NO. Court File No. VLC-S-S-175217
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

THOMAS GARNER

PLAINTIFF

AND:

JOHNSON & JOHNSON INC., JOHNSON & JOHNSON MEDICAL COMPANIES, JOHNSON & JOHNSON, JOHNSON & JOHNSON INTERNATIONAL, and ETHICON INC.

DEFENDANTS

Brought pursuant to 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 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 plaintiff,

(a) if you were served with the notice of civil claim anywhere in Canada, within 21 days after that service,

(b) if you were served with the notice of civil claim anywhere in the United States of America, within 35 days after that service,

(c) if you were served with the notice of civil claim anywhere else, within 49 days after that service, 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

1. This proposed class proceeding concerns the Ethicon Physiomesh Mesh Device ("**Physiomesh**"), a surgical mesh which is used in the repair and treatment of hernias. Physiomesh devices are made from dangerous materials, including polypropylene, which break down, leading to bowel obstruction, seromas, infection, mesh failures, hernia recurrence, and death. These complications often result in the need for one or more corrective surgeries and result in permanent damage.

2. The defendants were aware of Physiomesh's design defect at all material times. Despite this knowledge, the defendants cynically marketed Physiomesh as a safe device that was more effective than traditional methods of hernia treatment.

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 Physiomesh in British Columbia and elsewhere in Canada. The proposed class will be further defined in the plaintiff's application for certification.

The Parties

4. The plaintiff is retired and has an address for service of 671D Market Hill, Vancouver, British Columbia. On or about May 30, 2014, the plaintiff was implanted with Physiomesh to repair a hernia. The plaintiff's Physiomesh failed, causing the plaintiff to experience severe pain and suffering, and necessitating further surgery to remove the Physiomesh and/or otherwise repair the hernia.

5. The defendant, Johnson & Johnson Inc., is a federally incorporated company with an address for delivery at 2600 – 595 Burrard Street, Vancouver, Canada.

6. The defendant, Johnson & Johnson Medical Companies, is a division of Johnson & Johnson Inc., with its head office and address for delivery at 200 Whitehall Drive, Markham, Ontario, Canada.

7. The defendant, Johnson & Johnson, is a corporation with its worldwide headquarters and address for delivery at One Johnson & Johnson Plaza, New Brunswick, New Jersey, USA.

8. The defendant, Johnson & Johnson International, C/O European Logistics Centre, is headquartered with an address for delivery at Leonardo Da Vincilaan, 15, Diegem, Belgium.

9. The defendant, Ethicon Inc., is a wholly owned subsidiary of Johnson & Johnson with an address for delivery at Route 22 West, Somerville, New Jersey, USA.

10. The business of each of the defendants is inextricably interwoven with that of the other, and each is the agent of the other for the purposes of researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, Physiomesh in Canada.

11. At all material times, the defendants were engaged in the business of researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, importing, and/or selling Physiomesh in Canada.

The Product

12. Physiomesh is a surgical mesh designed for the repair of fascial deficiencies such as hernias. Physiomesh is affixed to the patient's abdominal wall to cover the defect in question. Over time, the patient's own tissue is meant to incorporate Physiomesh into the surrounding area. Physiomesh was approved for sale in Canada in or about September, 2010.

13. The defendants promoted and sold Physiomesh through carefully planned marketing campaigns and strategies, which included aggressively marketing Physiomesh to the medical community and public as a safe, effective, and reliable medical device that was more effective than traditional products and procedures for the treatment of hernias.

14. Contrary to the defendants' representations, Physiomesh demonstrated a high failure and complication rate, resulting in high rates of hernia recurrence and necessary reoperations. Physiomesh's high failure rate is attributable to a common design defect involving the polypropylene material used to make the device. This defect is the same or substantially similar to the defect in the defendants' transvaginal mesh device, which was earlier recalled by Health Canada due to similar failures.

15. Physiomesh failures have caused severe and irreversible patient injuries, including hernia recurrence, chronic pain, mesh contraction, mesh migration, scarring, adhesions, infection and abscess formation, bleeding, intestinal blockage, fistulas, hematomas, seromas, perforations, and the need for further invasive surgeries.

16. The risks associated with Physiomesh, which were known to the defendants at all material times, have not been adequately communicated to patients, physicians, hospitals, or the medical community. The defendants have failed to warn of the frequency,

seriousness, and predictability of the complications caused by Physiomesh. Physiomesh creates risks to the health and safety of patients that are more significant than the risks posed by other products and procedures available to treat hernias, and which outweigh the utility of Physiomesh. Furthermore, the defendants failed to provide adequate safety data to Health Canada with respect to Physiomesh. The defendants knew or ought to have known that Physiomesh was unsafe, defective, unreasonably dangerous, and not fit for its intended purpose.

The Plaintiff

17. The plaintiff underwent surgery on or about May 30, 2014 to treat a ventral hernia in which he was surgically implanted with Physiomesh. The surgery was conducted without complications. The plaintiff followed medical advice during the recovery period.

18. The plaintiff suffered severe complications following his surgery including abdominal pain, gastrointestinal malfunction, grotesque swelling, and hernia recurrence.

19. Ultimately, it was determined that the plaintiff's Physiomesh had failed and that further invasive surgery was required to remove the Physiomesh and/or otherwise repair the hernia.

20. The implantation and failure of the Physiomesh has had a devastating impact on the plaintiff, leaving him with permanent injuries including scarring, disfigurement, and chronic pain, and interfering with all aspects of his domestic, social, recreational, and vocational endeavors. The plaintiff has incurred, and will continue to incur, loss of employment income, cost of medical care, and out of pocket expenses.

21. The plaintiff's adverse reaction, complications, and further surgery directly and proximately resulted from the defective and dangerous condition of the Physiomesh. The plaintiff was not provided adequate warnings prior to being implanted with Physiomesh. If he had been aware of the risks, the plaintiff would not have agreed to be implanted with this defective device.

Part 2: RELIEF SOUGHT

1. The plaintiff claims on his behalf and on behalf of a class of similarly situated persons:

    a. An order certifying this action as a class proceeding and appointing him as representative plaintiff under the *Class Proceedings Act*;

    b. General damages;

    c. Special damages;

    d. Loss of earning capacity, both past and future;

e. Cost of future care;

f. Aggravated damages;

g. Punitive damages;

h. Declaratory and injunctive relief as well as statutory damages under the *Business Practices and Consumer Protection Act,* S.B.C. 2004, c. 2;

i. Recovery of health care costs incurred by the Ministry of Health Services on their behalf pursuant to the *Health Care Costs Recovery Act*, S.B.C. 2008, c. 27;

j. Interest pursuant to the *Court Order Interest Act*, [RSBC 1996] Chapter 79 and amendments thereto;

k. Costs; and,

l. Such further and other relief as this Honourable Court may deem meet and just.

Part 3: LEGAL BASIS

Negligence

1. As the researchers, designers, manufacturers, developers, preparers, processers, inspectors, testers, packagers, promoters, marketers, distributors, labelers, importers, and/or sellers of Physiomesh, the defendants were in such close and proximate relationship to the plaintiff and other class members so as to owe them a duty of care. The defendants caused Physiomesh to be introduced into the stream of commerce at a time when they knew that any defects in Physiomesh would cause foreseeable injury to the plaintiff and class members.

2. The defendants owed a duty to the plaintiff and class members to exercise reasonable care when researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, importing, and/or selling Physiomesh. The defendants breached the standard of care expected in the circumstances.

3. The defendants had a duty to the plaintiff and class members to disclose and warn of the defective nature of Physiomesh because the defendants were in a superior position to know the safety and efficacy of Physiomesh.

4. The plaintiff has sustained severe damages, loss and expense in consequence of the negligence of the defendants, particulars of which include, but are not limited to:

a. Selling, marketing, and promoting Physiomesh as a safe option for hernia repair when they knew or ought to have known of its risks and significant failure rate;

b. Failing to perform adequate testing or clinical trials of Physiomesh;

c. Failing to design or manufacture Physiomesh safely or in such a manner that rendered it sufficiently safe for its intended purpose;

d. Failing to conduct an adequate and timely analysis of adverse event reports;

e. Misrepresenting the purported benefits and safety of Physiomesh and its associated risks;

f. Failing to adequately educate their sales representatives and physicians regarding the risks associated with Physiomesh;

g. Failing to instruct their employees to accurately and candidly disclose consumer complaints and complications associated with Physiomesh 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 Physiomesh;

i. Failing to provide proper long term investigations of the effects and risks of Physiomesh;

j. Failing to recall Physiomesh in a timely manner;

k. Failing to provide effective, complete, and clear training and information to physicians;

l. Marketing Physiomesh, 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 Physiomesh;

n. Failing to design and establish a safe, effective procedure for removal of Physiomesh in the event of failure, injury, or complications;

o. Placing Physiomesh on the market when the defendants knew or ought to have known that its potential complications outweighed any potential benefits; and,

p. Failing to ensure that Physiomesh was not dangerous to recipients during the course of their use and that they were fit for their intended purpose and of merchantable quality;

q. Failing to adequately test Physiomesh in a manner that would fully disclose the magnitude of the risks associated with its use, including, but not limited to, the injuries, loss, and damage sustained by the plaintiff and class members;

r. Unreasonably and carelessly designing a product that was insufficient to withstand the foreseeable use of normal placement within the human body;

s. Failing to conduct any or any adequate follow-up or long-term studies on Physiomesh's efficacy, safety, and risks;

t. Failing to issue adequate warnings about problems with Physiomesh, implement a timely recall of Physiomesh, promptly publicize the problems with Physiomesh, and otherwise act properly and in a timely manner, to alert the public and other health care providers of Physiomesh's inherent dangers;

u. 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.

6. The defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees, and representatives.

Business Practices and Consumer Protection Act

7. In its sales brochures, advertisements, and other forms of representations to the public, the defendants made statements concerning the safety of Physiomesh that had the capability, tendency, or effect of deceiving or misleading customers.

8. These representations as to the safety of Physiomesh 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.

Sale of Goods Act

9. At all relevant times, the defendants knew the intended use of Physiomesh.

10. The plaintiff relied upon the defendants' representations and recommendations in using Physiomesh to repair his hernia.

11. It was an express and an implied condition of the contract of purchase and sale that Physiomesh would be reasonably fit for its intended purpose and of merchantable quality.

12. Physiomesh was unfit for its intended purpose and not of merchantable quality.

13. The plaintiff relies on and pleads the provisions of the *Sale of Goods Act*, R.S.B.C. 1996, c. 410 and amendments thereto, including, but not limited to, sections 17 and 18.

Regulatory Duties

14. The plaintiff pleads and relies upon the *Food and Drugs Act*, R.S.C. 1985, c. F-27; and *The Medical Devices Regulations*, SOR/98-282, which were breached by the defendants.

Causation and Damages

15. As a result of the defendants' negligence, breach of the *British Columbia Business Practices and Consumer Protection Act*, breach of the *Sale of Goods Act*, and breach of regulatory duties, the plaintiff and class members have suffered and will continue to suffer injury, loss, and damage. Such injury, loss, and damage was foreseeable by the defendants. Particulars of the injury, loss, and damage by the plaintiff and class members which were caused or materially contributed to by the aforementioned acts of the defendants include, but are not limited to:

    a. Personal injury;
    b. Special damages for medical expenses and out of pocket expenses;
    c. Loss of both past and future income; and,
    d. Cost of future care.

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

Health Care Costs Recovery

17. The plaintiff is a beneficiary as defined in section 1 of the *Health Care Costs Recovery Act*, SBC 2008 c.27 (the "**HCCRA**") who has received health care services as defined in section 2(1) of the HCCRA and who claims for the past cost and future cost of health care services required as a result of the negligence of the defendants pursuant to section 3 of the HCCRA.

Plaintiff's address for service:

Rosenberg Kosakoski LLP
671D Market Hill
Vancouver, BC
V5Z 4B5

Fax number address for service: 604-879-4934

Place of trial: Vancouver, British Columbia

The address of the registry is: 800 Smithe Street, Vancouver, B.C., V6Z 2E1

Dated: May 31, 2017

David Rosenberg, Q.C.
Lawyer for the plaintiff

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:

The plaintiff's claim is for injuries, loss and damages, suffered as the result of the negligence and breach of duty of the defendants in the course of providing medical treatment to the plaintiff.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

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
[x] 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:

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

Part 4:

Negligence Act, R.S.B.C. 1996, c. 333
Sale of Goods Act, R.S.B.C. 1996, c. 410
Food and Drugs Act, R.S.C. 1985, c. F-27
Business Practices and Consumer Protection Act, S.B.C. 2004, ch. 2