CANADA
PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO : 500-06-000550-109

SUPERIOR COURT
(CLASS ACTION)

ALAN DICK

Plaintiff

-vs-

JOHNSON & JOHNSON INC.

-and-

DEPUY ORTHOPAEDICS INC.

Defendants

DEFENCE

IN SUPPORT OF ITS DEFENCE TO THE MOTION TO INSTITUTE PROCEEDINGS (THE "MOTION"), THE DEFENDANTS STATE THE FOLLOWING:

1. With respect to the allegations contained in paragraphs 1 and 2 of the Motion, they refer to the Honourable Justice Robert Castiglio's judgment of May 13, 2014 ("Authorization Judgment") authorizing the Plaintiff to bring a class action suit, as appears from the Court record and deny anything not in conformity therewith;

2. They admit the allegations contained in paragraph 3 of the Motion;

3. They deny as drafted the allegations contained in paragraphs 4 and 6 of the Motion, and add that neither Defendant designed or manufactured the ASR implant systems, as will be more fully explained below;

4. They admit the allegations contained in paragraph 5 of the Motion;

5. With respect to the allegations contained in paragraph 7 of the Motion, they deny that DePuy Orthopaedics Inc. marketed the ASR systems in Canada, as is more fully explained below;

6. With respect to the allegations contained in paragraph 8 of the Motion, they admit that the total number of ASR acetabular cups sold to hospitals in Québec was 875, but state that the total number of Group Members who actually received ASR System Implants is 597;

7. They deny as drafted the allegations contained in paragraph 9 of the Motion;

8. They deny as drafted the allegations contained in paragraph 10 of the Motion, recognizing however that the premature failure of a hip arthroplasty could entail the inconvenience and risks of revision surgery, as more fully dealt with below;

9. They deny as drafted the allegations contained in paragraph 11 of the Motion, and add that each patient's situation is different in terms of risks, pain, convalescence and resumption of work and activity, for reasons unique to that patient and his or her surgeon's treatment;

10. They deny the allegations contained in paragraphs 12, 13, 14, 15 and 16 of the Motion;

11. With respect to the allegations contained in paragraphs 17 and 18 of the Motion, they refer to the Recall Notice (Exhibit P-3) and the Field Safety Notice of March 2010 therein mentioned, and deny anything not in conformity therewith;

12. They deny the allegations contained in paragraph 19 of the Motion;

13. With respect to the allegations contained in paragraph 20 of the Motion, they refer to the Recall Notice (Exhibit P-3) and deny anything not in conformity therewith;

14. With respect to the allegations contained in paragraph 21 of the Motion, they refer to Exhibit P-4 and deny anything not in conformity therewith;

15. With respect to the allegations contained in paragraph 22 of the Motion, they state that the reaction of any member of the Group upon learning of the Recall is a purely subjective matter which necessarily varies widely from patient to patient, depending on a number of factors, including the patient's surgeon's advice;

16. With respect to paragraph 23 of the Motion, they refer to the Recall documents and particularly the undertaking, on a without prejudice basis, to reimburse the out-of-pocket expenses of those patients availing themselves of the Crawford program described in the Recall documents;

17. They deny the allegations contained in paragraph 24 of the Motion, adding that the number of Group Members who have had revision surgery as of January 2014 is estimated by the *Régie de l'assurance maladie du Québec* as being 38 out of the aforementioned 597, representing a revision rate of less than 6.4% and that some of these patients were revised so soon after their implant surgery that the cause for the revision could not possibly be device related;

18. They deny the allegations contained in paragraph 25 of the Motion;

19. With respect to the allegations contained in paragraphs 26 and 27 of the Motion, they refer to Exhibit P-1 and deny anything not in conformity therewith;

20. They have no knowledge of the allegations contained in paragraph 28 of the Motion;

21. They have no knowledge of the allegations contained in paragraphs 29, 30, 31, 32, 33, 34 and 35 of the Motion, beyond what is contained in the Plaintiff's medical records of which copies have been furnished to date;

22. With respect to the allegations contained in paragraph 36 of the Motion, they refer to Exhibit P-2 and deny anything not in conformity therewith;

23. They deny as drafted the allegations contained in paragraph 37 of the Motion beyond what is established by the Plaintiff's medical records and the operative record (Exhibit P-2), but they do admit that the ASR Implant Systems had not been the object of a voluntary product recall in Canada by February 2010;

24. They have no knowledge of the allegations contained in paragraph 38 of the Motion;

25. They deny the allegations contained in paragraph 39 of the Motion, adding that the Plaintiff's earnings during this period were not impacted to any significant extent as a direct result of his surgery, as opposed to other factors;

26. They have no knowledge of the allegations contained in paragraphs 40 and 41 of the Motion;

27. With respect to the allegations contained in paragraph 42 of the Motion, they refer to the operative report Exhibit P-5 and deny anything not in conformity therewith;

28. They have no knowledge of the allegations contained in paragraph 43 of the Motion;

29. They deny paragraph 44 of the Motion;

30. They deny paragraph 45 of the Motion for the reasons set forth below;

31. They deny the allegations contained in paragraphs 46, 47, 48, 49, 50, 51 and 52 of the Motion;

32. With respect to the allegations contained in paragraph 53, they deny that the ASR Implant Systems were defective and have no knowledge of the remainder of the paragraph;

33. They have no knowledge of the allegations of paragraph 54 of the Motion beyond what is contained in the Plaintiff's medical records of which copies have been furnished to date;

34. They have no knowledge of the allegations contained in paragraphs 55, 56 and 57 of the Motion;

35. They deny the allegations contained in paragraphs 58, 59, 60, 61, 62, 63 and 64 of the Motion;

36. With respect to the allegations contained in paragraph 65 of the Motion, there are known adverse events associated with hip reconstructive surgery and they include infection and bone reduction;

37. They deny the allegations contained in paragraphs 66, 67, 68 and 69 of the Motion;

AND IN FURTHER SUPPORT OF ITS DEFENCE TO THE MOTION, THE DEFENDANTS ADD THE FOLLOWING:

The Defendants

38. The Defendant DePuy Orthopaedics, Inc. ("DePuy Orthopaedics") is a corporation based in Warsaw, Indiana in the United States of America. DePuy Orthopaedics did not design or manufacture the orthopaedic medical components that are the subject of the Motion, nor did it distribute or sell these devices in Canada;

39. At all material times, DePuy International Limited was responsible for the design and manufacture of the orthopaedic medical components ("DePuy products") that are the subject of the Motion. DePuy International Limited ("DePuy") is a United Kingdom private limited company based in Leeds, U.K. It carries on business as, among other things, a designer, manufacturer and distributor of orthopaedic components used in hip replacement surgery;

40. The Defendant Johnson & Johnson Inc. is a Canadian company that distributes DePuy products in Canada through its division Johnson & Johnson Medical Products ("JJMP"). Johnson & Johnson Inc. has never owned shares of the Defendant, DePuy Orthopaedics;

41. At all times material to this action, JJMP distributed and sold in Canada products known as the ASR™ XL Acetabular System and/or the DePuy ASR™ Hip Resurfacing System, consisting of component parts for use in hip replacement surgery (the "ASR™ Hip Systems"). At all times

material to this action, JJMP distributed and sold the ASR™ Hip Systems to hospitals in Canada, and did not distribute or sell them directly to the Plaintiff, to individual group members or to their treating physicians;

42. The parties identified above are collectively referred to herein as "the Defendants". References in this Defence to the "Group" or to "Group Members" refer to members of the ASR Implant Systems Group described in the Authorization Judgment, unless otherwise specified;

Total Hip Replacement, Hip Resurfacing, and the ASR™ Hip Systems

43. A natural hip joint has a ball and cup structure, where the "ball" of the joint is the femoral head, which rests inside the "socket" or "cup" called the acetabulum;

44. Hip reconstruction surgery (either total hip replacement or hip resurfacing) involves the surgical replacement of a patient's native hip joint with an artificial hip prosthesis. It is typically performed on patients who suffer from severe hip degeneration, in order to help relieve pain and improve mobility and function. In effect, hip reconstruction surgery involves using synthetic engineered structures to replace human tissues that have themselves failed to perform satisfactorily for the natural life of the patient;

45. In the case of total hip replacement surgery, the head and proximal neck of a patient's femur, the acetabular cartilage, and the subchondral bone are removed. Following removal, prosthetic components are implanted to replace the patient's native hip joint. A prosthetic total hip consists of three primary components: (i) a femoral stem; (ii) a femoral head or ball; and (iii) an acetabular cup;

46. Hip resurfacing is a surgical alternative to total hip replacement surgery. In hip resurfacing, the femoral neck and head are preserved rather than removed. The patient's own femoral head is shaped to fit a prosthetic femoral cap, which covers the femoral head;

47. A patient's initial hip reconstruction surgery is commonly referred to as the "primary" surgery. All patients who have had a primary hip implant surgery are at risk for additional hip surgeries after the primary hip reconstruction surgery regardless of implant design or manufacture. A surgery that follows the primary hip surgery is referred to as a "revision" hip surgery;

48. The failure of a patient's hip reconstruction surgery, which may lead to revision surgery, can be the result of a multitude of factors, including patient-specific characteristics and/or activities or surgical technique;

49. The ASR™ XL Acetabular System was designed for use in total hip replacement surgery. It consists of two components: (i) a metal femoral head (or ball) connected to the femoral stem component by a sleeve adaptor, which is placed inside the patient's femur, and (ii) a one-piece metal cup that lines the acetabulum ("ASR™ acetabular cup");

50. The ASR™ Hip Resurfacing System was designed for use in hip resurfacing surgery. It consists of two components: (i) a metal cap that is placed over the natural femoral head; and (ii) a one-piece metal cup that is placed in the acetabulum. While it was designed to be used with an ASR™ acetabular cup, the ASR™ Hip Resurfacing System does not utilize a femoral stem component or a sleeve adaptor because a patient's natural femoral head is maintained in resurfacing surgery;

51. Artificial hip joints may utilize a combination of metal and plastic, the bearing surfaces used in hip replacement surgery are varied and also include metal-on-polyethylene, metal-on-metal, ceramic-on-ceramic, and ceramic-on-polyethylene combinations. The ASR™ Hip Systems are both metal-on-metal devices. Each bearing surface has specific material and mechanical characteristics, as well as specific risks and benefits that must be assessed and considered individually for each patient. Individual patient factors that may impact the choice of bearing surface include:

(a) the patient's gender;
(b) any personal history of metal sensitivity;
(c) the size and shape of a patient's hip joint;
(d) a patient's bone quality; and
(e) dislocation risk for the patient;

Health Canada Approval of the ASR™ Hip Systems

52. On November 30, 2005, Health Canada issued a medical device license for the ASR™ Acetabular System, as appears from a printout from the Health Canada Medical Devices Licence database and licence, communicated herewith, *en liasse*, as **Exhibit D-1**;

53. On January 5, 2006, Health Canada issued a medical device license for the ASR™ Hip Resurfacing System, as appears from a printout from the Health Canada Medical Devices Licence database and licence, communicated herewith, *en liasse*, as **Exhibit D-2**;

54. The ASR™ Hip Systems remained on the market with Health Canada approval until they were voluntarily recalled on August 24, 2010, as appears from Exhibit P-3;

55. Prior to their alleged use in the Plaintiff and the Group Members, the ASR™ Hip Systems and their Instructions for Use ("IFU"), and the warnings provided therein, were reviewed and approved by Health Canada;

56. Further, at all material times, the Defendants provided appropriate and adequate disclosure of their knowledge about possible risks associated with the use of the ASR™ Hip Systems to Health Canada, and had discussions with Health Canada regarding the appropriate information and warnings to be provided in the IFUs;

57. Approval by Health Canada of the ASR™ Hip Systems and of the IFUs for those ASR™ Hip Systems, create a presumption that the design of the ASR™ Hip Systems met a reasonable standard of care, that it was reasonable to conclude that the products were safe and effective for use in hip replacement surgery and that the warnings and instructions provided by the Defendants in the IFUs for the ASR™ Hip Systems were reasonable at the time implanted in each Group Member;

58. The Defendants complied with the relevant provisions of the Food and Drugs Act (the "Act") and the Medical Device Regulations (the "Regulations"), and Health Canada's requirements for approval of the labelling of the ASR™ Hip Systems, in all relevant respects at the time each Group Member was implanted;

Distribution of the ASR™ Hip Systems in Canada

59. ASR™ acetabular cups were used when implanting both ASR™ Hip Systems. At all material times Defendant Johnson & Johnson Inc. exercised reasonable care in the distribution and sale of ASR™ Hip Systems to Canadian hospitals;

The ASR™ Hip Systems Were Free of Any Safety Defect

60. DePuy issued a voluntary, global recall of the ASR™ XL System and the ASR™ Hip Resurfacing System in August 2010. At all material times the Defendants exercised reasonable care in the monitoring and reporting to Health Canada of the performance of ASR™ Hip Systems, and in the voluntary recall of the ASR™ Hip Systems;

61. Defendants deny that the ASR™ Hip Systems are defective, as alleged by the Plaintiff;

62. Plaintiff also alleges that there are reported higher rates of revision surgery with ASR™ Hip Systems. There are numerous factors that can influence the ultimate clinical success of hip reconstruction surgery in an individual patient. These include: (i) patient factors; (ii) surgical factors; and (iii) implant factors;

63. Patient factors include:

(a) the patient's reasons for undergoing hip replacement surgery;
(b) the patient's body mass index;
(c) any co-morbidities the patient may have;
(d) the patient's individual anatomy;
(e) the patient's prior surgical history in the affected area;
(f) any personal history of smoking, or alcohol or medication consumption;
(g) any post-implant events or trauma; and
(h) the patient's compliance with the physician's post-operative recommendations;

64. Surgical factors, including surgical techniques as well as implant positioning and sizing, are also highly specific to each patient, will differ from patient to patient and must be looked at on an individual basis when assessing a specific patient's clinical outcome;

65. Implant factors that can affect the success and longevity of hip reconstruction surgery include the type of bearing surface, the sizing of the implants, the position of the implants, impingement, dislocation, stem fracture, manufacturing, or design;

66. Determining the "cause" of a patient's post-operative pain or revision surgery must take into account all three categories of factors and evidence of the relative risks of each potential cause;

No Failure to Warn

67. The Defendants did not market the ASR™ Hip Systems to the Plaintiff or Group Members;

68. As admitted to during his examination on discovery, pp. 94 and ss., Plaintiff did not see or rely upon any marketing of the ASR™ Hip Systems by either of the Defendants;

69. The ASR™ Hip Systems that are the subject of the action are highly technical in nature and were only available to the Plaintiff and Group Members through learned intermediaries such as physicians and hospitals. Accordingly, the Defendants could (and did) satisfy any duty to warn the Plaintiff and Group Members by warning their healthcare providers of the risks inherent in the use of the ASR™ Hip Systems;

70. While the ASR™ Hip Systems were available for sale and use in Canada, at all material times the component parts were distributed to hospitals and surgeons in Canada with the applicable IFU(s). At all material times the IFUs for the ASR™ Hip Systems, as approved by Health Canada, contained adequate warnings. Copies of relevant excerpts of the IFUs are communicated herewith, *en liasse*, as **Exhibit D-3**;

71. At all material times, the Defendants took all reasonable steps to inform the Plaintiff's and Group Members' healthcare providers regarding the medical and other conditions indicating use of the ASR™ Hip Systems and, to the extent required, to provide appropriate and adequate instructions and warnings regarding the ASR™ Hip Systems;

72. At all material times, the ASR™ Hip Systems were manufactured and were distributed in Canada with proper warnings, information, cautions, and instructions in accordance with the generally recognized and prevailing standards in existence at the time;

73. All hip replacement devices have potential risks to a patient associated with their use. The potential risks associated with the ASR™ Hip Systems were at all material times within the range of acceptable risks for hip replacement devices;

74. The Defendants do not have full information regarding the Plaintiff's and individual Group Members' medical conditions and communications with their physicians regarding the use of the ASR™ Hip Systems, and accordingly plead at this time that:

    (a) the Plaintiff and Group Members failed to disclose to their healthcare providers all relevant medical and health information, and such failures adversely impacted their physicians' warnings regarding the decision to undergo hip replacement surgery; and that

    (b) the conduct of each Group Members' healthcare providers made any alleged failure to provide an adequate warning irrelevant;

75. Alternatively, the Plaintiff and individual Group Members were aware at all material times of the risks associated with use of the ASR™ Hip Systems, from their physicians and other sources that they consulted prior to being implanted with the ASR™ Hip Systems. They knowingly and voluntarily assumed any and all risks associated with the use of the ASR™ Hip Systems;

Defendants committed no fault

76. The Defendants deny that they committed any fault which caused or contributed to the Plaintiff's or any Group Member's injuries, loss or damage, if any;

77. The ASR™ Hip Systems were designed, researched, manufactured, tested, examined, inspected, packaged, labelled, marketed, distributed and sold in accordance with the industry standards applicable at the time of manufacture and design, and in accordance with the reasonable standard of care;

78. The Defendants deny that any of the components of the ASR™ Hip Systems were defective and further deny that any alleged defect caused or materially contributed to any injury or harm alleged to have been suffered by the Plaintiff or any Group Member, which is denied;

79. The ASR™ Hip Systems implanted in the Plaintiff and Group Members were neither defective nor unreasonably dangerous when used according to their IFUs;

80. At all material times, the ASR™ Hip Systems conformed to state-of-the-art specifications and state of scientific knowledge for such products at the time each was implanted;

81. The Defendants closely monitored the performance of the ASR™ Hip Systems and evaluated data from a variety of sources, including registries throughout the world;

82. The revision rates reported in the National Joint Replacement Registry in Australia were reviewed thoroughly and found to not be in line with the experience of surgeons in the rest of the world;

83. The ASR™ Hip Systems were discontinued in the Australian market on December 31, 2009, for commercial reasons but remained available to surgeons in other countries, including Canada;

84. In a March 8, 2010 Field Safety Notice, the Defendants relayed that analyses suggested a higher than expected revision rate for the ASR™ Hip Systems when used with cups with smaller head sizes (less than 50 mm in diameter). Therein, surgeons were notified that DePuy would continue to monitor data from all available sources and would follow up if additional information became available that resulted in changes to the recommendations contained in the Field Safety Notice. A copy of the March 8, 2010 Field Safety Notice is communicated herewith as **Exhibit D-4**;

85. Several months later, the Defendants became aware of new data from the National Joint Registry of England and Wales showing a higher than expected revision rate for the ASR™ Hip Systems at five years and issued a voluntary, global recall of those devices on August 24, 2010, a copy of the Voluntary Product Recall having been communicated by Plaintiff as Exhibit P-3;

86. The voluntary recall was diligently implemented in Canada. Hospitals and physicians were promptly informed, and the Defendants requested that patients be notified;

87. The Defendants sought to ensure that cost would not be a barrier to any treatment patients might need for reasons related to the recall, including revision surgery if needed. The Defendants engaged an independent, third party claims processor, Crawford, to ensure that patients would be reimbursed quickly and efficiently for recall-related patient out-of-pocket expenses, including lost wages and travel costs, a copy of the claims process being communicated herewith as **Exhibit D-5**;

The Plaintiff's Personal Situation

88. Although incomplete, the Plaintiff's medical records which have been disclosed to date contain several indications of factors affecting the likelihood of success of hip implant surgery and the need for revision surgery, including, without limitation, bone condition, weight, family predisposition, engagement in high impact sports, and a history of knee surgery and other trauma. In particular, it is noteworthy that the need for revision of the Plaintiff's initial hip resurfacing procedure was precipitated by a femoral fracture. Defendants reserve their right to amend their defence upon review of the Plaintiff's complete medical records;

No Damages

89. The Defendants deny that any Group Member who has not had revision surgery is entitled to damages;

90. If the Plaintiff or any individual Group Member suffered injuries and damages, which is denied, the alleged injuries and damages were not the direct, proximate or foreseeable cause or consequence of either of the Defendants' conduct and the Defendants are not liable for same. The damages claimed are excessive, unreasonable and too remote to be recoverable at law;

91. The Defendants deny that any of their alleged conduct caused or contributed to the need for any of the past or future medical treatment provided to the Plaintiff or Group Members;

92. Further, or in the alternative, the injuries alleged are known sequelae of the risks of all surgical hip replacement procedures, and the Plaintiff and Group Members would have experienced the same or worse conditions had any other product been used;

93. Further, any injuries incurred by the Plaintiff or any individual Group Member arose from, were caused by, or contributed to by medical conditions existing prior to the implant of the ASR™ Hip Systems, from medical conditions that developed independently from the implant and use of the ASR™ Hip Systems, from an allergic, idiosyncratic or idiopathic reaction to the product and/or from the conduct and actions of persons beyond the control and knowledge of the Defendants;

94. In the further alternative, if the Plaintiffs or any individual Group Member have suffered damages as alleged in the Motion, or at all, which is denied, they failed to take any or all reasonable steps to mitigate any such loss or damage;

95. In the further alternative, the Plaintiff and the Group Members caused or materially contributed to their alleged injuries, which injuries are not admitted but expressly denied, by engaging in activities after their hip replacement surgeries in direct violation of their physicians' instructions and the common dictates of reasonable behaviour;

No Punitive Damages, Prescription and Collective Recovery

96. The Defendants expressly deny any bad faith on their parts or the parts of their employees and/or agents;

97. The Defendants further deny any basis for a claim for exemplary and punitive damages on behalf of the Group, since absent any intentional wrongdoings on Defendants' part, they should not be held liable for any such damages;

98. The Defendants contend that the claims of some of the Group Members are prescribed;

99. The Defendants contest Plaintiff's conclusions relating to collective recovery of punitive and non-pecuniary damages and state that any such damages as might be awarded can only be determined at the individual recovery phase.

WHEREFORE, MAY IT PLEASE THIS COURT TO:

DISMISS Plaintiff's Motion;

THE WHOLE with costs, including all expert fees for the preparation of their reports and their attendance at trial.

Montréal, February 16,.2015

Norton Rose Fulbright Canada

NORTON ROSE FULBRIGHT CANADA LLP
Attorneys for Defendants

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