

Amended pursuant to Rule 6-1(1)(a)(i) of the *Supreme Court Civil Rules*.
Original Notice of Civil Claim filed the 9th day of March, 2015.

SUPREME COURT
OF BRITISH COLUMBIA
VANCOUVER REGISTRY

NO. VLC-S-S-151970
VANCOUVER REGISTRY

JUN 07 2016

IN THE SUPREME COURT OF BRITISH COLUMBIA



BETWEEN:

RAYMOND EDSON MARSHALL

PLAINTIFF

AND:

ALLERGAN INC. and DR. WAI MAN LEUNG

DEFENDANTS

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

AMENDED 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 PRONOUNCED 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 Plaintiffs,

- (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

Overview and Parties

1. This action concerns the medical device Lap-Band, which is a laparoscopic adjustable gastric band implant marketed as a means to assist with weight loss in adults. The Lap-Band has a high failure, injury, and complication rate. These complications often result in the need for one or more corrective surgeries and often lead to permanent damage. The unacceptably high risks of the Lap-Band outweigh the benefits purportedly conferred by the device.
2. The Plaintiff, Raymond Edson Marshall, is a mortgage associate and has an address for service of 2020 – 650 West Georgia Street in Vancouver, British Columbia. In 2005, the Plaintiff was implanted with a Lap-Band. The Plaintiff's Lap-Band failed, causing the Plaintiff to experience severe pain and discomfort ultimately resulting in further surgery and removal of the Lap-Band. The Lap-Band has left the Plaintiff with permanent injuries.
3. The Plaintiff brings this claim on behalf of himself and on behalf of a proposed class of similarly situated persons who were implanted with a Lap-Band in British Columbia, and elsewhere in Canada. The proposed class will be further defined in the Plaintiff's application for certification.
- ~~3. The Defendant, Dr. Wai Man Leung, is a physician whose address is unknown to the Plaintiff (hereinafter referred to as "Dr. Leung").~~
4. The Defendant, Allergan Inc. is a federally incorporated pharmaceutical company with an address for delivery of #2300 – 550 Burrard St., Box 30, Vancouver BC

(hereinafter referred to as "Allergan"). The Lap-Band was developed, marketed, manufactured, imported, promoted, licensed, labeled, and/or placed in the stream of commerce by the Defendant.

Facts

4. ~~Allergan designs, manufactures, markets, and sells "Lap-bands." Lap-bands are medical devices that are surgically implanted around the stomach of patients. They are intended to constrict the stomach, thereby assisting in weight loss.~~
5. ~~Allergan marketed Lap-bands in a manner intended to lead consumers to believe that they were a safe approach to weight loss.~~
6. ~~In or about 2006, the Plaintiff met with the defendant Dr. Leung and discussed the possibility of having a Lap-band implanted in an effort to lose weight.~~
7. ~~Dr. Leung failed to properly advise the Plaintiff of the risks associated with laparoscopic gastric banding.~~
8. ~~With reliance on Allergan's promotional materials and the statements of Dr. Leung regarding the success rates and safety of the Lap-band, the Plaintiff decided to undergo surgery and have a Lap-band implanted. Dr. Leung performed that surgery in or about 2006.~~
9. ~~Following the surgery, the Plaintiff began to have difficulties with the Lap-band including pain and discomfort.~~
10. ~~Saline can be removed or added to the Lap-band and this was done on multiple occasions. However, the pain and discomfort did not resolve.~~

The Lap-Band

5. The Lap-Band is a Class III medical device, as that term is used in the *Food and Drugs Act Medical Device Regulations*, SOR/98-282. The Lap-Band may only be sold in Canada with the license and approval of Health Canada. At all material times, the Defendant obtained licenses to sell the Lap-Band in Canada.
6. The Lap-Band is a laparoscopic adjustable gastric band implant which is surgically inserted into the abdomen with the intention of constricting the stomach and thereby assisting in weight loss. The Defendant marketed the Lap-Band as a safe and effective method for adults to lose weight.

Defendant's Marketing Materials

7. The Defendant has promoted and sold the Lap-Band through carefully planned marketing campaigns and strategies. These campaigns and strategies have included, but have not been limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices. The Defendant also used brochures and websites offering exaggerated and misleading expectations as to the safety and utility of the Lap-Band. The Lap-Band has been marketed by the Defendant to the medical community and public as a safe, effective, and reliable medical device that is more effective than traditional products and procedures for the treatment of obesity.
8. The risks associated with the Lap-Band, which were known to the Defendant at all material times, have not been adequately communicated to patients or physicians.
9. The Defendant's warnings with respect to the Lap-Band have been and remain inadequate. The Defendant has failed to warn of the frequency, seriousness, and predictability of the complications caused by the Lap-Band. The Defendant also failed to advise that, while implantation of the Lap-Band exposes patients to significant risks, the success rate of the Lap-Band is no better than that of traditional procedures for the treatment of obesity.

Complications with the Lap-Band

10. The Lap-Band has a high failure, injury, and complication rate. It has caused severe and irreversible injuries, conditions, and damage to a significant number of patients including the Plaintiff. The Plaintiff alleges that the Lap-Band causes an unacceptably high rate of complications which include, but are not limited to, band erosion, band intolerance, band leak, band slippage, blood clots, constipation, dysphagia, bowel perforations, esophageal dilation, food trapping, gallstones, gastroesophageal reflux disease, scar tissue, and death.
11. These complications often result in the need for one or more corrective surgeries and often lead to permanent damage.

The Plaintiff's Injuries

12. The Plaintiff, Mr. Marshall, underwent surgery in or about 2005 to treat obesity. He was surgically implanted with the Defendant's Lap-Band. The Plaintiff followed his surgeon's advice during the recovery period.
13. The Plaintiff suffered complications following his surgery including but not limited to severe abdominal pain, chest pain, scarring, and productive burps. The Plaintiff underwent many adjustments of his Lap-Band by qualified physicians in attempt to remediate the complications.
14. Ultimately, it was determined that the Plaintiff's Lap-Band had failed and the Plaintiff underwent invasive corrective surgery to remove the Lap-Band.
15. The implantation and failure of the Lap-Band has had a significant impact on the Plaintiff and has resulted in permanent abdominal pain, scarring, and the requirement for further invasive surgical procedures. The Plaintiff has incurred and will continue to incur loss of employment income, cost of medical care, and out of pocket expenses.

16. The Defendant provided inadequate warnings to the Plaintiff prior to him being implanted with the Lap-Band. If he had been aware of the risks, the Plaintiff would never have agreed to be implanted with the Lap-Band.
18. In addition to severe pain and discomfort, the Plaintiff has been left with significant scarring as a result of the Lap-Band.
- ~~13. As a result of the actions of the defendants, the Plaintiff has suffered the following loss and damages:~~
- ~~a. — General damages for:~~
- ~~a) Pain, suffering and loss of amenities of life;~~
~~b) Loss or impairment of future earning capacity;~~
~~c) Loss of impairment of future ability to perform household tasks;~~
~~d) Cost of future care; and~~
~~e) Further particulars of general damages to be determined.~~
- ~~b. — Special Damages for:~~
- ~~a) Past loss of income;~~
~~b) Medical and rehabilitation expenses;~~
~~c) Cost of transportation to and from medical treatments;~~
~~d) Expenses incurred by third parties on behalf of the Plaintiff; and~~
~~e) Further particulars of special damages to be determined.~~

Part 2: RELIEF SOUGHT

~~The Plaintiff seeks against the Defendants:~~

The Plaintiff claims, on his own behalf and on behalf of a class of similarly situated persons:

1. An order certifying this action as a class proceeding and appointing him as representative plaintiff under the *Class Proceedings Act*;
2. General damages;
3. Special damages;
4. Aggravated damages;
5. Punitive damages;

6. Declaratory and injunctive relief as well as statutory damages under the Business Practices and Consumer Protection Act, S.B.C. 2004, c. 2;
7. 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;
8. Interest pursuant to the *Court Order Interest Act*, [RSBC 1996] Chapter 79 and amendments thereto;
9. Costs;
10. Such further and other relief as this Honourable Court may deem meet and just.

Part 3: LEGAL BASIS

Negligence of the Defendants

Negligence

1. As the manufacturers, marketers, developers, suppliers, distributors, promoters, and/or importers of the Lap-Band, the Defendant was in such a close and proximate relationship to the Plaintiff and other class members so as to owe them a duty of care. The Defendant caused the Lap-Band to be introduced into the stream of commerce at a time when it knew that any defects in the Lap-Band would cause foreseeable injury to the Plaintiff and class members.
2. The Defendant owed a duty to the Plaintiff and class members to exercise reasonable care when researching, designing, testing, manufacturing, marketing, labeling, promoting, distributing, importing, and selling the Lap-Band. The Defendant breached the standard of care expected in the circumstances.
3. The Defendant had a duty to the Plaintiff and class members to disclose and warn of the defective nature of the Lap-Band because the Defendant was in a superior position to know the safety and efficacy of the Lap-Band.
4. The Plaintiff has sustained severe damages, loss and expense in consequence of the negligence of the Defendant Allergan, particulars of which are as follows:

- a) selling the Lap-Band as a safe option for weight loss when it knew or ought to have known of the risks and significant failure rates of the product;
- b) failing to adequately warn the Plaintiff and general public about safety concerns arising from the Lap-Band;
- c) failing to perform adequate testing or clinical trials of the Lap-Band;
- d) failing to design or manufacture the Lap-Band safely;
- e) failing to design or manufacture the Lap-Band in a manner that would prevent it from slipping out of place;
- f) failing to conduct an adequately and timely analysis of adverse event reports;
- g) failing to instruct their employees to accurately and candidly disclose consumer complaints and complications associated with the Lap-Band to Health Canada in a timely manner, or at all;
- h) failing to warn consumers, their health providers, and Health Canada of the complications presented by the Lap-Band;
- i) failing to provide proper long term investigations of the effects and risks of the continued use of the Lap-Band;
- j) failing to recall the Lap-Band;
- k) failing to provide effective, complete, and clear training and information to physicians;
- l) marketing the Lap-Band which was unsafe, not fit for its intended purpose, and not of merchantable quality;

- m) failing to design and implement an appropriate post-marketing surveillance system to monitor and identify the complications associated with the Lap-Band;
- n) failing to design and establish a safe, effective procedure for removal of the Lap-Band in the event of failure, injury, or complications;
- o) placing the Lap-Band on the market when the Defendant knew or ought to have known that the potential complications of the Lap-Band outweighed any potential benefits;
- p) such further particulars as will be shown at trial.

2. — ~~The Plaintiff has sustained severe damages, loss and expense in consequence of the negligence of the defendant Dr. Leung, particulars of which are as follows:~~

- q) ~~failing to adequately warn the Plaintiff about safety concerns arising from the Lap-band;~~
- r) ~~failing to implant the Lap-band in a manner that would prevent it from slipping out of place;~~
- s) ~~failing to provide adequate post-surgical follow-up; failing to perform adequate testing or clinical trials of the Lap-band; and~~
- t) ~~such further particulars as will be shown at trial.~~

5. The Plaintiff pleads the provisions of the *Negligence Act*, R.S.B.c. 1996, c. 333 and amendments thereto.

Health Care Cost Recovery

6. The Plaintiff is a beneficiary as defined in Section 1 of the *Health Care Costs Recovery Act*, [SBC 2008] c.27, who has received health care services as defined in section 2(1) of the said Act and who claims ~~in this act~~ for the past cost and future cost of health care services required as a result of the negligence of the Defendant pursuant to section 3 of the said Act.

Sale of Goods Act

7. At all relevant times, the Defendants knew the intended use of the Lap-Band.
8. The Plaintiff relied upon the Defendant's representations and recommendations in choosing to undergo laparoscopic gastric banding.
9. It was an express and an implied condition of the contract of purchase and sale that the Lap-Band would be reasonably fit for its intended purpose and of merchantable quality.
10. The Plaintiff relies on and pleads the provisions of the *Sale of Goods Act*, R.S.B.C. 1996, c. 410 and amendments thereto.
11. The Lap-Band was unfit for its intended purpose and not of merchantable quality.
12. The Plaintiff relies on s.17 and s. 18 of the *Sale of Goods Act*, R.S.B.C. 1996, c. 410.
11. ~~By reason of the Defendant's negligence and breach of contract, the Plaintiff has suffered damage, loss and expense.~~

Business Practices and Consumer Protection Act

13. In its sales brochures, advertisements, and other forms of representations to the public, the Defendant made statements concerning the safety of the Lap-Band that had the capability, tendency, or effect of deceiving or misleading customers.
14. These representations as to the safety of the Lap-Band were untrue, deceptive, and misleading and as a result constituted deceptive and unconscionable acts. The Plaintiff pleads and relies upon the provisions of the *British Columbia Business Practices and Consumer Protection Act*, S.B.C. 2004, Ch. 2.

Regulatory Duties

15. The Plaintiff pleads and relies upon the following statute and regulations which were breached by the Defendant:

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

b. *The Medical Devices Regulations*, SOR/98-282

Causation and Damages

16. As a result of the Defendant's negligence and breach of the *British Columbia Business Practices and Consumer Protection Act*, the Plaintiff 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 by the Plaintiff and class members which were caused or materially contributed to by the aforementioned acts of the Defendant includes:

a. *Personal injury*;

b. *Special damages for medical expenses and out of pocket expenses*;

c. *Loss of both past and prospective income*; and

d. *Cost of future care*.

17. The conduct of the Defendant as hereinbefore set out showed reckless disregard for the well-being of the public, the Plaintiff, and members of the proposed class. The Defendant's negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions, omissions, or both, of the Defendant involved such want of care as could only have resulted from actual conscious indifference to the rights, safety, or welfare of the Plaintiff and all other members of the proposed class. Accordingly, the Plaintiff, on his own behalf and on behalf of the proposed class, hereby claims aggravated and punitive damages.

Plaintiffs' address for service

Rosenberg Law
671D Market Hill
Vancouver, B.C., Canada V5Z4B5

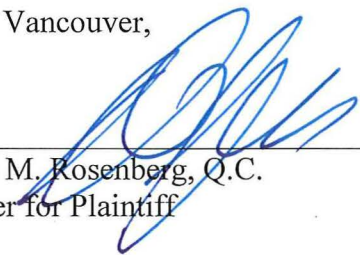
Fax number address for service: (604) 879-4934

E-mail address for service: N/A

Place of trial: Vancouver, British Columbia

The address of the registry is: 800 Smithe Street, Vancouver,

Dated: June 7, 2016



David M. Rosenberg, Q.C.
Lawyer for Plaintiff

Rule 7-1 (1) of the Supreme Court 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:

The Plaintiff's claims are against the Defendant for general, special and statutory damages and costs for negligence. The Plaintiff underwent a laparoscopic gastric banding that led to significant pain and discomfort and eventually had to undergo surgical revision.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

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 uses 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

Part 4:

Negligence Act, R.S.B.C. 1996, c. 333

Sale of Goods Act, R.S.B.C. 1996, c. 410

Court Order Interest Act, R.S.B.C. 1979, c. 76

Health Care Costs Recovery Act, [SBC 2008], c.27 and amendments thereto.