SUPREME COURT
OF
BRITISH COLUMBIA
SEAL
15-Sep-25

Vancouver
REGISTRY

Original filed August 24, 2023
Amended pursuant to Rule 6-1(1)(a)

NO.S235885
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

ETHAN RIBALKIN

PLAINTIFF

AND:

CARTIVA, INC., STRYKER CANADA ULC,
and WRIGHT MEDICAL TECHNOLOGY CANADA ULC

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 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

The Parties

1. The plaintiff is a mortgage broker. For the purposes of this action, the plaintiff's address for service is Suite 2020 – 650 West Georgia Street, Vancouver, British Columbia.

2. The defendant, Cartiva, Inc., is, and at all times relevant to this action was, a corporation with its principal place of business and headquarters located at 6120 Windward Parkway, Suite 220, Alpharetta, Georgia, USA, 30005.

3. The defendant, Stryker Canada ULC, is, and at all times relevant to this action was, a company duly formed under the law of the Province of British Columbia, with its registered and records office address of 1500 Royal Centre, 1055 West Georgia Street, Vancouver, British Columbia.

4. The defendant, Wright Medical Technology Canada ULC is, and at all times relevant to this action was, a company duly formed under the law of the Province of British Columbia, with its registered and records office address of 1500 Royal Centre, 1055 West Georgia Street, Vancouver, British Columbia.

5. At all times material, Cartiva, Inc., Stryker Canada ULC, and Wright Medical Technology Canada ULC, are hereinafter referred to collectively as "Stryker" or the "defendants", developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product under the name Cartiva® Synthetic Cartilage Implant ("SCI") (hereinafter referred to as "Cartiva", "Cartiva implant(s)", or the "defective device"), either directly or indirectly, to members of the general public within Canada, including the plaintiff.

6. 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, Cartiva implants in Canada.

7. 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 Cartiva implants in Canada.

8. The plaintiff brings this claim on behalf of himself and on behalf of a proposed class of similarly situated persons who were implanted with Cartiva implants in British Columbia and elsewhere in Canada (the "class members"). The proposed class will be further defined in the plaintiff's application for certification.

The Defective Product

9. The Cartiva implant is intended to treat first metatarsophalangeal joint osteoarthritis (also known as big toe arthritis). Cartilage is a specialized tissue responsible for mediating contact between bones on surfaces with relative movement. As osteoarthritis deteriorates joint cartilage in the first metatarsophalangeal joint ("MTP"), a person loses the protective cushion of joint cartilage, which causes extremely painful bone-on-bone rubbing. Since cartilage is not vascularized, it does not restore itself or recover quickly from injury.

10. This condition has been surgically treated with arthrodesis (also known as "fusion"), or a Cartiva implant, which is intended to act like a cushion to prevent bone-on-bone pain.

11. Arthrodesis is a procedure in which the phalangeal and metatarsal bones are cut and shaped to fit together to relieve toe joint pain. The two bones are then aligned, set at a predetermined angle, and permanently fixed with either screws and/or a plate so the two bones "fuse" together permanently. A typical fusion procedure eliminates the ability to move the first joint of the big toe.

12. In contrast to arthrodesis, the Cartiva implant is a molded cylindrical implant that is placed into the metatarsal head in the first metatarsophalangeal joint via press-fit implantation using instruments specifically designed for placement of the device. The Cartiva instrumentation is used to drill an appropriately sized cavity in the metatarsal head and deploy the Cartiva implant into the prepared cavity.

13. The defendants allege joint repair with a Cartiva implant is simple, does not require significant removal of healthy tissue, and typically results in nominal surgical trauma and rapid recovery.

14. The defendants promoted and sold Cartiva implants through carefully planned marketing campaigns and strategies, which included aggressively marketing

Cartiva implants 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 hallux rigidus or hallux limitus. For example, Cartiva promotional materials from 2018 include the following claims:

a. Cartiva is a long-term treatment.
b. There have been limited cases where the Cartiva was removed because a patient still had pain in their big toe joint.
c. Only nine out of every 100 Cartiva subjects had the device removed within two years after surgery.

15. Contrary to the defendants' representations, clinically, Cartiva implants demonstrate~~s~~ a high failure and complication rate, resulting in high rates of failure and necessary reoperations and the studies the defendants rely on are not reliable.

16. Cartiva implant failures have caused severe and irreversible patient injuries, including, but not limited to, subsidence, recurrence, chronic pain, scarring, infection, and the need for further invasive surgeries.

17. The risks associated with Cartiva implants, which were known, or ought to have been known, to the defendants at all material times, ~~have~~ were 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 Cartiva implants. Cartiva implants create~~s~~ risks to the health and safety of patients that are more significant than the risks posed by other products and procedures available to treat big toe arthritis and which outweigh the utility of Cartiva implants. Furthermore, the defendants failed to provide adequate safety data to Health Canada with respect to Cartiva implants. The defendants knew or ought to have known that Cartiva implants were ~~was~~ unsafe, defective, unreasonably dangerous, and not fit for ~~its~~ their intended purpose. If the risks associated with Cartiva implants were appropriately and fully disclosed, patients such as the plaintiff would have chosen alternative treatment options.

The Recall

18. The defendants issued an Urgent Medical Device Recall notice dated October 31, 2024, to the attention of "Surgeons and Hospital Risk Managers" advising that there was a higher incidence of revision/removal required for all Cartiva implants, that all unused Cartiva implants should be removed/quarantined, and that patients with Cartiva implants should be closely monitored for complications.

19. On November 11, 2024, Health Canada issued a recall of the Cartiva implants. The recall applied to all lots of the Cartiva implants. The recall notice noted the following:

Stryker has become aware of recently published data and post market reports indicating that patients implanted with Cartiva SCI may experience a higher-than- expected occurrence rate when compared to data submitted in the 2016 PMA of the following documented hazards: revision, removal, implant subsidence, displacement, pain, nerve damage or fragmentation. Cartiva SCI devices have been observed in some cases to be revised/removed at higher rates than previously observed in the initial Cartiva SCI premarket and post-approval studies.

20. The plaintiff alleges that the high failure rate of the Cartiva implants was known, or ought to have been known, to the defendants before or while they marketed Cartiva implants as a long-term effective solution to the first metatarsophalangeal joint osteoarthritis.

The Representative Plaintiff

~~18.~~21. The plaintiff underwent surgery in February 2021, in which he received a Cartiva implant. The surgery was conducted without complications and the plaintiff followed medical advice during the recovery period.

~~19.~~22. In approximately September 2021, it was determined that the plaintiff's Cartiva implant had failed and the plaintiff required a further invasive surgery including the removal of the Cartiva implant and arthrodesis, which took place in 2022.

~~20.~~23. The implantation and failure of the Cartiva implant has had a devastating impact on the plaintiff, leaving him with permanent injuries including, but not limited to, chronic pain and functional limitations, 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.~~24. The plaintiff's complications and further surgery directly and proximately resulted from the defective and dangerous condition of the Cartiva implant. The plaintiff was not provided adequate warnings prior to being implanted with Cartiva implant. If he had been aware of the risks, the plaintiff would not have agreed to be implanted with this defective device.

The Cartiva Implants

25. Cartiva implants were aggressively marketed as having advantages over other first metatarsophalangeal joint osteoarthritis treatment options.

26. As further described below, the Cartiva implants were designed and manufactured improperly, causing serious bodily injury and economic loss to the plaintiffs and the class members. The defendants should not have sold, or distributed Cartiva in Canada given it was designed and manufactured improperly, which all defendants

involved variously in the design, manufacture and distribution of the Cartiva implants knew or ought to have known at the time they introduced Cartiva implants into the marketplace. No proper warning was given by any of the defendants to the plaintiff or the class members about the risks associated with Cartiva implants, which are described below.

27. The failure of the Cartiva implants often requires complicated, expensive and painful revision surgery to correct, with many of the revision surgeries taking place shortly after the original implant, or sooner than was intended or marketed.

28. Despite these serious and numerous reports of failure of the Cartiva implants, no warning was provided to Canadian patients of the significant risk of failure of the Cartiva implants.

29. As set out above, the Cartiva implants were withdrawn from the Canadian market and Health Canada announced a recall of the Cartiva implants in or about October 2024.

30. The Cartiva implants all share common defective design characteristics.

Damages

31. The plaintiff and the class members have suffered and will continue to suffer damages as a direct result of the defendants' negligence including, but not limited to, damages for personal injuries, mental anguish, pain and suffering, loss of employment income and benefits, loss of enjoyment of life, possibly death, and special damages and expenses of all sorts including, but not limited to, costs of future care and medical monitoring.

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. In-trust claims;

g. Loss of housekeeping capacity;

h. Damages for medical monitoring and emotional distress for those who were implanted with a Cartiva implant but who have not had a revision surgery;

~~f.~~i. Aggravated damages;

~~g.~~j. Punitive damages;

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

~~i.~~l. 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, and comparable legislation in other provinces and territories;

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

~~k.~~n. Costs; and,

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

Part 3: LEGAL BASIS

Negligence

1. As the designers, manufacturers, developers, preparers, processers, inspectors, testers, packagers, promoters, marketers, distributors, labelers, importers, and/or sellers of Cartiva implants, 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 Cartiva implants to be introduced into the stream of commerce at a time when they knew that any defects in Cartiva 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 Cartiva implants. 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 Cartiva implants because the defendants were in a superior position to know the safety and efficacy of Cartiva implants.

4. The plaintiff and the class members have ~~has~~ sustained 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 Cartiva implants as a safe option 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 Cartiva implants;

   c. Failing to adjust the production method or combining PVA with other materials to produce a more suitable and stable material than the current design;

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

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

   f. Misrepresenting the purported benefits and safety of Cartiva implants and its associated risks;

   g. Failing to adequately educate their sales representatives and physicians regarding the risks associated with Cartiva implants;

   h. Misrepresenting the safety and efficacy of Cartiva implants;

   i. Relying on studies to support the safety and efficacy of Cartiva when they knew or ought to have known about the shortcomings of such studies;

   j. Failing to instruct their employees to accurately and candidly disclose consumer complaints and complications associated with Cartiva to Health Canada in a timely manner, or at all;

   k. Failing to warn consumers, their health providers, and Health Canada of the complications presented by Cartiva implants;

l. Failing to provide proper long-term investigations of the effects and risks of Cartiva implants;

m. Failing to recall Cartiva implants in a timely manner;

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

o. Marketing Cartiva, which was unsafe, not fit for its intended purpose, and not of merchantable quality;

p. Failing to design and implement an appropriate post-marketing surveillance system to monitor and identify the complications associated with Cartiva implants;

q. Placing Cartiva on the market when the defendants knew or ought to have known its potential complications outweighed any potential benefits; ~~and,~~

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

s. Failing to adequately test Cartiva implants 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;

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

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

v. Failing to issue adequate warnings about problems with Cartiva implants, implement a timely recall of Cartiva implants, promptly publicize the problems with Cartiva implants, and otherwise act properly and in a timely manner, to alert the public and other health care providers of Cartiva implants' inherent dangers;

w. Failing to adequately monitor, evaluate and act promptly upon adverse reactions and high revision rates in Cartiva implants;

x. Failing to conduct adequate tests and clinical trials initially and on an ongoing basis to determine whether the design or material of the Cartiva implants were defective, thereby increasing the risks of injury and harm associated with the use of the Cartiva implants;

y. Failing to fix the defects in the Cartiva implants or to withdraw the Cartiva implants from the marketplace as soon as possible after they became aware of the defects and the injuries and risks associated with their use;

z. Using inappropriate materials to manufacture the Cartiva implants;

aa. Failing to properly train or supervise their employees and consultants involved in the development, testing, marketing, manufacturing, or distribution of the Cartiva implants;

bb. Failing to give Health Canada complete and accurate information concerning the Cartiva implants by failing to disclose the problems with the Cartiva implants on a timely basis or at all;

cc. Failing to adequately warn the plaintiff, the class members, or their physicians of the risks then known or which were reasonably foreseeable in using the Cartiva implants; and,

~~w.~~dd. Such further particulars as will be shown at trial.

5. The injuries of the plaintiff and the class members would not have occurred but for the negligence of the defendants.

6. The plaintiff pleads that they and the other class members would not have had the Cartiva implants implanted had the defendants not acted negligently. There were safer, economically feasible alternative treatments available. The propensity of the Cartiva implants to injure those who were implanted far outweighed any value to their use.

~~5.~~7. The plaintiff pleads the provisions of the *Negligence Act*, R.S.B.C. 1996 c. 333 and amendments thereto.

~~6.~~8. 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.~~9. In its sales brochures, advertisements, and other forms of representations to the public, the defendants made statements concerning the safety of Cartiva implants that had the capability, tendency, or effect of deceiving or misleading customers.

~~8.~~10. These representations as to the safety of Cartiva implants 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, c. 2.

Sale of Goods Act

~~9.~~11. At all relevant times, the defendants knew the intended use of Cartiva implants.

~~10.~~12. The plaintiff relied upon the defendants' representations and recommendations in using Cartiva implants.

~~11.~~13. It was an express and an implied condition of the contract of purchase and sale that Cartiva implants would be reasonably fit for ~~its~~ their intended purpose and of merchantable quality.

~~12.~~14. Cartiva implants were ~~was~~ unfit for ~~its~~ their intended purpose and not of merchantable quality.

~~13.~~15. 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.~~16. 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.~~17. 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 were 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.~~

18. The defendants knew or ought to have known that their conduct was likely to, or would, injure the plaintiff and the class members, and motivated entirely by their

own interests, disregarded the interests of the plaintiff and the class members and the effect that their conduct would have on them.

~~16.~~19. 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.

20. The conduct of the defendants was high-handed, outrageous, reckless, wanton, without care, disgraceful, reprehensible and represents a marked departure from ordinary standards of reasonable behaviour.

Health Care Costs Recovery

~~17.~~21. 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*.

22. The plaintiff and the class members claim for the recovery of health care costs incurred on their behalf by the British Columbia Ministry of Health, pursuant to s. 3 of the *HCCRA,* and by other provincial and territorial governments and the equivalent legislation from the other provinces and territories including:

a. The *Crown's Right of Recovery Act,* SA 2009, c C-35 with respect to Personal Injury Subclass Members in Alberta;

b. The *Health Administration Act,* RSS 1978, c. H-0.0001 with respect to Personal Injury Subclass Members in Saskatchewan;

c. The *Hospital Insurance Act,* CQLR c A-28 with respect to Personal Injury Subclass Members in Quebec;

d. The *Health Insurance Act,* RSO 1990, c. H.6 with respect to Personal Injury Subclass Members in Ontario;

e. The *Health Services Act,* RSNB 2014, c 112 with respect to Personal Injury Subclass Members in New Brunswick;

f. The *Health Services and Insurance Act,* RSNS 1989, c. 197 with respect to Personal Injury Subclass Members in Nova Scotia;

g. The *Health Services Payment Act,* RSPEI 1988, c H-2 with respect to Personal Injury Subclass Members in Prince Edward Island;

h. The *Hospital Insurance Agreement Act,* RSNL 1990, c H-7 with respect to Personal Injury Subclass Members in Newfoundland and Labrador;

i. The *Health Care Insurance Plan Act,* RSY 2002, c 107 with respect to Personal Injury Subclass Members in the Yukon;

j. The *Hospital Insurance and Health and Social Services Administration Act,* RSNWT 1988, c T-3 with respect to Personal Injury Subclass Members in the Northwest Territories; and

k. The *Hospital Insurance and Health and Social Services Administration Act,* RSNWT (Nu) 1988, c T-3 with respect to Personal Injury Subclass Members in Nunavut.

Plaintiff's address for service:

Murphy Battista LLP
Barristers and Solicitors
Suite 2020 – 650 West Georgia Street
Vancouver, B.C.
Canada V6B 4N7

Fax number address for service: 604-683-5084

Place of trial: Vancouver, British Columbia

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

Dated: ~~24/Aug/2023~~
Dated: 15/Sep/2025

Andrew D. Brine,
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:

This action is brought pursuant to the *Class Proceedings Act* for injury, loss, and damage suffered by the plaintiff and other class members as a result of the defendants' negligence and breach of duty related to the Cartiva implant issued and sold from 2005 to the present date in British Columbia and elsewhere in Canada.

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, c. 2