S-160879

Court File No.
Vancouver Registry

In the Supreme Court of British Columbia

Between

Amanda Olthuis and Joep Olthuis

Plaintiff

and

Ferring Inc.

Defendant

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.

THE PLAINTIFFS' CLAIM

Part 1: STATEMENT OF FACTS

Overview

1. This lawsuit concerns the fertility drug, Bravelle, which was manufactured by the Defendant. On October 23, 2015, the Defendant recalled four lots of this drug sold in Canada. The recall was issued due to a lack of the drug's potency. The Defendant had negligently shipped a bad batch of their drug from their factory to the public.

2. Bravelle is intended to work by stimulating the follicles of the ovaries to produce multiple oocytes that may be capable of fertilization. Bravelle is prescribed by fertility specialists to women as part of a course of fertility treatments, including for In-Vitro Fertilization ("IVF"). These fertility treatments can be very expensive for couples. They also expose the patient to health risks, and are invasive. Such financial costs, health risks and personal intrusions may be acceptable to couples if the prospect is that they may have child as a result. No one however would consume such a drug if they knew it was a dud.

3. Fertility treatments are time sensitive. A woman's fertility declines rapidly after her early 30s. Time is precious, and the opportunities to become pregnant are finite.

4. In shipping ineffective doses of their product to the public, the Defendant cost women and their spouses dearly, both financially and emotionally. The Defendant caused these consumers to pay for expensive fertility treatments that were doomed to fail, and they exposed women to unjustified health risks. Beyond this, the Defendant wasted the time of women whose biological clocks were ticking down to zero. Indeed, the Defendant may have squandered these women's last opportunity to get pregnant, causing serious mental and emotional harm to couples who now may be unable to start families of their own.

5. The Plaintiffs brings this action on their own behalf, and on behalf of a proposed class.

The Parties

6. The Plaintiffs are residents of Port Moody, British Columbia.

7. The proposed class is as follows:

> All women in Canada who were prescribed Bravelle bearing lot numbers H15940B, H15940C, K16990B or K169990C, and their spouses.

8. The Defendant, Ferring Inc., is incorporated under the *Canada Business Corporations Act* with its registered head office at 200 Yorkland Blvd., Suite 800, North York, Ontario, M2J 1S1. The Defendant is registered in British Columbia as an extra-provincial corporation with a registered address for service at 3200 – 650 Georgia Street, Vancouver, British Columbia, V6B 4P7.

9. The Defendant holds a licence with Health Canada as the manufacturer of Bravelle.

The Product

10. Bravelle is the brand name of the Defendant's product. This drug is a follicle stimulating hormone, known as urofollitropin, which is given by subcutaneous or intramuscular injection to women to induce the ovaries to produce multiple oocytes that may be capable of fertilization.

11. Bravelle is typically given as part of a cycle of treatments women undergo to enhance fertility, including IVF procedures. These treatments may last several months or longer, and may involve the administration of various drugs to the patient with multiple trips to the fertility clinic. Such treatments can be invasive for the patient.

12. If the Bravelle given to the patient lacks efficacy, then all of these various fertility treatments will be for nought. Pregnancy will not be achieved.

13. In Canada, a single round of fertility treatments can cost a woman, or couple, $20,000 or more. Frequently, these expenses are not covered by provincial health insurance. If the Defendant's drug is ineffective, then these expenses are wasted.

14. Furthermore, administrations of Bravelle, and other drugs necessary for IVF treatment, carry with them health risks. With respect to Bravelle, this includes the risk of ovarian hyperstimulation syndrome and pulmonary and vascular complications. Patients would not voluntarily accept such health risks unless there is an offsetting benefit. Women who received Bravelle from the recalled lots were exposed to health risks with no offsetting benefit.

The Plaintiffs

15. Joep Olthuis and Amanda Olthuis were married in August 2011.

16. Amanda was born March 10, 1978, and is currently 37 years old. Amanda has endometriosis and, as a result, IVF treatment is necessary for her to become pregnant.

17. Amanda and Joep have long wanted to start a family. They carefully saved and pooled their funds so that they could afford IVF treatment.

18. Finally, in April 2014 they were able to afford a round of IVF treatment. They both travelled to Vancouver to the Genesis Fertility Centre and they both underwent testing and counseling.

19. Amanda was then prescribed a series of treatments over the next several months in the hopes of becoming pregnant. These treatments included injection with Bravelle.

20. The total cost to Amanda and Joep of these treatments, tests and counseling was in excess of $14,000.

21. Amanda did not become pregnant after this initial round of IVF treatment. She and her husband could not afford further rounds of treatment. Their hopes of having a family were dashed.

22. On December 23, 2015, the Genesis Fertility Centre notified Amanda and Joep that the lots of Bravelle she received had been recalled two months earlier.

23. Amanda's IVF treatments failed because the Bravelle she received lacked efficacy.

The Differences Between the Recall in Canada and the United States

24. Bravelle was sold in both Canada and the United States, and has been recalled in both countries on the same date for the same reason: it lacked potency.

25. Unlike in Canada however, the Defendant's American affiliate, Ferring Pharmaceuticals Inc., wrote promptly and directly to American consumers, notifying them of the recall, and offering to compensate them for out-of-pocket expenses.

26. The Defendant's efforts to notify Canadian consumers of the recall, and to offer them compensation have been inadequate and untimely, and have fallen short of similar efforts by the Defendant's affiliate in the United States.

Part 2: RELIEF SOUGHT

27. The Plaintiffs claim, on their own behalf and on behalf of the class:

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

(b) general damages and special damages;

(c) punitive damages;

(d) pre-judgment interest;

(e) 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;

(f) costs; and

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

Part 3: LEGAL BASIS

Negligence

28. The Defendant was negligent in the manufacture, distribution and sale of Bravelle (the "Product"). Particulars of its negligence include the failure:

(a) to ensure proper quality control and efficaciousness of its Product before shipping it to the public;

(b) to ensure that the Product was reasonably fit for its intended purpose; and

(c) to more promptly detect a lack of effectiveness in their Product, and to issue a recall sooner than it did.

29. The Defendant owed to the Plaintiffs and the class a duty of care:

(a) to properly manufacturer the Product to ensure that all lots of the drug leaving its factory met reasonable standards of effectiveness and potency;

(b) to continually monitor the safety and effectiveness of the Product once sold into the marketplace, and to promptly take corrective action where the Product was ineffective, including warning patients, their doctors and regulators, and issuing a recall.

30. The Defendant breached its duty of care to the Plaintiffs and the class as described above with respect to their duties in the manufacture, distribution and sale of the Product as follows:

(a) It shipped units of the Product from its factory to the public which failed to meet the Defendant's own internal standards for quality, efficacy and potency;

(b) It failed to meet standards for quality, efficacy and potency in the manufacture and sale of the Product which are generally acceptable and recognized within the pharmaceutical industry;

(c) It failed to meet standards for quality, efficacy and potency in the manufacture and sale of the Product which are imposed by Health Canada regulation, including by Part C, Division 2 of the *Food and Drug Regulations*;

(d) It failed to meet standards for quality, efficacy and potency in the manufacture and sale of the Product as promised in the Product's own labelling;

(e) It failed to ensure adequate quality control in its manufacturing of the Product;

(f) It failed to promptly detect deficiencies in its quality control;

(g) It sold a Product which was not efficacious and which was not reasonably fit for its intended use;

(h) It failed to properly monitor the effectiveness of its Product once in the marketplace;

(i) It failed to take prompt corrective action, including issuing warnings to patients, doctors and regulators, and issuing a recall; and

(j) Such corrective action as the Defendant has taken since the recall of October 23, 2015, has been inadequate, and the Defendant has failed to take reasonable steps to ensure that patients receive actual, proper and timely notice of the recall.

Regulatory Duties

31. The Plaintiffs plead and rely upon the following statutes and regulations which were breached by the Defendant:

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

(b) the *Food and Drug Regulations*, C.R.C., c. 870

32. The Defendant's common law duties are informed by the *Food and Drug Act* and regulations thereto, and in particular, Part C, Division 2 of the *Food and Drug Act Regulations* regarding "Good Manufacturing Practices" which set out regulatory standards for quality control and finished product testing. The Plaintiffs plead that the Defendant breached its regulatory duties, and it did not adhere to the good manufacturing practices required of it by Health Canada.

Express and Implied Warranties

33. The product monograph and labelling for Bravelle specifically promises that the product contains 75 international units of follicle stimulating hormone per vial. The Product failed to meet this standard.

34. The Plaintiffs and class members were buyers of the Product at common law, and under the *Sales of Good Act*.

35. The Defendant was the seller of the Product at common law, and under the *Sale of Goods Act*.

36. The Product is a good at common law and under the *Sale of Goods Act*.

37. In acquiring the Product, the Plaintiffs and class members provided monetary consideration which was received by the Defendant.

38. The Defendant owed the Plaintiff and class members express and implied warranties at common law and under the *Sales of Goods Act* as to the quality and fitness of Product, including that the Product actually contained active doses of follicle stimulating hormone, as promised.

39. The Defendant breached these warranties. The Product lacked the necessary potency as had been promised.

40. The Defendant knew and understood that the sale of fertility drugs to the public is a matter of particular sensitivity. Consumers rely upon the Defendant to provide drugs of the highest quality. When promises of quality given by the Defendant are not met, the financial and emotional damages suffered by the Plaintiff and class members are foreseeable to the Defendant.

Business Practices and Consumer Protection Act

41. The Plaintiffs and class members who purchased the Product in British Columbia are "consumers" within the meaning of the *Business Practices and Consumer Protection Act*, SBC 2004, c. 2, ("BPCPA")

42. The Defendant is a "supplier" within the meaning of the BPCPA.

43. The Product is a "good" within the meaning of the BPCPA.

44. The supply of the Product by Defendant to the Plaintiffs and other class members who purchased the Product in British Columbia was a "consumer transaction" within the meaning of the BPCPA. The Product was acquired by these consumers for a personal or family purpose.

45. The labeling of the Product by the Defendant was a "representation" within the meaning of the BPCPA, and was used by the Defendant in connection with the supply of the Product.

46. The Defendant breached its statutory obligations under s.4 of the BPCPA in its supply of the Product. In particular, the Product did not meet the particular standard, quality or grade as described in the Defendant's labeling.

47. The Plaintiffs and class members who purchased the Product within British Columbia are entitled to damages under s. 171 of the BPCPA as a result of the Defendant' breaches of its statutory obligations under s. 4 of the BPCPA.

Causation

48. The Plaintiffs plead that they and other class members would not have purchased the Product if they knew it was ineffective.

49. The Defendant's negligence in selling an ineffective drug to the Plaintiffs and class members caused them loss and damage.

Damages

50. The Plaintiffs and the class have suffered and will continue to suffer damages as a direct result of the Defendant's negligence including, but not limited to:

(a) Wasted medical expenses, including the costs of failed fertility treatments and counselling;

(b) Other out-of-pocket expenses, including travel expenses;

(c) Personal injuries, including damages for pain and suffering, and for diminishment of quality of life, and for depression;

(d) Loss of income;

(e) The loss of opportunity to have biological children;

(f) In-trust and derivative claims for spouses, whether at common law or applicable provincial legislation;

(g) Interest; and

(h) Costs and disbursements.

51. The Plaintiffs claim punitive damages as a result of the egregious, outrageous and unlawful conduct of the Defendant. The Defendant understood the very personal and time sensitive nature of fertility treatments. Their failures in ensuring the adequate quality of their product, and then in failing to recall the product in timely way, and then in ensuring that proper notice of the recall was actually communicated to Canadians are all serious breaches of their obligations of the public for which an award of punitive damages is warranted.

Health Care Cost Recovery Act

52. 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. 2009, c.27, and comparable legislation in other provinces.

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

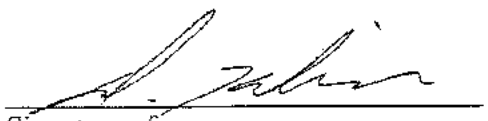
Fax number address for service (if any): (604) 874-7180

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

Place of trial: Vancouver

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

Date: January 22, 2016



Signature of
[ ] plaintiff [√] lawyer for plaintiff

Douglas Lennox
Klein Lawyers, Barristers & Solicitors

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. *Health Care Cost Recovery Act*, S.B.C. 2008, c.27
3. *Food and Drugs Act*, R.S.C. 1985, c. F-27