Court File No./N° du dossier du greffe: CV-22-00088312-00CP

Court File No.:

ONTARIO
SUPERIOR COURT OF JUSTICE

Electronically issued
Délivré par voie électronique : 12-Jan-2022
Ottawa

In the matter of a Claim under the
Class Proceedings Act, 1992, S.O. 1992, c. 6

B E T W E E N:

CASSANDRA LYON

Plaintiff

- and -

DEPUY SYNTHES COMPANIES, SYNTHES (CANADA) LTD. and DEPUY ORTHOPAEDICS INC. and JOHNSON & JOHNSON INC.

Defendants

STATEMENT OF CLAIM

TO THE DEFENDANT(S):

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a Statement of Defence in form 18A prescribed by the Rules of Civil Procedure, serve it on the Plaintiff's lawyer or, where the Plaintiff does not have a lawyer, serve it on the Plaintiff and file it, with proof of service, in this Court office, WITHIN TWENTY DAYS after this Statement of Claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your Statement of Defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a Statement of Defence, you may serve and file a Notice of Intent to Defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your Statement of Defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. If you wish to defend this proceeding but are unable to pay legal fees, legal aid may be available to you by contacting a local Legal Aid office.

DATED:_____ **Issued by:** _____

Court House
161 Elgin Street
Ottawa, Ontario, K2P 2K1

TO: **DePuy Synthes Companies**
200 Whitehall Drive
Markham, ON L3R 0P3

AND TO: **DePuy Orthopaedics, Inc.**
700 Orthopaedic Drive
Warsaw, IN 46582
USA

AND TO: **Johnson and Johnson Inc.,**
88 McNabb Street
Markham, ON L3R 5L2

AND TO: **SYNTHES (CANADA) LTD**
200 Whitehall Drive
Markham, ON L3R 0T5

CLAIM

RELIEF SOUGHT

1. The Plaintiff claims on behalf of herself and on behalf of a class of individuals described in the class below:

   (a) An order certifying this action as a class proceeding and appointing the Plaintiff as Representative Plaintiff;

   (b) Damages for each Class Member and the Plaintiff as follows:

      (i) General damages of $370,000 for pain and suffering and loss of amenities of life;

      (ii) Damages for past and future loss of income in the amount of $2,000,000;

      (iii) Damages for past and future cost of care in the amount of $3,000,000 per Class Member

      (iv) Damages to indemnify the subrogated interests of the Ontario Health Insurance Plan and/or other private or provincial or territorial health insurers;

   (c) A declaration that the Defendants were jointly and/or severally negligent in the design, construction, manufacturing, inspection, testing and marketing of its ATTUNE Knee System total knee replacement implant devices (the “Device”) used in patient total knee arthroplasty operations, as well as its failure to warn patients and/or surgeons and other healthcare providers of the inherent dangers and risks in using its Device and thereby causing

loss and damage to the Plaintiff and other Class Members;

(d) Aggravated, exemplary and/or punitive damages in the amount of $300,000,000 for these same claims to be divided pro rata amongst the Class Members;

(e) For Dependents of Class Members, damages pursuant to the *Family Law Act,* RSO 1990, c F-3 ("*FLA*"), or equivalent in other provinces, for out of pocket expenses, loss of care guidance and companionship in the amount of $20,000,000;

(f) An Order requiring the Defendants to disclose for purposes of providing Opt Out Notice, the names, addresses and all contact information for each patient who had a device implanted in Canada;

(g) An order directing a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

(h) Pre-judgment and post-judgment interest pursuant to the *Courts of Justice Act* ("*CJA")* ;

(i) Costs of this action on a substantial indemnity basis or in an amount that provides full indemnity plus, pursuant to s. 26(9) of the CPA, the costs of notice and of administering the plan of distribution of the recovery in this action plus applicable taxes; and

(j) Approval of a 25% contingency fee agreement plus disbursements, HST.

THE PARTIES

2. The Plaintiff, Cassandra Lyon, is a resident of Brampton, Ontario and underwent Total Knee Arthroplasty (TKA) or knee replacement procedure in approximately 2015 in which she had implanted the Defendants' ATTUNE® Knee System device.

3. The Defendant, DePuy Synthes Companies (Synthes), is a corporation duly incorporated with its head office in Markham, Ontario. It is part of the Defendant Johnson and Johnson Inc. group of companies as is Depuy Orthopaedics Inc.. The Defendant Depuy Orthopaedics Inc (Depuy) is duly incorporated in the United States. The Canadian companies Johnson and Johnson Inc and SYNTHES (CANADA) LTD are duly incorporated in Canada. All of the Defendant companies work together and carry on the business of supplying medical devices including the manufacturing, designing, construction and distribution of the ATTUNE® knee system ("the Device"). All companies marketed, distributed, and profited by sales in Canada of the Device to Canadian patients.

THE CLASS

4. The Plaintiff brings this claim on her own behalf and on behalf of all other individuals who were surgical recipients of the Defendant's ATTUNE® total knee arthroplasty implant which prematurely failed or is in the process of failing or has

the Device implanted; and those individuals who are entitled, by virtue of their relationship to a member of the Class, to assert claims pursuant to the *Family Law Act* and equivalent legislation from other Canadian jurisdictions ("the Family Class").

FACTS

5. The Corporate Defendants designed, manufactured and distributed the ATTUNE® Knee System ("the Device") which was advertised as being designed to deliver a "high level of stability and motion" and to improve efficiency and functional outcomes for patients and/or recipients of the implanted device in total knee arthroplasty procedures. It was also advertised as an "innovative" and "comprehensive" integrated knee system which better "resembles the biomechanics of the natural knee" compared to other products.

6. The ATTUNE® Knee Device uses smoother material than comparable products. During knee replacement surgeries, surgeons core the tibia and cement the implant materials to bond the Device to existing bone. The Device was improperly designed, manufactured and tested resulting in the implant failing, loosening, de-bonding and detaching from the tibial implant-cement-metal-bone interface. Given the smooth materials of the Attune components, the "glue" is unable to properly adhere the Attune implant to the patient's natural bone. The Class Members say that this is as a result of negligent design, testing, manufacturing for which the Defendants are individually, severally and/or jointly responsible at law.

7. The Plaintiff on behalf of the class state that all recipients in Canada will eventually require revision surgery to replace the defective Device.

8. The Plaintiff states that the Device has been proven to have early and premature septic failures as a result of the negligent design and procedures developed by the Defendants. The studies resulted in findings of early septic failures at the implant-cement-bone interface in the Attune system resulting in knee-destabilization, device failure, de-bonding and subsequent revision surgeries. The Plaintiff and Class Members are exposed to health risks associated with the revision as well as substantial care costs and income losses.

9. Class Members, including the Plaintiff, have experienced instability, swelling, inflammation, pain and stiffness that has impaired their ability to ambulate, walk, and otherwise perform their activities of daily living and employment. These complications have resulted in permanent injuries and the requirement of future surgery and care.

10. The Device is no longer used, surgeons have routinely determined that the part was insufficient and/or failed and have replaced it. If the design was updated, changed or abandoned; the defendant should have withdrawn the product for use.

THE PLAINTIFF'S EXPERIENCE

11. The Plaintiff had been experiencing degenerative symptoms and pain in her right knee for a few years. An x-ray done by her doctor, Dr. Chan, on November 7, 2012 showed osteoarthritis in both knee joints. In August of 2013 she saw Dr. Chan, who said she would need knee replacement surgery with time and further degeneration.

12. On February 17, 2015, the Plaintiff underwent a total knee replacement surgery on her right knee. The procedure was performed by Dr. Rodriguez-Elizalde at Humber River Hospital. The implants used were the DePuy total knee arthroplasty system, Attune size 3 fixed baseplate cemented, size 5 tibial insert, 35 mm dome patella, and a 5 right cemented posterior stabilized narrow femoral component. The surgery took approximately 75 minutes, and the Plaintiff tolerated the procedure quite well. She was discharged from the hospital on February 20, 2015.

13. Following her surgery, the Plaintiff had an ultrasound with Dr. Chan of her right knee and leg on November 6, 2015. It showed fluid around right knee joint, a large effusion, and a Baker's cyst. On December 3, 2015, the Plaintiff was seen by Dr. Rodriguez for a follow-up. She had the surgery approximately 10 months ago and was already experiencing pain and inflammation. She was given a cortisone injection which provided temporary relief, but the symptoms returned.

14. On May 3, 2016, the Plaintiff had a follow-up with Dr. Chan. The surgery did not help the Plaintiff with her pain. She continued to experience persistent pain and swelling of the right knee. The differential diagnosis would include loosening of the prosthesis, osteolysis or chronic infection.

15. On May 26, 2016, the Plaintiff saw Dr. Rodriguez with arthritis in her left knee and pain, swelling and tenderness in her right knee. She was given an injection of cortisone. The Plaintiff continued having increasing knee pain and on July 27, 2016 she was given a prescription for Vimovo.

16. In 2017, the Plaintiff also started having back pain and right shoulder pain, likely as a result of shifted weight and gait due to the knee pain. She was given an orthotics prescription on February 13, 2017 to help with the pain, and was referred to an orthopedic surgeon.

17. The Plaintiff saw Dr. Syed, an orthopedic surgeon at Toronto Western Hospital, in May 2017. They recommended revision surgery, but the Plaintiff was worried about the risk of a periprosthetic fracture. Dr. Syed gave her a motion brace to improve her range of motion. She also recommended various physical exercises to help with pain and stiffness.

18. However, the Plaintiff continued to experience pain, stiffness, and reduced range of motion in her right knee. At 65 years of age, on September 18, 2019, the

Plaintiff underwent revision surgery with by Dr. David Backstein at Mount Sinai Hospital. Based on the Operative Report, both the pre-operative and post-operative diagnosis was aseptic loosening on the tibial side of the right total knee replacement.

19. The procedure went well, and the Plaintiff remained at the hospital for 4 days. She was monitored by nurses and received rehabilitation and physiotherapy. She was discharged on September 21, 2019.

20. Six weeks after her surgery, Dr. Backstein noted that her wound was healing well. The Plaintiff used a cane for walking, had a 0 to 100 degree range of motion and had no swelling around her knee. The doctor recommended physical exercises to strengthen her muscles.

21. On June 18, 2020, the Plaintiff was doing well at her follow-up, but still complained of knee pain, especially with increased activity. Almost one year after her revision surgery, the Plaintiff had a follow-up consultation with Dr. Backstein and PT Allison Drynan on October 1, 2020. She has been doing much better and returned to work, although she still experiences knee pain, particularly due to the Baker’s cyst. She still has occasional shooting pain along her lower leg, and diffuse anterior knee pain after long shifts for which she uses Voltaren and takes Tylenol.

22. The Plaintiff continues to do exercises at home to strengthen and maintain her knee. She lives in a two-story home in Brampton and occasionally struggles with the stairs. There is a pull-out bed on the main floor of the house though. She lives with her supportive daughter, and her two grandchildren.

THE LIABILITY OF THE DEFENDANTS
Overview;

23. The corporate Defendants are liable to the Plaintiff and Class Members for all consequential damages incurred as a result of injuries to the Plaintiff and Class including economic and non-economic damages, past loss of income, future loss of earning capacity, pain, suffering, psychological and emotional distress, medical expenses, medical treatment costs, hospitalization and rehabilitation costs, attendant care, nursing care, loss of earnings, punitive damages and costs and prejudgment interest.

24. The Plaintiff states that she relied on the representations of the Defendants and had no way of knowing that the said Device used in her total knee replacement surgery was defective in design, manufacture and marketing and even when properly implanted by surgeons and/or healthcare providers.

25. Thousands of Class Members have or will experience Attune® Knee system failures, causing them to suffer and continue to suffer from emotional, physical and psychological injuries as a result of Attune Knee system failure and loosening implants, requiring medical attention and complicated revision

surgeries to replace the defective Device. In addition, all recipients of these devices will suffer failure and future surgical revision and care as a result of this defective device.

26. At all times relevant to this action, the Corporate Defendants were engaged in the business of manufacturing, producing, inspecting, testing, packaging, warranting, distributing, selling and otherwise placing the Devices into the stream of commerce. The Devices were manufactured and used for the purpose of implantation in TKA procedures and other related uses and the Corporate Defendants were the designers, manufacturers, testers, marketers, sellers and/or distributors of the ATTUNE Knee System for use by ultimate consumers, including the Plaintiff Joanne.

27. The Plaintiff and Class Members directly or indirectly purchased the Devices manufactured by the Corporate Defendants through their distributors and/or healthcare providers to be used in the course of surgical procedures.

28. The Devices were defective and unreasonably dangerous, when sold, in that they failed to properly bond and adhere to the patient's bone to be used as a knee replacement, despite proper implantation by the surgeons and/or healthcare providers and/or due to a foreseeable misuse of the Device attributable to the corporate Defendants' faulty design, training or instruction and not due to any want of care by the Plaintiff.

Negligence/Breach of Contract/Breach of Statutory Warranties;

29. The Plaintiff states that aforesaid negligence and/or breach of contract of the corporate Defendants or any or all of them, jointly and severally, and/or individually includes:

(a) The Device was defectively designed;

(b) The Device was defectively manufactured;

(c) The Device was not properly inspected. As a result of these design, manufacturing and testing failures there have been an unusually high rate of failures and de-bonding of all Device implants has and will continue to occur ;

(d) The Device was not properly tested, designed or inspected to ensure that it would properly adhere and/or bond to patients' natural bone and/or remain stabilized and positioned in place in the patients' knee;

(e) Consumers and/or patients who were implanted with the Device would not have a reasonable opportunity or have the knowledge to inspect and/or understand how the Device would function once implanted and consequently had a high duty to ensure its reliability given its critical orthopedic function;

(f) They knew or ought to have known that the failure of the Device could or would result in serious health risks and consequences for patients but even after discovering the problems still sold the device for implantation;

(g) They knew or ought to have known that the Devices would be purchased by healthcare providers, physicians and/or patients for the purpose of total knee replacements and serious medical and operative procedures. The Device failed to function properly despite proper use of the Device by medical professionals trained to use it;

(h) The Device was inherently dangerous for its intended use due to the design and/or manufacturing defect and improper functioning. The corporate Defendants and/or any of them used defective inspection and testing techniques and failed to institute proper quality control testing in their production facilities which manufactures their Attune products;

(i) There were safer alternative designs which could have prevented or significantly reduced the risk of Device failure and displacement of the Device in patients;

(j) They failed to warn consumers/and or patients implanted with the Device of the inherent risks of their defectively designed, manufactured and inspected Device;

(k) The Device failed to adhere to patients' natural bone and resulted in loosening and/or displacement of the Device while implanted inside the patients; and

(l) They failed to provide timely assistance or have equipment proximately available to replace or correct the defective equipment.

30. The Plaintiff and Class Members were not able to discover nor could they have

discovered through exercise of reasonable care the defective nature of the Device. Further, in no way could they have known that the corporate Defendants had designed, developed and manufactured the Device in such a way as to increase risk of harm or injury to the recipients of the Device.

Breach of Express and Statutory Warranties;

31. At all relevant times, the Defendants or any of them used advertising, publications and sales representatives to advertise and market the use and purchase of the Devices for use in TKA procedures and/or knee replacement surgeries and expressly warranted that the Device was state-of-the-art technology and improved the mobility, range of motion, and/or quality of life for thousands of individuals.

32. The Defendants or any of them expressly warranted that the Device would function efficiently similar to the biomechanics of the natural knee. DePuy expressly warranted to healthcare providers and/or patients that the Device was safe for implantation and/or use in patients.

33. By consenting to implantation of the Device, the Plaintiff and Class Members specifically relied on the skill and judgment of the Defendants and their express warranties and representations that the Device was safe for use.

34. The Defendants or any of them breached the express warranty by designing,

manufacturing and marketing a defective product that failed to properly adhere and stay in place after implantation in the patient.

35. This defective product fails to comply with explicit warranties provided by the manufacturer as well as the implied warranties of fitness for intended purpose and merchantability in the *Sale of Goods Act*, R.S.O. 1990 C.S1 sections 14 and 15 as well as the provisions of the *Consumer Protection Act*, 2002, S.O. 2002, c.30 sections 14 and 15, as amended.

DAMAGES

36. The Plaintiff and other putative class members' injuries and damages were caused by the negligence of the Defendants, their servants and agents.

37. As a result of the Defendants' negligence, the Plaintiff has suffered and continues to experience serious personal injuries and harm with resultant pain and suffering.

38. As a result of the conduct of the Defendants, the Plaintiff 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.

39. Some of the expenses related to the medical treatment that the Plaintiff and

Class Members have undergone, and will continue to undergo, have been borne by the various provincial health insurers.

40. The Plaintiff claims punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendants.

SERVICE OUTSIDE OF ONTARIO

41. The Plaintiff and class members rely on R.R.O. 1990, Regulation 195: *Rules of Civil Procedure,* under *Courts of Justice Act, R.S.O. 1990, c. C.43*, *Rule 17.02(f) and (g)* for service out of Ontario.

PLACE OF TRIAL

42. The Plaintiff proposes the within action be Tried in the City of Ottawa in the Regional Municipality of Ottawa Carleton.

Dated: January 12, 2022

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CASSANDRA LYON
Plaintiff

-and-

DEPUY SYNTHES COMPANIES et al
Defendants

Court File No.

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED AT
OTTAWA

STATEMENT OF CLAIM

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