Court File No. VLC-S-S-116652
Court File No.
Vancouver Registry

In the Supreme Court of British Columbia

Between

Theodore Wilson

Plaintiff

and

Depuy International Ltd., Depuy Orthopaedics Inc.,
Depuy, Inc. and Johnson & Johnson Inc.

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.

Part 1: STATEMENT OF FACTS

The Parties

1. The Plaintiff, Theodore Wilson, is a resident of Vancouver, British Columbia.

2. The Plaintiff brings this action on his own behalf, and on behalf of a class of persons resident in British Columbia, and elsewhere in Canada, who were implanted with a DePuy ASR XL Acetabular Hip System and/or DePuy ASR Hip Resurfacing System (the "Product").

3. The Defendant, Depuy International Ltd, is a corporation with offices at St. Anthony's Road, Leeds, Great Britain, LS11 8DT. It is licensed by Health Canada as a manufacturer of medical devices.

4. The Defendant, Depuy Orthopaedics Inc., is a corporation with offices at 700 Orthopaedic Drive, Warsaw, Indiana, U.S.A., 46582. It is licensed by Health Canada as a manufacturer of medical devices.

5. The Defendant, Depuy, Inc. is a corporation with offices at 700 Orthopaedic Drive, Warsaw, Indiana, U.S.A., 46582.

6. The Defendant, Johnson & Johnson Inc., is a corporation registered extra-provincially in British Columbia with an address for service at Suite 2600, Three Bentall Centre, P.O. Box 49314, 595 Burrard Street, Vancouver, British Columbia.

7. The Defendants are all inter-related corporations, with each being the parent, subsidiary or affiliate of the others.

The Hip Implant

8. The Defendants individually and collectively participated in one or more of the following: the manufacture, development, distribution, marketing, promotion, importation and sale of the Product. This is a Class III medical device under the *Food and Drugs Act*, R.S.C. 1985, F-27. It may only be sold in Canada with the licence and approval of Health Canada.

9. The Defendants obtained the licence to sell the DePuy ASR XL Acetabular Hip System from Health Canada on or about November 30, 2005, and the licence to sell the DePuy ASR Hip Resurfacing System on or about January 5, 2006. These licences were cancelled on or about November 11, 2010.

10. In March 2010, the Defendants issued a "field safety notice" reporting that they had received data that demonstrated that the Product had a higher than expected failure rate as compared to other hip implants.

11. On or about August 24, 2010, the Defendants sent a letter to doctors, entitled "Urgent-Voluntary Product Recall". The letter indicated that the Product had a failure rate after five years of approximately 13%.

12. On or about August 25, 2010, Health Canada issued a Class II recall of the Product.

13. The Plaintiff alleges that the actual failure rate of the Product after five years is significantly higher than 13%, but even this failure rate is much too high, and is far out of line with other, similar products.

14. Hip implants are generally expected to last at least 15 years, and may sometimes last many years longer. Many patients can reasonably expect their implant to last for the rest of their life.

15. The premature failure of a hip implant is a serious medical event, and in a properly designed implant, it occurs only rarely. Such a failure results in substantial pain and disability for the patient, and may require surgery to remove the implant and replace it with a new one.

Patients may endure this pain and disability for many months, or longer, while they wait to be scheduled for revision surgery.

16. Revision surgery itself carries significant risks of complications. Patients receiving hip implants will want to minimize the total number of hip surgeries they have during their lifetimes as each surgery becomes progressively more risky, particularly as each surgery reduces the amount of bone remaining to support the implant. It is therefore important that hip implants be safe and long lasting so as to minimize risk and complications to the patient.

17. The Defendants' Product was defective in design. It had features which made it unlike other hip implants, and which made it more likely to fail.

18. In particular, the Defendants' Product employed an all metal design, and it had a distinctive shape. This shape made the Product less suited for fixture to the hip bone, and its metal components may grind against each other, creating metal debris. This debris may then escape the Product, causing injury to the surrounding tissue, and further undermining the fixation of the Product to the bone.

19. Other hip implants will use different materials and/or shape to avoid such flaws.

20. Hip implants have been on the market for decades, and the design flaws of the Product ought to have to been known by the Defendants through proper testing and research.

21. The Defendants, in their marketing and promotional materials provided to doctors and patients, portrayed the Product as safe and effective. They advertised the Product as superior, and longer lasting, when compared to other implants, and stated in patient brochures that it "reduces wear compared to traditional hip replacement." These marketing statements were untrue.

22. The Plaintiff was implanted with the Product during hip surgery on January 28, 2005. The Product failed. The Plaintiff required surgery to remove the Product and replace it with another hip implant. The revision surgery occurred on February 19, 2007. He has suffered personal injuries as a result of the Product's failure.

23. The Plaintiff did not reasonably have all of the necessary facts within his knowledge to pursue a claim against the Defendants, including that a breach of duty by the Defendants caused him injury, prior to the recall of the Product in August 2010.

Part 2: RELIEF SOUGHT

24. The Plaintiff claims, on his own behalf, and on behalf of class members:

(a) an order certifying this action as a class proceeding;
(b) general damages;
(c) special damages;
(d) punitive damages;
(e) declaratory and injunctive relief as well as damages and statutory compensation available under the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2;
(f) recovery of health care costs pursuant to the *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27, and comparable legislation in other provinces and territories
(g) pre-judgment interest;
(h) costs; and
(i) such further and other relief as this Honourable Court may deem just.

Part 3: LEGAL BASIS

Defendants' Negligence

25. As the manufacturers, marketers, developers, distributors, and/or importers of the Product, the Defendants were in such a close and proximate relationship to the Plaintiff, and other class members, as to owe them a duty of care. They caused the Product to be introduced

into the stream of commerce in Canada, and they knew that any defect in the Product would cause foreseeable injury to the Plaintiff and class members.

26. The Defendants were negligent in the research, development, testing, manufacture, distribution and sale of the Product. The Defendants owed a duty to use all reasonable care and skill to ensure that the Product was safe and effective before marketing it, and to continually monitor its safety thereafter. The Defendants further owed a duty to warn the Plaintiff, class members, their health care providers, and the regulator of any safety problems with the Product.

27. Particulars of the Defendants' negligence are:

(a) manufacturing and/or marketing a device which they knew, or ought to have known, had an unreasonably high risk of failure;
(b) failing to adequately test the safety and efficacy of the Product before bringing it to market;
(c) failing to do follow-up studies on the safety and efficacy of the Product after bringing it market;
(d) failing to monitor and follow up on reports of adverse reactions to the Product;
(e) failing to recall the Product sooner;
(f) failing to warn consumers, their health care providers, and Health Canada, sooner of the increased risks of failure presented by the Product;
(g) marketing a product which was unsafe, not fit for its intended purpose, and not of merchantable quantity;
(h) designing, manufacturing and/or marketing a product which was not reasonably safe and effective in comparison with already available, alternative designs; and
(i) incorrectly blaming failures of the Product on surgical error instead of properly and promptly investigating the Product's unreasonably high rate of failure as due to design defects.

28. The Defendants' common law duties are informed by the *Medical Devices Regulations*, SOR/92/82. Pursuant to s.1 of 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.

29. 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 action, including issuing a warning or recall, if new information becomes available which alters the Product's risk profile.

30. Pursuant to s. 9(2) of the *Medical Devices Regulations*, the Defendants were required to maintain objective evidence to establish the safety of the device. The Defendants breached this section. They failed to adequately obtain such information before licensing and they failed to promptly update such information thereafter.

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

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

33. 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

34. The Defendants' solicitations, 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 are "consumers" and the Defendants are "suppliers" within the meaning of the Consumer Protection Act.

35. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of the Product, had the capability, tendency or effect of deceiving or misleading consumers regarding the safety, efficacy and durability of the Product. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of the Product were deceptive acts and practices contrary to s. 4 of the Consumer Protection Act. The Defendants' deceptive acts and practices included the Defendants' failure to properly disclose all material facts regarding the safety and efficacy of the Product.

36. Further, in their marketing brochures, promotional materials, and website directed both to consumers and their physicians, the Defendants made representations concerning the safety, efficacy and durability of the Product. In reality, the Product's failure rate is unreasonably high compared to other, available implants. The Defendants knew or ought to have known that their marketing claims regarding the Product were inaccurate, incomplete or misleading, and that the Product had an unreasonably high failure rate. Such marketing claims were deceptive and had the tendency, capability or effect of misleading consumers and their physicians.

37. As a result of the Defendants' deceptive acts and practices, the Plaintiff and class members have suffered loss and damages. The Plaintiff seeks injunctive relief and declaratory relief and damages and statutory compensation pursuant to ss.171 and 172 of the Consumer Protection Act on his own behalf and on behalf of class members implanted with the Product in British Columbia.

Plaintiffs' Injuries

38. The Plaintiff underwent hip surgery on January 28, 2005. He was implanted with the Product.

39. His implant failed. He required two surgeries, first on February 19, 2007 and then on May 14, 2007, to remove the Product, to treat the consequences of its failure, and to install a new implant.

40. The Plaintiff experienced pain and suffering as a result of the failure of the Product, and the additional surgeries.

41. That the Plaintiff's injuries were due to the Product being defective were only reasonably discoverable by him, and by other Class Members, on or after the recall in August 2010.

Causation and Damages

42. As a result of the Defendants' negligence and the Defendants' deceptive acts and practices, the Plaintiff and class members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendants. Particulars of the loss and damage suffered by the Plaintiff and class members which were caused or materially contributed to by the aforementioned acts of the Defendants include:

(a) pain, suffering, loss of quality and enjoyment of life;
(b) damages for past and future loss of income; and
(c) special damages and expenses including medical expenses.

43. The Defendants' conduct was reprehensible and departed to a marked degree from ordinary standards of decent behaviour. The Defendants' reckless disregard for public safety is deserving of punishment and condemnation by means of an award of punitive damages. This case raises issues of general deterrence. A punitive damage award in this case is necessary to express

society's condemnation of conduct such as the Defendants', to advance public safety and to achieve the goal of both specific and general deterrence.

Health Care Cost Recovery Act

44. 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. 2008, c.27 ("HCCRA"), and comparable legislation in other provinces.

Jurisdiction

45. The Plaintiff relies upon ss. 3, 7 and 10 of the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, c.28. The Plaintiff pleads that there is a real and substantial connection between the subject matter of this action and the Province of British Columbia by reason that the Defendants marketed and sold the Product in British Columbia and this action concerns a tort committed in British Columbia.

Joint Enterprise

46. The Defendants functioned as a joint enterprise for the promotion and sale of their brands of the Product within Canada. The Defendants divided among themselves certain responsibilities for the manufacture and marketing of the Product, but each had an independent right and responsibility to ensure the safety of the Product. Within this joint enterprise, the Defendants individually and jointly researched, tested, developed, marketed, manufactured, imported, promoted, licensed, labeled, monitored adverse reactions to, and placed into the stream of commerce the Product for sale in Canada.

Plaintiff's address for service:
Suite 1100, 1333 West Broadway
Vancouver, BC V6H 4C1 Canada

Fax number address for service: 604-874-7180

Place of trial: Vancouver

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

Date: October 4, 2011:

.....
Signature of
[ ] plaintiff [x] lawyer for plaintiff

Mr. David A. Klein

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

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

1. This action is a proposed class proceeding concerning an allegedly defective hip implant which was recalled from the market on August 25, 2010. The implant has an unreasonably high failure rate when compared with other, similar devices, and has designs not found in other products. The Plaintiff and other class members suffered personal injuries when their implants failed. The Defendants are the manufacturers, marketers and distributors of the implant. They breached duties to the Plaintiff and class members in failing to adequately test the product, in failing to adequately monitor and investigate failures of the product, and in failing to issue a

more timely recall or warnings about the product. The Defendants also breached statutory obligations under the *Business Practices and Consumer Protection Act*.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

[*Check one box below for the case type that best describes this case.*]

A personal injury arising out of:

[ ] a motor vehicle accident
[ ] medical malpractice
[x] 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
[x] a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[check all boxes below that apply to this case]

[x] a class action
[ ] maritime law
[ ] aboriginal law
[ ] constitutional law
[ ] conflict of laws
[ ] none of the above
[ ] do not know

Part 4:

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

Class Proceedings Act R.S.B.C. 1996, c. 50

Court Order Interest Act, R.S.B.C. 1996, c. 79

Court Jurisdiction and Proceedings Transfer Act, S.B.C. 2003, c. 28

Health Care Cost Recovery Act, S.B.C. 2008, c. 27