C A N A D A
PROVINCE OF QUEBEC
DISTRICT OF MONTREAL
NO: 500-06-000786-166

(Class Action)
SUPERIOR COURT

ARTHUR JOHN BOEHMER,

Applicant;

v.

BARD CANADA INC.,

And

C.R. BARD, INC

And

BARD PERIPHERAL VASCULAR, INC.,

Defendants;

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT THE STATUS OF REPRESENTATIVE PLAINTIFF
(ND: 67-183 IVC Filters)
(Article 575 C.C.P. and following)

TO ONE OF THE HONOURABLE JUDGES OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, THE APPLICANT RESPECTIVELY SUBMITS THE FOLLOWING:

GENERAL PRESENTATION

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

> "All natural persons residing in Quebec who were who were implanted with a Retrievable IVC Filter Product which was manufactured, marketed and/or sold or otherwise placed into the stream of commerce in Quebec by one or more of the Defendants, and/or their family members, assigns and heirs."

or such other group definition as may be approved by the Court;

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

THE APPLICANT

2. The Applicant was implanted with one of the Defendants' Retrievable IVC Filter Products on May 28, 2015, specifically a G2 X Filter in advance of upcoming surgery to potentially catch any blood clots. The filter was implanted on what was supposed to be a temporary basis;

3. Removal of the filter was attempted on January 14, 2016. At that time it was discovered that the filter may have broken and was lodged in the vein. It could not be removed. A vascular technician stated to the Applicant and his wife that he was the luckiest man in the world because of the filter's "spidery" legs had just missed puncturing his pancreas;

4. As a result of the filter remaining in the Applicant's body, he continues to suffer from sporadic pain below the sternum and over the right and left breast area. He now also experiences shortness of breath whenever he walks up one or more flights of stairs or walks for more than a few minutes. Furthermore, the Applicant now experiences atrial fibrilation. Another vascular technician stated to him at the time of the unsuccessful removal on January 14, 2016 that he was suffering from an AF "echo"/low-intensity reading according to her instrumentation;

5. Prior to and at the time which the Applicant was implanted with the Defendants' Retrievable IVC Filter Product, he received no or inadequate warnings about the magnitude of risks of developing Injuries and Complications (as defined herein) from using one of the Defendants' Retrievable IVC Filter Products;

6. Had the Applicant been aware of the magnitude of risks of developing Injuries and Complications, he would not have agreed to being implanted with one of the Defendants' Retrievable IVC Filter Products and would have requested use of an alternative, safer filter or treatment. But for the Defendants' wrongful conduct, the Applicant would not have incurred his damages;

THE DEFENDANTS

7. Bard Canada Inc. is a Canadian corporation with a registered head office in Oakville, Ontario. Bard Canada Inc. is an affiliate or a subsidiary of C.R. Bard, Inc., the whole as it appears from the extract of the State of information from the *Registraire des entreprises du Québec* produced herein as **Exhibit P-1**;

8. C.R. Bard, Inc. is incorporated in the State of New Jersey, with its head office located in Murray Hill, New Jersey;

9. Bard Peripheral Vascular, Inc. ("Bard Peripheral"), a wholly owned subsidiary of C.R. Bard, Inc., is located in Tempe, Arizona;

10. Bard Peripheral designed, set specifications, manufactured, prepared, compounded, assembled, and processed the Defendants' Retrievable IVC Filter Products. Bard Canada Inc. distributes in Quebec the Retrievable IVC Filter Products developed by Bard Peripheral. Collectively, the Defendants, under the direction of C.R. Bard, Inc. and its affiliated companies, is responsible for the designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, Bard Retrievable IVC Filter Products in Quebec. The development of Bard Retrievable IVC Filter Products for sale in Quebec, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Bard Retrievable IVC Filter Products, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in Quebec and elsewhere;

THE FACTS

Overview

11. This claim involves the Defendants' Retrievable IVC Filter Products, expandable metal devices placed within the vena cava using a catheter. This claim arises out of the Defendants' unlawful, negligent, inadequate, improper, unfair and deceptive practices and misrepresentations related to, *inter alia*, their design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution and sale of Retrievable IVC Filter Products;

12. The Defendants misrepresented that their Retrievable IVC Filter Products are safe, effective, and retrievable, when, in reality, they have a very high failure rate and often cannot be explanted;

13. Members of the Class were misled as to the products' safety and efficacy, and as a result have suffered serious, life-threatening, results;

THE DEFENDANTS' RETRIEVABLE IVC FILTER PRODUCTS

14. A vena cava filter is an expandable metal device placed within the vena cava using a catheter. Once in place, the device opens, allowing it to trap blood clots. Inferior vena cava ("IVC") filters are devices designed to filter blood clots which may otherwise travel to the heart and/or lungs;

15. IVC filters were originally intended to be a last resort option for people at risk of pulmonary embolism who could not take blood-thinning drugs. IVC filters were originally intended to be permanently implanted and those models had an excellent safety record;

16. Beginning in or around 2003, in order to differentiate the products in the market, retrievable IVC filters were introduced. The Defendants modified an existing product, already proven to be safe and effective, that was intended to remain in the patient's body;

17. Retrievable IVC filters are supposed to be removed after the patient is no longer at risk of a pulmonary embolism. The introduction of retrievable IVC filters resulted in a dramatic increase in the use of IVC filters;

18. Retrievable filters, including the Defendants' Retrievable IVC Filters, are fitted with a device that allows them to be snared and pulled back into a catheter and removed from the body, often through the jugular vein;

19. No studies demonstrating the safety and/or effectiveness of the retrievable IVC filter products were required because the Defendants sought approval based on the claim that these new products were "substantially equivalent" to other IVC filter products already in widespread use as the predicate device;

20. The Defendants' Retrievable IVC Filter Products sold in Quebec include the Recovery line of filters and the G2 line of filters, collectively referenced herein as the Defendants' Retrievable IVC Filter Products;

21. The Defendants introduced its Retrievable IVC Filters as improved versions of their original lines of permanent IVC filters, with features designed to enhance the retrieval process;

22. All of the Defendants' Retrievable IVC Filter Products share a common design defect attributable to their failure to withstand the normal anatomical and physiological loading cycles exerted in the human body. This design defect is not shared by the permanent IVC filters, which do not share the same safety concerns;

23. The Defendants' Retrievable IVC Filter Products have been and continue to be marketed to the medical community, and in turn to patients, as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava, despite the fact that there is little or no proven evidence of their efficacy or safety for this use;

24. The Defendants have marketed and sold their Retrievable IVC Filter Products to the medical community at large, and in turn to patients, through carefully planned, multifaceted marketing campaigns and strategies;

THE RISKS

25. Contrary to the representations made to the medical community, and ultimately to the patients themselves, the Defendants' Retrievable IVC Filter Products have high failure, injury, and complication rates, fail to perform as intended, and have caused serious and irreversible injuries to a significant number of patients, including the Applicant and other putative class members;

26. The injuries suffered from the Defendants' Retrievable IVC Filters Products are: fracture, migration, perforation, and damage to the vena cava wall. Such failures exposed patients to serious injuries including: death; hemorrhage; cardiac/pericardial tamponade; deep vein thrombosis ("DVT"); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain, perforations of tissue, vessels and organs; inability to remove the device; physical pain; mental anguish; scarring and disfigurement; diminished enjoyment of life; continued medical care and treatment due to chronic injuries/illness; and the continued risk of requiring additional medical and surgical procedures (collectively the "Injuries and Complications");

27. Multiple incidents of fracture, migration, and perforation causing life threatening conditions have been reported to Health Canada and the United States Food and Drug Administration ("FDA"). The number of adverse event reports associated with IVC filters suggest that the Defendants' Retrievable IVC Filter Products are more prone to device failure then are other similar devices and/or the previous permanent IVC filters;

28. The Recovery filters are prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard's Recovery filters having a fracture and migration rate ranging from 21% to 31.7%. When such failures occur, shards of the device or the entire device can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction and death. These fractured shards may also become embedded in tissue or migrate to locations, such as the lungs, such that they are too dangerous to remove. These individuals are exposed to a lifetime of future risk;

29. These failures are attributable, in part, to the fact that the Defendants' Retrievable IVC Filter Products were designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*;

30. Executives at C.R. Bard, Inc. were aware of the dangers their Retrievable IVC Filters Products posed. A confidential study commissioned by the Defendants showed that the Recovery line of filters had higher rates of relative risk for death, filter fracture and movement than all of its competitors. An outside doctor hired to conduct the study wrote that "further investigation…is urgently warranted.";

31. In late 2004 or early 2005, without notifying consumers of the design flaws inherent in the Recovery line of filters, the Defendants began redesigning the Recovery filter in an attempt to correct those flaws. The redesigned filter became the G2 line of filters, which stands for second generation Recovery filter;

32. The Defendants' cited the Recovery line of filters as the substantially equivalent predicate device for the G2 line of filters, stating the differences were primarily dimensional and no material changes or additional components were added;

33. The Defendants' marketed the G2 line of filters as having "enhanced fracture resistance", "improved centering", and "increased migration resistance." However the defendants again failed to conduct adequate clinical testing, such as animal studies, to ensure that the device would perform safely and effectively once implanted in the human body and subjected *in vivo* stresses. The G2 line of filters design causes it to also be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava, sharing the same defects and health risks as its predicate device;

34. A confidential memo written in December 2005 by a Bard vice president soon after the G2 line of filters was released showed his concern about "problems with...migration," "tilting" and "perforation." He also noted that Bard had another filter on the market with virtually no complaints. "Why shouldn't doctors be using that one rather than the G2?" he asked;

35. In August 2010, the FDA issued a safety communication to healthcare professionals expressing concern about the potential of retrievable IVC filters to fracture, the possibility that some of the device components may detach, and that part or all of a filter may spontaneously migrate which can cause perforation of bodily structures such as the vena cava, the whole as it appears from the article produced herein as **Exhibit P-2**;

36. A 2010 study published in the Archives of Internal Medicine concluded that the Recovery Filter and the G2 Filter are associated with "high prevalence of fracture and embolization, with potentially life-threatening sequelae." the whole as it appears from the study produced herein as **Exhibit P-3;**

37. A 2012 study published in the Journal of Vascular and Interventional Radiology reported that the Recovery Filter had a 40% facture rate within 5.5 years of implantation. Significantly, of more than 360 people included in the study, only 97 underwent removal of the device the whole as it appears from the study produced herein as **Exhibit P-4**;

38. A 2013 study published in the Journal of the American College of Cardiology reported that complication rates of retained filters include filter migration or embolization in up to 69% of cases, and strut facture and penetration of up to 24% of cases, the whole as it appears from the study produced herein as **Exhibit P-5**;

39. A study published in the medical journal *JAMA Internal Medicine* in March 2013 raised questions about the effectiveness of IVC filters, indicating that less than 10% of filters evaluated in the study were successfully removed from patients and 8% of recipients of IVC filters suffered a pulmonary embolism despite the device's presence, the whole as it appears from the study produced herein as **Exhibit P-6**;

40. The FDA updated its safety warning with respect to retrievable IVC filters on May 6, 2014 recommending retrievable IVC filters be removed between the 29th and 54th day after

implantation in patients in which the pulmonary embolism risk had subsided, the whole as it appears from the warning produced herein as **Exhibit P-7**;

41. This recommendation followed the findings of an October 2013 study which concluded that "the risks of complications start to outweigh the protective benefits of the filter at day 35 post implantation", the whole as it appears from the study produced herein as **Exhibit P-8**;

42. In a 2015 article entitled "Bard Denali Inferior Vena Cava Filter Fracture and Embolization Resulting in Cardiac Tamponade: A Device Failure Analysis", the authors concluded that "the high-cycle fatigue fractures we detected in this new Bard filter appear similar to the high-cycle fracture patterns described in earlier Bard filters" and that "Despite the updated design and manufacturing process, the overall geometry of the Bard Denali filter is similar to earlier models. Specifically, a hinge point along each filter element remains at the apex where high repetitive stress and strain naturally occur.", the whole as it appears from the article produced herein as **Exhibit P-9**;

43. On July 13, 2015, the U.S. FDA sent C.R. Bard, Inc. a warning letter stating failure to submit a report no later than 30 calendar days after the day of receiving or otherwise becoming aware of information, from any source, that reasonably suggests their IVC Filter devices had malfunctioned and would be likely to cause or contribute to a death or serious injury, the whole as it appears from the warning letter produced herein as **Exhibit P-10**;

44. A study published in the October 2015 issue of the *Annals of Surgery* found that patients who received IVC filters did not have a statistically significant increase in longevity as compared to trauma patients who did not receive the IVC filters. The researchers determined that "[h]igh rates of prophylactic IVC filter placement have no effect on reducing trauma patient mortality and are associated with an increase in DVT events." ., the whole as it appears from the study produced herein as **Exhibit P-11**;

45. The Defendants' Retrievable IVC Filter Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their physicians;

46. The Defendants' Retrievable IVC Filter Products create risks to the health and safety of the patients that are significantly greater than the risks posed by other products and procedures available to treat the underlying medical conditions, and which outweigh the utility of their Retrievable IVC Filter Products;

47. Despite the Defendants' knowledge of the Injuries and Complications caused by their Retrievable IVC Filter Products, the Defendants have, and continue to, manufacture, market, and sell their Retrievable IVC Filter Products, without adequately warning, labeling, instructing, and/or disseminating information with respect to these risk, either prior to and/or after the marketing and sale of the Retrievable IVC Filter Products;

48. At all material times, the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Applicant and putative class

members, of the risk of Injuries and Complications caused by their Retrievable IVC Filter Products;

49. The Defendants did not provide adequate safety data to Health Canada with respect to their Retrievable IVC Filter Products. The Defendants knew or should have known that their Retrievable IVC Filter Products were unsafe, defective, unreasonably dangerous, and not fit for their intended purposes;

50. At all materials times, the Defendants knew or should have known that the risks of using their Retrievable IVC Filter Products included severe Injuries and Complications;

51. At all material times, the Defendants, through their servants and agents, negligently, recklessly and/or carelessly marketed, distributed and/or sold their Retrievable IVC Filter Products without adequate warnings of the products' serious side effects and unreasonably dangerous risks associated with these products;

THE DEFENDANTS' FAULTS

52. The Defendants at all material times owed a duty of care to the Applicant to:

    (a) ensure that their Retrievable IVC Filter Products were fit for their intended and/or reasonably foreseeable use;

    (b) conduct appropriate testing to determine whether and to what extent use of their Retrievable IVC Filter Products posed serious health risks, including the magnitude of risk of developing Injuries and Complications;

    (c) properly, adequately, and fairly warn the Applicant and his physicians of the magnitude of the risk of developing Injuries and Complications with use of their Retrievable IVC Filter Products compared to alternative treatments;

    (d) ensure that physicians were kept fully and completely informed of all risks associated with their Retrievable IVC Filter Products;

    (e) monitor, investigate, evaluate and follow up on adverse reactions to the use of their Retrievable IVC Filter Products; and

    (f) properly inform Health Canada and other regulatory agencies of all risks associated with their Retrievable IVC Filter Products;

53. The Defendants negligently breached their duty of care;

54. The Applicant states that his damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following:

(a) the Defendants failed to ensure that their Retrievable IVC Filter Products were not dangerous to recipients during the course of their use and that they were fit for their intended purpose and of merchantable quality;

(b) the Defendants failed to adequately test their Retrievable IVC Filter Products in a manner that would fully disclose the magnitude of the risks associated with their use, including but not limited to Injuries and Complications;

(c) The Defendants unreasonably and carelessly designed products that were insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

(d) the Defendants failed to provide Health Canada complete and accurate information with respect to their Retrievable IVC Filter Products as it became available;

(e) the Defendants failed to conduct any or any adequate follow-up studies on the efficacy and/or safety of their Retrievable IVC Filter Products;

(f) the Defendants failed to conduct any or any adequate long-term studies of the risks of their Retrievable IVC Filter Products;

(g) the Defendants failed to provide the Applicant, his physicians and Health Canada with proper, adequate, and/or fair warning of the risks associated with use of their Retrievable IVC Filter Products, including but not limited to risk of Injuries and Complications;

(h) the Defendants failed to design and establish a safe, effective procedure for removal of their Retrievable IVC Filter Products. In the event of failure, injury, or complications, it can be impossible to easily and safely remove the Defendants' Retrievable IVC Filter Products;

(i) the Defendants failed to adequately monitor, evaluate and act upon reports of adverse reactions to their Retrievable IVC Filter Products in Quebec and elsewhere;

(j) the Defendants failed to provide any or any adequate updated and/or current information to the Applicant, his physicians and/or Health Canada respecting the risks of their Retrievable IVC Filter Products as such information became available, from time to time;

(k) the Defendants have consistently underreported and withheld information about the propensity of their Retrievable IVC Filter Products to fail and cause Injuries and Complications, and have misrepresented the efficacy and safety of their Retrievable IVC Filter Products through various means and media, misleading Health Canada, the medical community, patients, and the public at large;

(l) the Defendants failed to provide adequate warnings of the risks associated with their Retrievable IVC Filter Products, including the risk of Injuries and

Complications in all persons receiving their Retrievable IVC Filter Products on the customer information pamphlets in Quebec;

(m) the Defendants, after noticing problems with their Retrievable IVC Filter Products, failed to issue adequate warnings, timely recall their Retrievable IVC Filter Products, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Applicant and his physicians of their Retrievable IVC Filter Products inherent dangers, including but not limited to the danger of Injuries and Complications;

(n) the Defendants failed to establish any adequate procedures to educate their sales representatives and physicians respecting the risks associated with their Retrievable IVC Filter Products;

(o) the Defendants represented that their Retrievable IVC Filter Products were safe and fit for their intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

(p) the Defendants misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of their Retrievable IVC Filter Products and their associated risks, including the risk of Injuries and Complications;

(q) the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known by the Defendants;

(r) the Defendants failed to timely cease the manufacture, marketing and/or distribution of their Retrievable IVC Filter Products when they knew or ought to have known that their Retrievable IVC Filter Products caused Injuries and Complications;

(s) the Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;

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

(u) the Defendants breached other duties of care to the Applicant and putative class members, details of which breaches are known only to the Defendants; and

55. In all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of the Applicant and putative class members;

56. The Defendants' Retrievable IVC Filter Products are defective because they are unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by the Applicant, putative class members, or their physicians. Any benefit from using the Defendants' Retrievable IVC Filter Products is outweighed by the serious and undisclosed risks associated with their use, when used as the Defendants intended. There are no individuals for whom the benefits of the Defendants' Retrievable IVC Filter

Products outweigh the risks, given that there are alternative products and procedures that are at least as efficacious as the Defendants' Retrievable IVC Filter Products and carry far less and/or less serious risks than the Defendants' Retrievable IVC Filter Products;

57. The risks associated with use of the Defendants' Retrievable IVC Filter Products, including Injuries and Complications in all persons receiving their Retrievable IVC Filter Products are in the exclusive knowledge and control of the Defendants. The extent of the risks were not known to, and could not have been known by, the Applicant. The Applicant's injuries would not have occurred but for the negligence of the Defendants in failing to ensure that their Retrievable IVC Filter Products were safe for use, or, in the alternative, for failing to provide an adequate warning of the risks associated with using their Retrievable IVC Filter Products to the Applicant and putative class members, and to their physicians;

DAMAGES

58. The Applicant's and other putative class members' injuries and damages were caused by the negligence of the Defendants, their servants and agents;

59. As a result of the Defendants' negligence, the Applicant has suffered and continues to suffer serious personal injuries and pain and suffering;

60. The Applicant and other putative class members have suffered special damages for medical costs incurred in the screening, diagnosis, and treatment of Injuries and Complications related to use of the Defendants' Retrievable IVC Filter Products;

61. As a result of the conduct of the Defendants, the Applicant and other putative class members suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial;

PUNITIVE DAMAGES

62. The Applicant pleads that the Defendants' conduct, as particularized above, in the design, development, testing, manufacturing, distribution, marketing, sale and promotion of their Retrievable IVC Filter Products renders the Defendants liable to pay punitive damages to the Class members;

LIABILITY OF THE DEFENDANTS

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

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

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

65. Class members have either received one of the Defendants' Retrievable IVC Filter Products or are the successfor, family member, assign, and/or dependant of a person who received one of the Defendants' Retrievable IVC Filter Products;

66. The Class members' damages would not have occurred but for the acts and/or omissions and/or negligence and/or fault of the Defendants in failing to ensure that their Retrievable IVC Filter Products were safe for use, for failing to provide adequate waring of the risks associated with their use, and for over-promoting and misrepresenting their efficacy;

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

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

68. The composition of the Class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings, with respect to provision 575 (3) of the *Code of civil procedure*, for the following reasons :

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

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

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

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

    a. Do the Defendants' Retrievable IVC Filter Products cause a materially increased risk of serious, life threatening injuries?

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

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

d. Are the members of the Class entitled to claim material, bodily and/or moral damages in compensation for injury arising from receipt of one of the Defendants Retrievable IVC Filter Products?

e. Are members of the Class entitled to claim punitive damages?;

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

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

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

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

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT:

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

74. The conclusions sought by the Applicant against de Defendants are as follows:

GRANT the Applicant's action against the Defendants;

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

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

GRANT the class action of the Applicant on behalf of all the Class members;

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

ALTERNATIVELY, ORDER individual recovery of the claims of the Class members for damages, the whole in accordance with articles 599 to 601 C.C.P.;

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

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

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

    a. The Applicant understands the nature of the action;

    b. The Applicant is well-informed of the facts alleged in this motion;

    c. The Applicant is available to dedicate the time necessary for an action to collaborate with members of the Class;

    d. The Applicant has retained an established law firm with experience in class actions;

    e. The Applicant does not have any interests in conflict with other members of the Class;

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

    a. Applicant's counsels have an office in Montreal;

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

77. The present motion is well founded in law an in fact;

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present motion;

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

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

"All natural persons residing in Quebec who were who were implanted with a Retrievable IVC Filter Product which was manufactured, marketed and/or sold or otherwise placed into the stream of commerce in Quebec by one or more of the Defendants, and/or their family members, assigns and heirs.

or such other group definition as may be approved by the Court."

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

a. Do the Defendants' Retrievable IVC Filter Products cause a materially increased risk of serious, life threatening injuries?

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

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

d. Are the members of the Class entitled to claim material, bodily and/or moral damages in compensation for injury arising from receipt of one of the Defendants Retrievable IVC Filter Products?

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

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

GRANT the Applicant's action against the Defendants;

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

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

GRANT the class action of the Applicant on behalf of all the Class members;

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

ALTERNATIVELY, ORDER individual recovery of the claims of the Class members for damages, the whole in accordance with articles 599 to 601 C.C.P.;

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

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

DECLARE that all Class members that have note requested their exclusion from the Class in the prescribed delay to be bound by any judgment to be rendered on the class action to be instituted;

FIX the delay of exclusion at 30 days from the date fo the publication of the notice to the Class members;

ORDER the publication of a notice to the Class members in accordance with article 576 C.C.P.;

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

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

Montreal, March 31, 2016

Siskinds, Desmeules, Avocats, SENCRL.

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Lawyers for the Applicant

SUMMONS

(Articles 145 and following C.c.p.)

Filing of a Judicial Application

Take notice that the Applicant has filed this Application for Authorization to Institute a Class Action and to Appoint the Status of Representative Plaintiff in the office of the Superior Court in the judicial district of Montreal.

Defendants' Answer

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal situated at 1 Rue Notre-Dame Est, Montréal, Québec, H2Y 1B6, within 15 days of service of the Application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the Applicant's lawyer or, if the Applicant is not represented, to the Applicant.

Failure to Answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgement may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of Answer

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the case required by the Code, cooperate with the Applicant in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of the summons or, in family matters or if you have no domicile, residence or establishment in Québec, within 3 months after service;
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Change of judicial district

You may ask the court to refer the originating Application to the district of your domicile or residence, or of your elected domicile or the district designated by an agreement with the plaintiff.

If the application pertains to an employment contract, consumer contract or insurance contract, or to the exercise of a hypothecary right on an immovable serving as your main residence, and if you are the employee, consumer, insured person, beneficiary of the insurance contract or hypothecary debtor, you may ask for a referral to the district of your domicile or residence or the district where the immovable is situated or the loss occurred. The request must be filed with the special clerk of the district of territorial jurisdiction after it has been notified to the other parties and to the office of the court already seized of the originating application.

Transfer of application to Small Claims Division

If you qualify to act as a plaintiff under the rules governing the recovery of small claims, you may also contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Calling to a case management conference

Within 20 days after the case protocol mentioned above is files, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing this, the protocol is presumed to be accepted.

Exhibits supporting the application

In support of the Application for Authorization to Institute a Class Action and to Appoint the Status of Representative Plaintiff, the Applicant intends to use the following exhibits:

Exhibit P-1: Extract of the State of information from the *Registraire des entreprises du Québec;*

Exhibit P-2: August 2010, safety communication issued by the FDA;

Exhibit P-3: Study of 2010 published in the Archives of Internal Medicine;

Exhibit P-4: Study of 2012 published in the Journal of Vascular and Interventional Radiology;

Exhibit P-5: Study of 2013 published in the Journal of the American College of Cardiology;

Exhibit P-6: Study of 2013 published in JAMA International;

Exhibit P-7: Warning of May 2014 from the FDA;

Exhibit P-8: Study of October 2013 which concluded that "the risks of complications start to outweigh the protective benefits of the filter at day 35 post implantation";

Exhibit P-9: A 2015 Article entitled "Bard Denali Inferior Vena Cava Filter Fracture and Embolization Resulting in Cardiac Tamponade: A Device Failure Analysis";

Exhibit P-10: Warning letter for 8 violations of the Federal Law send by the FDA to the Defendants;

Exhibit P-11: Study published in the October 2015 issue of the *Annals of Surgery.*

These exhibits are available on request.

Notice of presentation of an application

If the application is an application in the course of a proceeding or an application under Book III, V, excepting an application in family matters mentioned in Article 409, or VI of the Code, the establishment of a case protocol is not required; however, the application must be accompanied by a notice stating the date and time it is to be presented.

Montreal, March 31, 2016

Siskinds, Desmeules, Avocats, SENCRL

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Lawyers for the Applicant

NOTICE OF PRESENTATION
(Articles 146 and 574 al. 2 C.P.C.)

To:

BARD CANADA INC.
2715 Bristol Circle, Unit #1,
Oakville, Ontario, L6H 6X5, Canada

And

C.R. BARD, INC.
730, Central Avenue
Murray Hill, New jersey, 07974, United States

And

BARD PERIPHERAL VASCULAR, INC.
1625 West 3rd Street Tempe
Arizona, 85281, United States

And

Defendants

TAKE NOTICE that the present *Application For Authorization To Institute A Class Action And To Appoint The Status of Representative Plaintiff* will be presented before this Honourable Court, at the Palais de justice, located at 1, Notre-Dame Street East, in the City and District of Montreal, on the date set by the coordinator of the class actions chamber.

PLEASE ACT ACCORDINGLY.

Montreal, March 31, 2016

Siskinds, Desmeules, Avocats, SENCRL.

Karim Diallo, lawyer
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SISKINDS DESMEULES AVOCATS s.e.n.c.r.l.
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C A N A D A
PROVINCE OF QUEBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT (Class Action)
NO : 500-06-000786-166

ARTHUR JOHN BOEHMER

Applicant;

v.

BARD CANADA INC.

And

C.R. BARD, INC.

And

BARD PERIPHERAL VASCULAR, INC.

Defendants.

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT THE STATUS OF REPRESENTATIVE PLAINTIFF, SUMMONS AND NOTICE OF PRESENTATION

BB-6852 **Casier 15**

Me Karim Diallo
N/D : 67-183

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