Court File No. S-139332
Vancouver Registry

In the Supreme Court of British Columbia

Between

Gary Carlson

Plaintiff

and

Smith & Nephew Inc. of Canada, Smith & Nephew Inc.,
and Smith & Nephew PLC

Defendants

Brought under the *Class Proceedings Act*, R.S.B.C. 1996, c. 50

NOTICE OF CIVIL CLAIM

This action has been started by the plaintiff for the relief set out in Part 2 below.

If you intend to respond to this action, you or your lawyer must

(a) file a response to civil claim in Form 2 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim on the plaintiff.

If you intend to make a counterclaim, you or your lawyer must

(a) file a response to civil claim in Form 2 and a counterclaim in Form 3 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim and counterclaim on the plaintiff and on any new parties named in the counterclaim.

JUDGMENT MAY BE PRONOUCED AGAINST YOU IF YOU FAIL to file the response to civil claim within the time for response to civil claim described below.

Time for response to civil claim

A response to civil claim must be filed and served on the plaintiff,

(a) if you reside anywhere in Canada, within 21 days after the date on which a copy of the filed notice of civil claim was served on you,

(b) if you reside in the United States of America, within 35 days after the date on which a copy of the filed notice of civil claim was served on you,

(c) if you reside elsewhere, within 49 days after the date on which a copy of the filed notice of civil claim was served on you, or

(d) if the time for response to civil claim has been set by order of the court, within that time.

CLAIM OF THE PLAINTIFF

Part 1: STATEMENT OF FACTS

Overview

1. On September 2, 2009, the Plaintiff was implanted with a hip implant manufactured by the Defendants. The product failed, and the Plaintiff had to undergo revision surgery to remove the faulty device on October 9, 2013.

2. The fundamental flaw with the Defendants' product is that it is a metal-on-metal ("MoM") hip implant. That is, the components of device which come into contact with one another are all made of metal, as opposed to other alternative materials commonly used for hip implants. Metal hip implant components are subject to corrosion and fretting as they grind upon each other, releasing metal debris into the surrounding tissue.

3. This metal debris is toxic. Patients exposed to this debris suffer pain, disability and personal injury, and it becomes necessary for them to undergo surgery to remove the faulty implant.

4. The Defendants sell MoM hip implants under the brand name Birmingham Hip Resurfacing system ("BHR"). It is a modular system consisting of a number of components.

5. On June 1, 2012, the Defendants initiated a recall of one of the key metal-on-metal components used in the BHR, including the BHR with which the Plaintiff was implanted. This is the R3 Acetabular System metal liner. In a press release, the Defendants conceded that "they are not satisfied with the clinical results of this component."

6. The problems with the Defendants' product however are more extensive than the Defendants have so far been willing to admit.

7. The Plaintiff brings this action on his own behalf, and on behalf of a proposed class.

Parties

8. The Plaintiff is a resident of Victoria, British Columbia.

9. The proposed definition of the class is as follows:

> "All persons who were implanted in British Columbia and elsewhere in Canada with a metal-on-metal hip implant system manufactured by the Defendants."

10. The Defendant, Smith & Nephew Inc. is an American corporation with a registered office at 1450 Brooks Road, Memphis, TN, 38116. It is licenced by Health Canada as a manufacturer of medical devices, with company ID number 109544. It is licenced by Health Canada to sell hip implants, including metal-on-metal products.

11. The Defendant, Smith & Nephew Inc. of Canada ("Smith & Nephew Canada") is a Canadian corporation, incorporated under the *Canada Business Corporations Act*, and registered in British Columbia as an extra-provincial company with a mailing address at 199 Bay Street, 4000, Toronto, ON, M5L 1A9.

12. The Defendant, Smith & Nephew PLC, is a British Corporation with a registered office at 15 Adam Street, London, UK, WC2N 6RJ.

13. The Defendants are all inter-related corporations with each being the parent, subsidiary, or affiliate of the others. The Defendants individually and/or collectively participated in one or more the following: the development, testing, manufacture, distribution, marketing and promotion of metal-on-metal hip implants into Canada.

14. The Defendants are joint tortfeasors. They each knew, or ought to have known that their metal-on-metal hip implants were defective, and they each were in such a close and proximate relationship to the Plaintiff and class members as to owe them a duty of care. They each could have taken reasonable steps to have prevented injury to the Plaintiff and class members, including ensuring that their metal-on-metal hip implants were properly designed, tested and manufactured before marketing them, promptly recalling them, and properly warning consumers of the risk of harm.

Hip Implants

15. Hip implants have been around for more than 40 years. When designed properly, they are an effective treatment for arthritis and other degenerative injuries to the hip joint.

16. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

17. Hip implants mimic the hip joint, and generally consist of the following components: a femoral stem inserted inside the femur bone; a femoral head (or ball) connected to the top of the stem; a liner which makes contact with the ball; and an acetabular cup which is implanted in the pelvis, connected to the liner, and provides the socket in which the ball rotates.

18. A MoM hip implant uses all metal components. Other hip implants will use different materials, including plastic or ceramic liners to avoid metal-on-metal contact between the ball and the socket.

19. A properly designed hip implant, which avoids metal-on-metal components, may be reasonably expected to last for many years, and potentially for the remainder of the patient's lifetime.

20. Potential problems with metal-on-metal designs have been known by hip implant manufacturers since the 1970s.

21. The Defendants knew or ought to have known of the inherent risks of metal-on-metal designs before they ever marketed them.

22. The Defendants' decision to market their MoM products was negligent. Their products have an unreasonable propensity for premature failure.

23. The failure of a hip implant is a serious medical event. Revision surgery is a difficult procedure. When a patient is revised, there may be less bone and tissue to support a replacement implant. Revision surgery carries with it a substantial risk of serious complications and disability.

24. In recent years, a number of MoM hip implants from other manufacturers have been subject to recall, including the Zimmer Durom in 2008, the Depuy ASR in 2010, and the Stryker Rejuvenate in 2012. Such product failures ought to have alerted the Defendants of the need to take prompt corrective action with their own product which had similar problems.

The Plaintiff's Experience

25. The Plaintiff saw his surgeon on January 25, 2013, to complain of pain around the site of his hip implant. The Plaintiff was informed by his doctor at that visit about the recall of the R3 liner to his BHR implant which had occurred in June 2012.

26. The Plaintiff underwent various testing to determine whether his pain might be due to the failure of his implant. This included blood testing which found that the Plaintiff had substantially elevated levels of heavy metals in his blood stream. Such test results are indicative

of MoM implant failure.

27. The Plaintiff's pain continued and worsened. He finally underwent revision surgery on October 9, 2013.

28. The revision surgery confirmed that there had been damage to the tissue surrounding the Plaintiff's implant. In particular, the Plaintiff was diagnosed as having suffered "metal-on-metal adverse local soft tissue reaction (ALSTR) with associated subfascial extensive effusion/fluid collection".

29. The Plaintiff's replacement hip implant is a ceramic device. He is currently doing his best to recover from his revision surgery.

30. The full cost of the Plaintiff's BHR implant was not covered by provincial health insurance. The Plaintiff contributed approximately $4,000 of his own money towards the purchase of the device. In addition to damages for personal injury, the Plaintiff seeks a refund from the Defendants for the cost of this defective device.

Part 2: RELIEF SOUGHT

31. The Plaintiff claims, on his own behalf and on behalf of the class, as follows:

(a) an order certifying this action as a class proceeding and appointing him as representative plaintiff under the *Class Proceedings Act*;

(b) general damages and special damages;

(c) damages under the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2

(d) punitive damages;

(e) pre-judgment interest;

(f) recovery of health care costs incurred by the Ministry of Health Services on their behalf pursuant to the *Health Care Cost Recovery Act*, S.B.C. 2008, c.27, and comparable legislation in the other provinces and territories;

(g) costs; and

(h) such further and other relief as this Honourable Court may deem just.

Part 3: LEGAL BASIS

Negligence

32. The Defendants were negligent in the research, development, testing, manufacture, distribution and sale of their metal-on-metal hip implants (the "Product"). Particulars of their negligence include failure:

(a) to properly design, develop, test, manufacture, licence, assemble and distribute their Product;

(b) to ensure their Product was safe and free from defects prior to its distribution;

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

(d) not to use inappropriate materials to manufacture the Product;

(e) to properly train their employees who were responsible for the design, testing, assembly and manufacturing of the Product;

(f) to properly supervise their employees and consultants;

(g) to conduct adequate tests and clinical trials to determine the degree of risk associated with using the Product prior to their manufacture, assembly and distribution;

(h) to monitor, investigate, evaluate and follow up on adverse reactions to the use of the Product throughout the world;

(i) to warn the Plaintiff and the class that the Product carried a significant risk of premature component loosening, misalignment, dislocation and fracture, and a significant risk of metal debris in the hip socket or related complaints, including metallosis and aseptic lymphocyte dominated vasculitis-associated lesion (commonly known as "ALVAL");

(j) to ensure that physicians and surgeons were kept fully and completely informed of all risks associated with using the Product, including the excessive risk of premature failure, the excessive risk of contracting metallosis and ALVAL and the excessive risk that the implant would have to be replaced in significantly less than 15 years;

(k) to conduct ongoing clinical trials with long term follow up to determine the long term effects and risks of continued use of the Product;

(l) to properly and promptly inform Health Canada and other regulatory agencies of the changing and increasing risks associated with using the Product;

(m) to fix the defects in the Product as soon as possible after they became aware of the defects and the injuries and risks associated with their use; and,

(n) to provide clear and proper instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damage from the Product.

33. The Defendants owed to the Plaintiff and the class a duty of care:

(a) to properly label, market, distribute and sell the Product and to ensure it was safe and free from defects prior to labelling, marketing, distributing and selling them;

(b) to ensure that the Product was fit for its intended or reasonably foreseeable use prior to labelling, marketing, distributing and/or selling it;

(c) to properly supervise its employees and consultants;

(d) to monitor, investigate, evaluate and follow up on adverse reactions to the use of the Product throughout the world;

(e) to warn the Plaintiff and the class that the Product carried a significant risk of premature component loosening, misalignment, dislocation and fracture, and a significant risk of metal debris in the hip socket or related complaints, including metallosis and aseptic lymphocyte dominated vasculitis-associated lesion (commonly known as "ALVAL");

(f) to ensure that physicians and surgeons were kept fully and completely informed of all risks associated with using the Product, including the excessive risk of premature failure, the excessive risk of contracting metallosis and ALVAL and the excessive risk that the implant would have to be replaced in significantly less than 15 years;

(g) to properly and promptly inform Health Canada and other regulatory agencies of the changing and increasing risks associated with using the Product; and

(h) to provide clear and proper instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damage from the Product.

Breaches of Duty

(i) Defective Design

34. The Defendants breached their duty of care to the Plaintiff and the class as described above with respect to the design of the Product as follows:

(a) they improperly designed the Product, causing it to fail well before the natural life cycle of non metal-on-metal hip implants;

(b) they failed to conduct adequate tests and clinical trials initially and on an ongoing basis to determine whether the design of the Product was defective, thereby increasing the risks of injury and harm associated with the use of the Product;

(c) they were aware or ought to have been aware that the Product was unfit and defective and ought not to have been introduced into the market place;

(d) they failed to provide proper long term investigations of the effects and risks of continued use of the Product; and

(e) they failed to fix the defects in the Product or to withdraw the Product from the marketplace as soon as possible after they became aware of the defects and the injuries and risks associated with their use.

(ii) Defective Manufacturing

35. The Defendants breached their duty of care to the Plaintiff and the class as described above with respect to the manufacturing and assembly of the Product as follows:

(a) they failed to assemble and manufacture the Product so they would operate safely and effectively without exposing their consumers to undue risks;

(b) they used inappropriate materials to manufacture the Product;

(c) they failed to properly train their employees who were responsible for the assembly and manufacturing of the Product; and

(d) they failed to properly supervise their employees and consultants involved in the assembly and manufacture of the Product.

(iii) Failure to Warn

36. The Defendants breached their duty of care to the Plaintiff and the class as described above with respect to their duty to warn of the defects in the design and manufacture of the Product as follows:

(a) they failed to properly label, distribute, market and sell the Product and failed to ensure it was safe and free from defects prior to selling or distributing it;

(b) they failed to ensure that the Product was fit for its intended or reasonably foreseeable use prior to labelling, marketing, distributing and selling it;

(c) they failed to properly supervise their employees and consultants involved in labelling, marketing, distributing and selling it;

(d) they were aware or ought to have been aware that the Product was unfit and defective and ought not to have been introduced into the market place;

(e) they labelled, marketed, distributed and sold the Product without adequately disclosing the risks associated with using the Product;

(f) they failed to give Health Canada complete and accurate information concerning the Product by failing to disclose the problems with the Product on a timely basis or at all;

(g) they failed to adequately warn the Plaintiff, the class and their physicians and surgeons of the risks then known or which were reasonably foreseeable in using the Product;

(h) with full knowledge that the Product posed significant risk of premature failure, of contracting metallosis and ALVAL and that the implants would have to be replaced in significantly less than 15 years, they failed to warn the Plaintiff and the class and instead continued to sell, market and distribute the Product throughout Canada;

(i) they failed to warn the Class and their physicians and surgeons about the need for comprehensive regular medical monitoring to ensure early discovery of complications from the use of the Product set out above;

(j) they failed to adequately monitor, evaluate and act promptly upon adverse reactions and high revision rates in the Product in Canada and throughout the world;

(k) they failed to establish any adequate procedures to educate their sales representatives respecting the risks associated with the Product; and

(l) they failed to provide clear and proper instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damage from the Product.

37. The defects and risks associated with the Product were in the Defendants' exclusive knowledge and control. The extent of the defects and risks was not known and could not have been known to the Plaintiff or the class. The injuries of the Plaintiff and the Class would not have occurred but for the negligence of the Defendants in failing to ensure that the Product was safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with the Product to the Plaintiff, the class and to their physicians.

Regulatory Duties

38. The Plaintiff pleads and relies upon the following statutes and regulations which were breached by the Defendants:

(a) *Food and Drugs Act*, R.S.C. 1985, c. F-27, s.20(1); and

(b) the *Medical Devices Regulations*, SOR/98-282, s. 9, 10-13, 15-18, 59- 61.1 and 64-65.1

39. The Defendants' common law duties are informed by the *Medical Devices Regulations,* SOR/98-282. Pursuant to those regulations, each of the Defendants is a "manufacturer". They designed and assembled the Product, attached their trade name to it, labeled it and assigned it a purpose.

40. The regulations impose continuous obligations on the Defendants, commencing at licensing and continuing thereafter. They require the Defendants to ensure the safety of the Product before selling it, and to continuously monitor the safety of the Product thereafter, monitoring any complaints from doctors, hospitals and patients, keeping up with any new developments in the scientific literature, conducting further testing as necessary, and promptly

taking corrective actions, including issuing a warning or recall, if new information becomes available which later alters the Product's risk profile.

41. Pursuant to s.9 of the *Medical Devices Regulations*, the Defendants were required to maintain objective evidence to establish the safety of the Product. The Defendants breached this section. They failed to adequately obtain such information before licencing and they failed to promptly update such information thereafter.

42. Pursuant to s.10 of the *Medical Devices Regulations*, the Defendants were required to identify the risks of the Product, to eliminate or reduce those risks if possible, and to provide safety information with the Product concerning those risks which remained. The Defendants breached this section. They failed to eliminate the risk that the Product would prematurely fail and cause injury, and they failed to warn against this risk.

43. Pursuant to s.11 of the *Medical Devices Regulations*, the Defendants were required to assess the risks of the Defendants' Product against its benefits, and to not sell a product whose risks outweigh its benefits. The Defendants breached this section. The risk of the Product outweighed its benefits.

44. Pursuant to s.12 of the *Medical Devices Regulations*, the Defendants were required to ensure that the Product was effective for the uses for which it was represented. The Defendants breached this section. The Product was not effective.

***Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2**

45. The Defendants' solicitation, offers, advertisements, promotions, sales and supply of the Product for personal use by the Plaintiff and by class members were "consumer transactions" within the meaning of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2 ("Consumer Protection Act"). With respect to those transactions, the Plaintiff and class members who were implanted with the Product in British Columbia are "consumers" and the Defendants are "suppliers" within the meaning of the Consumer Protection Act.

46. The Defendants' conduct in their solicitation, offers, advertisements, promotions, sales and supply of the Product, as particularized above, had the capacity, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of the Product. The Defendants' conduct constituted deceptive acts and practices contrary to s.4 of the Consumer Protection Act. These deceptive acts and practices included the Defendants' failure to properly disclose all material facts regarding the safety and efficacy of the Product.

47. Further, in their marketing brochures, promotional materials, and website directed both to consumers and their physicians, the Defendants made representations concerning the safety and efficacy of the Product. Such representations were incorrect.

48. As a result of the Defendants' breach of the Consumer Protection Act, the Plaintiff and class members have suffered damages entitling them to compensation under the Consumer Protection Act.

Causation

49. The Plaintiff pleads that he and the other class members would not have had the Product implanted had the Defendants not acted negligently. There were safer, economically feasible alternative implants available in the marketplace. The propensity of the Product to injure those who were implanted outweighed any benefit.

Damages

50. The Plaintiff and the class have suffered and will continue to suffer damages as a direct result of the Defendants' negligence including, but not limited to, damages for personal injuries, mental anguish, pain and suffering, loss of employment income and benefits, loss of enjoyment of life, possibly death, and special damages and expenses.

51. Members of the class who do not require revision surgeries to remove the Product will nonetheless suffer damages from the cost of additional monitoring of the Product including but

not limited to frequent physician visits, blood tests, diagnostic imaging and will suffer psychiatric and psychological injuries as well.

52. As a result of the Defendants' conduct described above, the Plaintiff and other class members have suffered damages and losses, including, but not limited to:

(a) enduring or having to endure painful medical procedures to implant the Product;

(b) enduring or having to endure painful medical procedures to explant the Product;

(c) enduring painful medical procedures to implant new hip replacement systems that are free of defects;

(d) personal injury, including immobility, pain, inflammation, swelling, scarring, pseudo-tumours and other adverse effects and complications associated with the Product and the adverse effects of the diseases which necessitated the implant of the Product in the first place;

(e) severe emotional distress related to the pain and suffering associated with defective Product;

(f) the risk of death or other serious injuries;

(g) costs associated with replacing the Product;

(h) costs associated with monitoring the Product;

(i) out-of-pocket expenses incurred by the class members or for their benefit; and

(j) loss of income.

53. The Plaintiff and the other class members have suffered injuries which are permanent and lasting in nature, including diminished enjoyment of life as well as the need for lifelong medical treatment, monitoring and/or medications.

Punitive Damages

54. The Plaintiff claims punitive damages as a result of the egregious, outrageous and unlawful conduct of the Defendants and, in particular, their callous disregard for the health and lives of vulnerable patients in Canada. In particular, the Defendants' conduct in continuing to

manufacture and/or market, sell and distribute the Product after obtaining knowledge they were failing and not performing as represented and intended showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages in a sum which will serve to deter the Defendants from similar conduct in the future.

Health Care Cost Recovery Act

55. The Plaintiff and class members have a claim for the recovery of health care costs incurred by provincial health ministries on their behalf. The Plaintiff pleads the *Health Care Cost Recovery Act,* S.B.C. 2009, c.27, and comparable legislation in other provinces.

Jurisdiction

56. The Plaintiff relies upon ss.3, 7 and 10 of the *Court Jurisdiction and Proceedings Transfer Act.*

FORM 11
(Rule 4-5(2))
ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

The Plaintiff claims the right to serve this pleading on the Defendants outside British Columbia pursuant to s.10 of the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, c. 28, as amended, on the grounds that the proceeding concerns a tort committed in British Columbia and the proceeding concerns a business carried on in British Columbia.

Plaintiff's address for service: Klein Lyons
400 - 1385 West 8th Avenue
Vancouver, BC V6H 3V9

Fax number address for service (if any): (604) 874-7180

E-mail address for service (if any): dlennox@kleinlyons.com

Place of trial: Vancouver

The address of the registry is: 800 Smithe Street
Vancouver, BC V6Z 2E1

Date: December 16, 2013

Signature of
[ ] plaintiff [√] lawyer for plaintiff

Douglas Lennox
Klein Lyons, Barristers & Solicitors

James Newland
Stevensons LLP

Jonathan Ptak
Koskie Minsky

Rule 7-1 (1) of the Supreme Court Civil Rules states:

(1) Unless all parties of record consent or the court otherwise orders, each party of record to an action must, within 35 days after the end of the pleading period,

(a) prepare a list of documents in Form 22 that lists

(i) all documents that are or have been in the party's possession or control and that could, if available, be used by any party at trial to prove or disprove a material fact, and

(ii) all other documents to which the party intends to refer at trial, and

(b) serve the list on all parties of record.

APPENDIX

[*The following information is provided for data collection purposes only and is of no legal effect.*]

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This action concerns a dangerously defective product. It asserts claims in negligence and under the *Business Practices and Consumer Protection Act.*

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

[ ] a motor vehicle accident

[ ] medical malpractice

[√] another cause

A dispute concerning:

[ ] contaminated sites

[ ] construction defects

[ ] real property (real estate)

[ ] personal property

[ ] the provision of goods or services or other general commercial matters

[ ] investment losses

[ ] the lending of money

[ ] an employment relationship

[ ] a will or other issues concerning the probate of an estate

[ ] a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[√] a class action

[ ] maritime law

[ ] aboriginal law

[ ] constitutional law

[ ] conflict of laws

[ ] none of the above

[ ] do not know

Part 4:

1. *Class Proceedings Act*, R.S.B.C. 1996, c. 50.
2. *Business Practices and Consumer Protection Act,* S.B.C. 2004, c.2

3. *Court Jurisdiction and Proceedings Transfer Act,* SBC 2003, c.28
4. *Health Care Cost Recovery Act*, S.B.C. 2008, c.27
5. *Food and Drugs Act*, R.S.C. 1985, c. F-27