S-095493

Court File No.
Vancouver Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

Between:

DENNIS JONES and SUSAN WILKINSON

Plaintiffs

and:

ZIMMER GMBH, ZIMMER, INC., and ZIMMER OF CANADA LIMITED

Defendants

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

STATEMENT OF CLAIM

The Parties

1. The Plaintiff, Dennis Jones, is a resident of Langley, British Columbia.

2. The Plaintiff, Susan Wilkinson, is a resident of Osoyoos, British Columbia.

3. The Plaintiffs bring this action on their own behalf, and on behalf of a class of persons resident in British Columbia, and elsewhere in Canada, who were implanted with a Durom Hip Resurfacing System.

4. The Defendant, Zimmer, Inc. ("Zimmer US"), is incorporated in the State of Delaware with its principal place of business in Warsaw, Indiana. It is licensed by Health Canada as a manufacturer of medical devices.

5. The Defendant, Zimmer GMBH ("Zimmer Europe"), is a Swiss corporation with its principal place of business in Winterthur, Switzerland. It is licensed by Health Canada as a manufacturer of medical devices.

6. The Defendant, Zimmer of Canada Limited ("Zimmer Canada"), is incorporated in Ontario with its head office in Toronto, Ontario. Zimmer Canada is registered as an extra-provincial company in British Columbia with its address for delivery at 1500 – 1040 West Georgia Street, Vancouver, British Columbia V6E 4H8. It is a wholly owned subsidiary of Zimmer US. It imports and distributes into Canada medical devices manufactured by related Zimmer corporations.

The Durom Cup Hip Implant

7. The Defendants individually and collectively participated in one or more of the following: the development, manufacture, distribution, marketing, promotion and importation of the "Durom Hip Resurfacing System", (hereinafter referred to as the "Product"). The Product 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. The Defendants obtained the license to sell the Product in Canada in or about April 2005.

8. The Plaintiffs were implanted with the Product during hip surgery. The Product was defective. The Plaintiffs require surgery to remove the Product and replace it with another hip implant. The Plaintiffs have suffered personal injuries as a result.

9. The source of the Product's defect is one of its components, the Durom Acetabular Component or Durom Cup. This is a non-cemented cup with a coating of titanium plasma spray. It is designed to act as an artificial joint socket and to allow the patient's bone to grow into or around it, thus keeping the cup or artificial socket in place.

10. The cup was defective in that it fails to properly heal or adhere to the surrounding bone. Instead, it remains loose, or separates from the bone, causing the patient excruciating pain. It must be removed, requiring the patient to undergo further hip surgery.

11. Problems with the Durom Cup became publicly known in or about April 2008, when Lawrence Dorr, MD., a world-renowned orthopedic surgeon and Director of the Dorr Institute for Arthritis Research and Education, wrote a letter dated April 22, 2008 to his colleagues at the American Association of Hip and Knee Surgeons, warning of failures and defects associated with the Defendants' Durom Cup. Dr. Dorr wrote:

> "This failure rate has occurred within the first two years. In the first year the x-rays looked perfect. We have revised four that did not have any radiolucent lines or migration (and John Moreland revised one). These early cups fooled us, but the symptoms were so classic for a loose implant that we operated the patients. When we hit the edge of the cup it would just pop free. As time goes by the cups begin developing radiolucent lines. We now have one cup at two years that has actually migrated a short distance. It has tilted into varus. We do not believe the fixation surface is good on these cups. Also there is a circular cutting surface on the periphery of the cup that we believe prevents the cup from fully seating. We stopped using the cup after the first revisions."

12. Prior to writing that letter, Dr. Dorr had communicated his concerns about the product to the Defendants in early 2008. The Defendants failed to initiate a timely investigation into these concerns. Instead, the Defendants took the position that surgical error was the cause of any problems with the Product, even though the concerns relayed to the Defendants were coming from a highly experienced and respected surgeon.

13. Subsequent to the publication of Dr. Dorr's letter, the Defendants received many more complaints from orthopedic surgeons about the Product's failures. Finally, in late May 2008, the Defendants began an investigation into these complaints.

14. On July 22, 2008, the Defendants recalled the Product in the United States. To date, the Defendants have not initiated a similar recall in Canada.

15. According to the Defendants own investigation, as of July 2008, some clinics using the Product experienced a failure of at least 5.7%.

16. Notwithstanding the absence of a recall in Canada, a similarly high rate of failure has been seen in this country with the Durom Cups.

Defendants' Negligence

17. As the manufacturers, marketers, developers, distributors, and/or importers of the Product, the Defendants were in such a close and proximate relationship to the Plaintiffs, 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 Plaintiffs and class members.

18. The Defendants were negligent in the research, development, testing, manufacture, distribution and sale of the Product. Effective adhesion of the Durom Cup to the patient's bone was critical to the safety and medical efficacy of the Product. The Defendants owed a duty to use all reasonable care and skill to ensure that the Product was effective at adhering to bone before marketing it, and to continually monitor its safety thereafter. The Defendants further owed a duty to warn the Plaintiffs, class members, their health care providers, and the regulator of any safety problems with the Product.

19. 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 loosening and of implant failure in patients;
(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;
(f) failing to warn consumers, their health care providers, and Health Canada, of the increased risks of loosening and implant 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.

20. 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.

21. 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.

22. 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.

23. 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 remained. 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.

24. 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.

25. 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

26. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of the Product for personal use by the Plaintiffs and by class members were "consumer transactions" within the meaning of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 ("BPCPA"). 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 BPCPA.

27. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of the Product, as particularized above, had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy 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 BPCPA. The Defendants' deceptive acts and practices included the Defendants' failure to properly disclose all material facts regarding the safety and efficacy of the Product.

28. Further, in their marketing brochures, promotional materials, and website directed both to consumers and their physicians, the Defendants made representations concerning the

efficacy of the Product, including a description of studies that suggested that the Product had a success rate of up to 99%. 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.

29. As a result of the Defendants' deceptive acts and practices, the Plaintiffs and class members have suffered loss and damages. The Plaintiffs seek injunctive relief and declaratory relief and damages and statutory compensation pursuant to ss.171 and 172 of the BPCPA on their own behalf and on behalf of class members implanted with the Product in British Columbia.

Plaintiffs' Injuries

30. The Plaintiff, Mr. Jones, underwent hip surgery on January 14, 2008. He was implanted with the Product.

31. His implant failed. He required further surgery on May 11, 2009, in which the Product was removed and a new implant was inserted.

32. Mr. Jones has experienced pain and suffering as a result of the failure of the Product, and the additional surgery. He has incurred, and will continue to incur, loss of employment income and out of pocket expenses.

33. The Plaintiff, Ms. Wilkinson, underwent hip surgery on April 28, 2008. She was implanted with the Product.

34. Her implant failed. She has been advised that she requires further surgery and that the implant must be replaced. She is currently on the waiting list for surgery to remove the Product.

35. Ms. Wilkinson has experienced pain and suffering as a result of the failure of the Product. She will incur further pain when she undergoes replacement surgery. She has incurred, and will continue to incur, loss of employment income and out of pocket expenses.

Causation and Damages

36. As a result of the Defendants' negligence and the Defendants' deceptive acts and practices, the Plaintiffs and class members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendant. Particulars of the loss and damage suffered by the Plaintiffs 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.

37. 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. The Defendants' failure to initiate a recall in Canada, even while calling one in the United States, is particularly worrisome. 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

38. The Plaintiffs and class members have a claim for the recovery of health care costs incurred by provincial health ministries on their behalf. The Plaintiffs plead the *Health Care Cost Recovery Act*, S.B.C. 2008, c.27, and comparable legislation in other provinces.

Jurisdiction

39. The Plaintiffs rely upon ss. 3, 7 and 10 of the *Court Jurisdiction and Proceedings Transfer Act.*

Joint Enterprise

40. The Defendants functioned as a joint enterprise for the promotion and sale of their brands of the Product within Canada. The Defendants dividing 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 and to ensure that timely and adequate warnings were issued with respect to 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.

Relief Sought

41. The Plaintiffs claim, on their 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 BPCPA;

(f) pre-judgment interest;

(g) costs; and

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

Dated: July 24, 2009

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