 article published in a German magazine reported that Xarelto had been linked to 968 adverse events (including 72 deaths) in Germany during the first 8 months of 2013. In 2012, Xarelto had been associated with 750 adverse events, including 58 deaths in Germany.

29. A November 2013 study linked Xarelto to a 3-fold increase in bleeding risk for acutely ill patients and a 4-fold increased risk of major bleeding in patients following knee surgery.

THE PROPOSED CLASS AND REPRESENTATIVE PLAINTIFFS

30. The proposed representative Plaintiffs seek certification of the following class:

    (a) All persons throughout Alberta who purchased and/or ingested the drug Xarelto and their estates, administrators or other legal representatives (the **Class**); and

    (b) All persons who have a derivative claim on account of a family relationship with a person in (a) (the **Family Class**).

CAUSES OF ACTION

Failure to Warn

31. The Defendants owed the Plaintiffs and other putative Class members a duty of care as follows:

(a) to warn them and their treating healthcare professionals that ingestion of Xarelto carried significant, and specifically identified, health risks including the risk of excessive bleeding;

(b) to warn them and their treating healthcare professionals that there existed no antidote to excess bleeding caused by Xarelto;

(c) to ensure that prescribing physicians and other healthcare professionals were apprised and fully and regularly informed of all of the health risks associated with ingesting Xarelto;

(d) to warn them and their treating healthcare professionals that elderly patients, patients with impaired renal functions, and patients with a history of gastro-intestinal bleeding are particularly vulnerable to the risks of unstoppable, excessive bleeding caused by Xarelto;

(e) to inform Health Canada fully, properly, and in a timely manner of the health risks and complaints, including those listed herein, associated with the ingestion of Xarelto;

(f) to provide truthful and complete information to Health Canada when submitting the New Drug Submission (**NDS**) for Xarelto;

(g) to provide complete and accurate clinical and non-clinical data to Health Canada throughout the approval process for Xarelto and subsequently, including: when they submitted to Health Canada for approval of the NDS for Xarelto, when they submitted to Health Canada for approval the product monographs for Xarelto, and subsequent to the issuance by Health Canada of the Notice of Compliance for Xarelto;

(h) promptly to report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to Xarelto subsequent to its approval for sale in Canada;

(i) to issue prompt, up-to-date, and accurate Health Professional Communications and Public Communications, which are the modes of communication through which manufacturers are required to communicate with healthcare professionals and the public, respectively, regarding the safety concerns affecting a health product;

(j) to provide truthful and complete information in the product monographs for Xarelto, and particularly in Parts I and III of such monographs, which are directed to healthcare professionals and patients, respectively; and

(k) to advertise Xarelto to healthcare professionals in a manner that adequately discloses the drug's risk of harm and the lack of an effective antidote in the event of bleeding caused as a side effect by Xarelto.

32. The Defendants breached their duty of care, *inter alia*, by failing to make the following disclosures in their original labelling, product monograph, and prescribing information:

(a) The Defendants' original labelling, product monograph, and prescribing information for Xarelto failed to disclose, adequately or at all, that Xarelto could cause excess bleeding;

(b) The Defendants' original labelling, product monograph, and prescribing information for Xarelto failed to warn patients with renal impairments and elderly patients that they were particularly vulnerable to excess bleeding caused by Xarelto;

(c) The Defendants' original labelling, product monograph, and prescribing information for Xarelto, failed to disclose, adequately or at all, that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto;

(d) The Defendants failed to warn the Plaintiffs and other putative Class members, healthcare professionals and Health Canada that Xarelto was prone to cause excess bleeding, that elderly patients and patients with renal impairments were particularly vulnerable to harm from excess bleeding caused by Xarelto, and that there was no known antidote for the excess bleeding caused by Xarelto;

(e) The Defendants failed to advise prescribing physicians to: instruct patients that Xarelto was prone to cause excess bleeding, monitor the renal function of patients being prescribed Xarelto, exclude those patients identified as having severe renal impairment or a history of gastro-intestinal bleeding, be alert to a decline in the renal function of patients being administered Xarelto, and warn patients that there was no agent to reverse the anticoagulation effects of Xarelto;

(f) The Defendants knowingly or recklessly provided misleading or incomplete information to Health Canada when submitting the NDS for Xarelto. More particularly, but without limitation, the Defendants did not disclose to Health Canada complete evidence regarding the clinical effectiveness of Xarelto, the drug's contra-indications and side effects, and the fact that there was no effective antidote for excessive bleeding caused by Xarelto;

(g) The Defendants withheld important clinical and non-clinical data from Health Canada throughout the approval process for Xarelto and subsequently, including: when they submitted to Health Canada for approval the NDS for Xarelto, when they submitted to Health Canada for approval the product monographs for Xarelto, and subsequent to the issuance by Health Canada of the Notice of Compliance for Xarelto;

(h) The Defendants failed promptly or at all to report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to Xarelto subsequent to its approval for sale in Canada;

(i) The Defendants failed to issue prompt, up-to-date, and accurate Health Professional Communications and Public Communications;

(j) The Defendants knowingly or recklessly provided misleading or incomplete information in the product monographs for Xarelto, and particularly in Parts I and III of such monographs, which are directed to healthcare professionals and patients, respectively; and

(k) The Defendants advertised Xarelto to healthcare professionals in a manner that did not adequately or at all disclose the drug's risk of harm and the lack of an effective antidote in the event of bleeding caused as a side effect by Xarelto.

33. Even if the Defendants had properly warned physicians, pharmacists, or other healthcare professionals regarding the safe and effective use of Xarelto, this fact alone would be insufficient to discharge the Defendants' duty to the Plaintiffs and other putative Class members because:

(a) The Plaintiffs and other putative Class members placed their primary reliance regarding the safety of Xarelto not on healthcare professionals, but on the Defendants themselves; and

(b) The Defendants advertised, promoted and marketed Xarelto directly to the Plaintiffs and other putative Class members by means of so-called "reminder advertising", in which the name of a product, its strength, dosage, form and price are revealed, but not the product's indication or effectiveness. The Defendants also advertised, promoted and marketed Xarelto directly to the Plaintiffs and other putative Class members by means of cross-over advertising, promotion, and marketing that was, or may have been, targeted to patients outside of Canada, but that was nonetheless consumed by Canadians.

Negligence

34. The Defendants additionally owed the Plaintiffs and other putative Class members a duty of care as follows:

(a) to conduct adequate tests and clinical trials prior to releasing Xarelto into the market to determine the degree of risk associated with ingesting the drug;

(b) to ensure that Xarelto was not released into the market prior to satisfying themselves that there existed an agent or means with which to reverse the excessive bleeding that could be caused by Xarelto;

(c) to ensure that Xarelto was fit for its intended or reasonably foreseeable use;

(d) once Xarelto was released into the market, to conduct ongoing tests and clinical trials with long term follow-up to determine the long-term effects and risks associated with the long-term ingestion of Xarelto;

(e) to monitor the post-market effects of Xarelto;

(f) to exercise reasonable care in designing, researching, developing, testing, manufacturing, marketing, packaging, promoting, distributing, licensing, inspecting, labelling, advertising, supplying and selling Xarelto;

(g) to manufacture, package, label, test, import, distribute and sell Xarelto in accordance with the *Food and Drugs Act*, RSC, 1985, c F-27 (the ***Food and Drugs Act***) and the Regulations thereto;

(h) to submit truthful and complete information to Health Canada when submitting the NDS for Xarelto;

(i) to provide Health Canada with complete and accurate clinical and non-clinical data throughout the approval process for Xarelto and subsequent to its approval;

(j) to promptly report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to Xarelto subsequent to its approval for sale in Canada; and

(k) to advertise Xarelto in a manner that adhered with the standards set out in the Pharmaceutical Advertising Advisory Board Code of Advertising Acceptance.

35. The Defendants breached their duty of care as follows:

(a) They failed to conduct adequate tests and clinical trials prior to releasing Xarelto into the market to determine the degree of risk associated with ingesting the drug;

(b) They released Xarelto into the market when they knew or ought to have known that there existed no agent or means with which to reverse the excessive bleeding that could be caused by Xarelto;

(c) They released Xarelto into the market when they knew or ought to have known that it was fit neither for its intended use nor for its reasonably foreseeable use. Indeed, the drug was unreasonably dangerous. Accordingly, any benefit of Xarelto was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended;

(d) Xarelto distributed by the Defendants was defectively manufactured;

(e) Once Xarelto was released into the market, the Defendants failed to conduct ongoing tests and clinical trials with long term follow-up to determine the long-term effects and risks associated with the long-term ingestion of Xarelto;

(f) They failed to monitor the post-market effects of Xarelto;

(g) They failed to exercise reasonable care in designing, researching, developing, testing, manufacturing, marketing, packaging, promoting, distributing, licensing, inspecting, labelling, advertising, supplying and selling Xarelto;

(h) They failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Xarelto;

(i) They overstated the benefits of Xarelto for anticoagulation therapy in patients suffering from AF and understated the risk of excessive and/or uncontrollable bleeding;

(j) They failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Xarelto;

(k) They failed to include a 'boxed warning' about serious bleeding events associated with Xarelto;

(l) They failed to manufacture, package, label, test, import, distribute and sell Xarelto in accordance with the *Food and Drugs Act* and the regulations thereto;

(m) They knowingly or recklessly provided misleading or incomplete information to Health Canada when submitting the NDS for Xarelto. More particularly, but without limitation, the Defendants did not disclose to Health Canada complete evidence regarding the clinical effectiveness of Xarelto, the drug's contra-

indications and side effects, and the fact that there was no effective antidote for excessive bleeding caused by Xarelto;

(n) They withheld important clinical and non-clinical data from Health Canada throughout the approval process for Xarelto and subsequent to its approval, including when they submitted to Health Canada for approval the NDS for Xarelto, when they submitted to Health Canada for approval the Product Monographs for Xarelto, and subsequent to the issuance by Health Canada of the Notice of Compliance for Xarelto;

(o) They failed promptly or at all to report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to Xarelto subsequent to its approval for sale in Canada; and

(p) They advertised Xarelto in a manner that failed to adhere to the standards set out in the Pharmaceutical Advertising Advisory Board Code of Advertising Acceptance.

36. At all material times, the Defendants' warnings to Canadians with respect to Xarelto lagged behind the Defendants' state of knowledge regarding the drug's risks.

37. At all material times, the Defendants' warnings to Canadians with respect to Xarelto lagged in their timing and comprehensiveness behind the Defendants' warnings in respect to Xarelto abroad.

38. At all material times, the dangerous propensities of Xarelto were known to the Defendants, or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed,

supplied, or sold their respective product, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

39. The Defendants knew or should have known that Xarelto posed a serious risk of bodily harm to consumers. Nevertheless, the Defendants continued to manufacture and market Xarelto for use by consumers.

40. As a direct and proximate result of the Defendants' failure to exercise reasonable care in the design, research, development, testing, manufacture, marketing, packaging, promotion, distribution, licensing, inspecting, labelling, advertising, supplying and sale of Xarelto, the Plaintiffs and other putative Class members were exposed to Xarelto and thereby suffered personal injuries, economic and non-economic damages including pain and suffering. More particularly:

(a) It was as a result of the Defendants' claims regarding the effectiveness, safety, and benefits of Xarelto, and the Defendants' failure to warn about the risks of serious injury associated with Xarelto, that Paul, other putative Class members, Paul's physicians and healthcare professionals, and Health Canada, were unaware, and could not reasonably have known or have learned through reasonable diligence that Paul, and other putative Class members, would be exposed to the risk of excessive and/or uncontrollable bleeding and the other risks and injuries described herein;

(b) As a result of the Defendants' failure to warn about the risks of serious injury associated with Xarelto, Paul and Class members were unaware of the increased risk for developing life-threatening injuries attached to Xarelto as compared to

another anticoagulant therapy, such as warfarin. Had the Plaintiffs and the other putative Class members, healthcare providers and Health Canada known of the risks and dangers associated with Xarelto, as well as the lack of additional benefits, and had the Defendants provided adequate warnings that there is no agent to reverse the anticoagulation effects of Xarelto, Paul and the other putative Class members would not have used Xarelto; and

(c) As a direct and proximate result of using Xarelto, the Plaintiffs and the Class members have suffered severe personal injuries, physical pain and mental anguish.

Breach of Express Warranty

41. The Defendants expressly warranted, through their direct-to-consumer marketing, reminder marketing, labeling, product monographs, and sales representatives, that Xarelto was a safe and effective prescription blood thinner. The safety and efficacy of Xarelto constitute material facts in connection with the marketing, promotion, and sale of Xarelto.

42. Xarelto did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

43. As a direct and proximate result of the Defendants' breach of warranty, the Plaintiffs and the other putative Class members have suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

Breach of Implied Warranty

44. At the time the Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released Xarelto into the stream of commerce, the Defendants knew of the use for which Xarelto was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

45. The Defendants breached their implied warranties of the Xarelto product sold to the Plaintiffs and other putative Class members because this product was not fit for its common, ordinary, and intended use.

46. As a direct, foreseeable and proximate result of the Defendants' breaches of implied warranties, Paul and other putative Class members suffered bodily injury and consequential economic and other losses, as described above, when Paul and other putative Class members ingested Xarelto, in reasonable reliance upon the implied warranties.

47. In particular, the Plaintiffs plead and relies upon the implied conditions contained in s.16 of the *Sale of Goods Act,* RSA 2000, c S-2 that Xarelto would be fit for its intended purpose and of merchantable quality as a safe and effective anti-coagulant.

48. The Plaintiffs plead that Xarelto was neither fit for its intended purpose nor of merchantable quality.

49. The Plaintiffs further plead and rely upon the *Competition Act*, RSC, 1985, c C-34 (the ***Competition Act***).

50. The Defendants' claims regarding Xarelto's safety, effectiveness, and effectiveness as compared with other comparable drugs, were representations made for the purpose of promoting the business interests of the Defendants and promoting Xarelto. These representations were made to the public, including the Plaintiffs and other injured Class members. They were false and misleading in a material respect, they were made by the Defendants knowingly or recklessly, as aforesaid.

51. The Plaintiffs and other putative Class members relied on the Defendants' claims regarding the safety and effectiveness of Xarelto and suffered injury and loss as a result.

52. Accordingly, the Defendants breached s.52 of the *Competition Act*, in knowingly or recklessly making false and/or misleading representations to the public. By reason of such breach, the Defendants are liable under s.36 of the *Competition Act* in damages, and for the costs of investigating and pursuing this action.

53. The Plaintiffs plead and rely upon the *Food and Drugs Act,* RSC, 1985, c F-27. Contrary to s 9 of the *Food and Drugs Act*, the Defendants labelled, packaged, treated, processed, sold or advertised Xarelto as aforesaid in a manner that was false, misleading or deceptive or was likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Waiver of Tort

54. The Plaintiffs and the other putative Class members are entitled to waive the tort and require the Defendants to account for all the revenue they received from the sale of Xarelto in Alberta.

55. The Plaintiffs plead that waiver of tort is appropriate for the following reasons, among others:

(a) Such revenue was acquired in such circumstances that the Defendants cannot in good conscience retain it;

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

(c) Xarelto could not have been marketed, and the Defendants would not have received any revenue from its sale in Alberta, absent the Defendants' egregious conduct;

(d) The Defendants engaged in wrongful conduct by putting into the marketplace a pharmaceutical product which causes or has the potential to cause increased risks of injury and death; and

(e) The Defendants would be unjustly enriched if they were permitted to retain revenues realized from the sale of Xarelto.

Unjust Enrichment

56. The Defendants voluntarily accepted and retained profits and benefits, derived from the Plaintiffs and other putative Class members. The Defendants did so with full knowledge that, as a result of the Defendants' intentional wrongdoings, the Plaintiffs and other putative Class members did not receive a product of the quality, nature or fitness that had been represented by the Defendants or reasonably expected by the Plaintiffs.

57. By virtue of the wrongdoings alleged, the Defendants have been unjustly enriched at the expense of harm to the Plaintiffs and other putative Class members.

58. There is no juristic reason for the Defendants' enrichment.

DAMAGES AND OTHER SUBROGATED CLAIMS

General and Special Damages

59. As a result of the Defendants' negligence and other actionable conduct as set out above, Paul and the other putative Class members have suffered and will continue to suffer damages and loss including:

(a) Personal injury;

(b) Out of pocket expenses including those connected with medical care and treatment, medications, and the cost of Xarelto as paid for by Class members;

(c) Cost of past care and services;

(d) Cost of future care and services; and

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

60. As a result of the Defendants' negligence and other actionable conduct as set out above, the resulting injuries to Paul and other putative Class members, Heli and members of the Family Class have suffered loss and damage. They have incurred out-of-pocket expenses for the benefit of Paul and other putative Class members. They have suffered and will continue to suffer loss of income. They have paid for or provided nursing, housekeeping and other services. They have suffered a loss of support, guidance, care and companionship that they might reasonably have expected to receive if the injuries

to Paul and other putative Class members had not occurred. In some instances, they have also suffered as a result of bereavement.

Subrogated Claims

61. The cost of the purchase of Xarelto by the Plaintiffs and other putative Class members was covered, in whole or in part, individually or by third party parties, including private or group health insurers and private drug benefit plans, or by provincial health insurers and public drug benefit plans.

62. Class members who paid for their own Xarelto seek a full indemnification of the purchase price. Third party payors have a subrogated interest in their expenditures for Xarelto on behalf of the Plaintiffs and other members of the Class and they seek a full indemnification of the purchase price.

63. The Plaintiffs state that Paul and the other putative Class members would not have used Xarelto if the Defendants had acted reasonably and responsibly.

64. The Plaintiffs and the other Class members are entitled to recover from the Defendants as special damages the cost of purchasing Xarelto. But for the Defendants' wrongdoing, as particularized above, the Plaintiffs and other putative Class members would not have incurred the expense of purchasing Xarelto.

Punitive and Aggravated Damages

65. At all material times, the Defendants knew or should have known that Xarelto was dangerous.

66. Despite their knowledge, the Defendants continued aggressively to market Xarelto to consumers, including the Plaintiffs and other putative Class members, without disclosing its dangerous side-effects, and despite the existence of safer alternative products.

67. Despite the Defendants' knowledge of Xarelto's defective and unreasonably dangerous nature, the Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiffs and other putative Class members, in conscious disregard of the foreseeable harm caused by Xarelto.

68. The Defendants' conduct was high-handed, outrageous, reckless, egregious, deliberate, disgraceful, wilful, callous, and in wanton disregard of the rights and safety of Paul and of the other members of the Class. The Defendants' conduct was indifferent to the consequences and motivated by economic considerations such as the maintaining of profits and market share. Such conduct renders the Defendants liable to pay punitive damages to the Plaintiffs and other members of the Class.

69. The Defendants' conduct, as particularized above, in the design, development, testing, manufacturing, licensing, distribution, marketing, sale and promotion of Xarelto, and the delayed withdrawal or recall and/or the failure to withdraw or recall, was high-

handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, willful, an intentional disregard of the rights and safety of the Plaintiffs and the rights and safety of the other putative Class members, indifferent to the consequences and motivated by economic considerations, such as the maintenance of profits and market share. Such conduct renders the Defendants liable to pay punitive damages to the putative Class members.

70. The Defendants' conduct, as aforesaid, was injurious to the feelings of pride, dignity and self-respect of the Plaintiffs and other putative Class members. The Defendants are therefore liable to the Plaintiffs and other Class members for aggravated damages.

DISCOVERABILITY

71. Relative to any applicable limitations statutes or any applicable common law limitation periods, the Plaintiffs and putative Class members plead and rely on the doctrine of discoverability.

STATUTES

72. The Plaintiffs plead and rely upon the following legislation:

(a) Alberta Health Care Insurance Act, RSA, 2000, c A-20;

(b) Class Proceedings Act, SA 2003, c C-16.5;

(c) Fair Trading Act, RSA c F-2;

(d) Fatal Accidents Act, RSA 2000, c F-8;

(e) Hospitals Act, RSA 2000, c H-12;

(f) Sale of Goods Act, RSA 2000 c S-2;

(g) Competition Act, RSC, 1985, c C-34;

(h) Food and Drugs Act, RSC, 1985, c F-27;

and all relevant amendments thereto.

73. The Plaintiffs propose that Trial of this Action take place in Calgary, Alberta.

RELIEF SOUGHT

74. The Plaintiffs, Paul and Heli, personally and on behalf of all Class Members, claim:

(a) damages in the amount of $100,000,000.00;

(b) aggravated damages in the amount of $25,000,000;

(c) punitive damages in the amount of $25,000,000;

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

(e) special damages on account of, *inter alia*, all medical and other expenses for testing and treatment (including the subrogated claims of all governmental providers of medical services in Alberta) in such amount as may be proven at trial;

(f) an interim interlocutory and permanent order, pursuant to s. 1.3 of the Alberta *Rules of Court*, Alta Reg 124/2010 and the *Judicature Act*, RSA 2000, c J-2, compelling the Defendants to fund a medical monitoring programme supervised by the Court for the review and monitoring of the health of the putative Class members by medical and other experts and to make recommendations regarding the treatment of Class members;

(g) in the alternative to the claims for damages, payment of the gross revenues or, in the alternative, the net revenues realized by the Defendants from their sales of the drug rivaroxaban, marketed by the Defendants as Xarelto;

(h) an order certifying the herein action as a class proceeding pursuant to the *Class Proceedings Act*, SA 2003, c C-16.5;

(i) an order appointing the Plaintiffs as representative Plaintiffs for the Class in the herein action pursuant the *Class Proceedings Act*, SA 2003, c C-16.5;

(j) pre-judgment interest pursuant to *Judgment Interest Act*, RSA 2000, c J-1;

(k) post-judgment interest pursuant to *Judgment Interest Act*, RSA 2000, c J-1;

(l) costs on a substantial indemnity scale; and,

(m) such further and other relief as this Honourable Court deems just and appropriate having regard to the circumstances.

NOTICE TO THE DEFENDANT(S)

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

20 days if you are served in Alberta

1 month if you are served outside Alberta but in Canada

2 months if you are served outside Canada.

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

WARNING

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