Court File No. CV-10-408365000

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

GLORIA McSHERRY

Plaintiff

-and-

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

Defendants

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM

TO THE DEFENDANTS:

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 WILL 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.

Date of Issue: August 10 2010

Issued by: S. DiSanza
Local Registrar

Address of court office:
393 University Avenue, 10th Flr. - SV
Toronto, Ontario
M5G 1E6

TO: Zimmer of Canada Limited
2323 Argentia Road
Mississauga, ON
L5N 5N3

AND TO: Zimmer GMBH
Sulzer Allee 8
Winterthur, SZ, CH, 8404

AND TO : Zimmer, Inc.
P.O. Box 708
1800 West Center Street
Warsaw, IN
46591-0708

CLAIM

1. The Plaintiff claims:

   (a) an order certifying this action as a class proceeding;

   (b) general damages;

   (c) special damages;

   (d) punitive damages;

   (e) pre-judgment and post-judgment interest;

   (f) costs, including the costs of notice and of administering the plan of distribution of the recovery in this action, plus applicable taxes; and

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

The Parties

2. The Plaintiff, Gloria McSherry, is a resident of Toronto, Ontario.

3. The Plaintiff brings this action on her own behalf, and on behalf of a class of persons resident in Ontario who were implanted with the Durom acetabular hip implant.

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 a place of business at 2323 Argentia Road, Mississauga, Ontario. Zimmer Canada 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 manufacture, development, distribution, marketing, promotion and importation of a hip implant under the brand name "Durom Hip Resurfacing System", (hereinafter referred to as 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. The Defendants obtained the license to sell the Product in Canada in April 2005.

8. The Plaintiff was implanted with the Product during hip surgery. The Product was defective. The Plaintiff required surgery to remove the Product and replace it with another hip implant. The Plaintiff has suffered personal injuries as a result.

9. The source of the Product's defect is one of its components, the Durom acetabular hip implant or Durom Cup. This was 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 first 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 very 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.

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

16. A similarly high failure rate with the Product also occurred in Canada and in Europe.

17. The Defendants initially (and negligently) took the position that the Durom Cup sold in the United States was materially different from that sold in Canada and in Europe, and they did not promptly investigate problems with the Product outside of the United States, nor did they promptly initiate a recall of the Product in Canada or Europe.

18. Subsequently and belatedly, the Defendants did initiate a recall of the Product in Canada and Europe. An urgent field safety notice was sent by the Defendants to the

United Kingdom Medicines and Healthcare Product Regulatory Agency by the Defendants on October 13, 2009. The Defendants filed a recall notice with Health Canada, under Recall Number 51631, with a start date of December 7, 2009.

19. The Canadian recall of the Product came nearly 16 months after the U.S. recall.

Defendants' Negligence

20. 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.

21. 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.

22. 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 promptly recall the Product, and indeed, failing to recall the Product in Canada until 16 months after the Product had been recalled in the United States;

(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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

Plaintiffs' Injuries

29. The Plaintiff underwent hip surgery in August 1, 2007. She was implanted with the Product.

30. Her implant failed. She underwent revision surgery on June 29, 2010 to remove the defective Durom Cup.

31. The Plaintiff endured nearly three years of chronic pain as a result of the defective cup. Her implant never properly healed or adhered to the bone.

32. The Defendants' delay in admitting to a problem with the Product in Canada, and in initiating a recall in this country, exacerbated the Plaintiff's pain and suffering, and caused her delay in seeking appropriate medical treatment, and in having the defective cup finally removed.

Causation and Damages

33. As a result of the Defendants' negligence, 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 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.

34. 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 promptly initiate a recall in Canada, even after 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.

Joint Enterprise

35. 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. 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.

Service Outside of Ontario

36. The originating process may be served without court order outside Ontario because the claim is:

(a) in respect of a tort committed in Ontario (Rule 17.02(g));

(b) in respect of damages sustained in Ontario arising from a tort (Rule 17.02(h);

(c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (Rule 17.02(o)); and

(d) against a person carrying on business in Ontario (Rule 17.02(p)).

Place of Trial

37. The Plaintiff proposes that this action be tried at the City of Toronto in the Province of Ontario.

August 10, 2010

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Solicitors for the Plaintiff

Gloria McSherry
Plaintiffs

- and -

Zimmer GMBH et al
Defendants

Court File No.
CV-10-408365 00CP

ONTARIO
SUPRIOR COURT OF JUSTICE

PROCEEDINGS COMMENCED AT
TORONTO

STATEMENT OF CLAIM

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