



Court File No.

**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN:

PAUL PEDERSEN

Plaintiff

- and -

**ADVANCED BIONICS LLC., ADVANCED BIONICS CORPORATION,
SONOVA HOLDING AG, SONOVA USA INC., and NATIONAL HEARING
SERVICES INC. c.o.b. as CONNECT HEARING**

Defendants

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM

TO THE DEFENDANT

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 MAY 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

- 2 -

FEEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date April 27, 2023

Issued by _____

Local registrar

Address of court office 393 University Avenue
Toronto, ON
M5G 1E6

TO: ADVANCED BIONICS LLC.
12740 San Fernando Road
Sylmar, California, 91324
United States

AND TO: ADVANCED BIONICS CORPORATION
28515 Westinghouse Place
Valencia, CA 91355
United States

AND TO: SONOVA HOLDING AG
Laubisrütistrasse 28
8712 Stäfa
Switzerland

AND TO: SONOVA USA INC.
750 N Commons Dr,
Aurora, IL 60504
United States

AND TO: NATIONAL HEARING SERVICES
INC. c.o.b. as CONNECT HEARING
50 Queen Street North
Suite 1020
Kitchener, ON N2H 6M2
Canada

CLAIM

1. The Plaintiff, Paul Pedersen (“Paul” or the “Plaintiff”), claims on his own behalf and on behalf of all members of the Class (as defined below):

- (a) an order certifying this action as a Class Proceeding and appointing Paul as representative Plaintiff for the Class;
- (b) a declaration that the Defendants were negligent in the research, design, manufacture, regulatory licensing, sale and post-market monitoring of the Cochlear Implants (as defined below);
- (c) a declaration that the Cochlear Implants are dangerous and not fit for their intended use;
- (d) on behalf of the Class, compensatory damages in the amount of \$100,000,000.00, or such other sum as counsel may advise and this Honourable Court deems just;
- (e) special damages in an amount to be determined, including but not limited to past and future loss of income, medical care, the cost of the device and its replacement device, screening, diagnosis, examinations, surgical care, and all other medical expenses, including medical expense for monitoring, treatment, recovery, and medical imaging, on behalf of the Plaintiffs and the subrogated interest of the Ontario Health Insurance Plan pursuant to sections 30 and 31 of the *Health Insurance Act*, R.S.O. 1990, c. H.6, as amended, and the other provincial and territorial health insurers pursuant to the legislation in the Class members’ respective provinces or territories of residence;
- (f) punitive damages in the sum of \$10,000,000.00;
- (g) on behalf of the Family Law Claimants, damages pursuant to the *Family Law Act*, R.S.O. 1990 c. F.3 (“FLA”);
- (h) pre-judgment and post-judgment interest in accordance with the

- 4 -

Courts of Justice Act, as amended, compounded annually;

- (i) costs of this action, including the costs of notice and of administering the plan of distribution of the recovery in this action, plus applicable taxes;
- (j) a *Cy-près* award for any undistributed recovery; and
- (k) such further and other relief as counsel may advise and this Honourable Court considers just.

OVERVIEW

2. On August 23, 2019, Paul was implanted on the right side of his skull above the ear with a Cochlear Implant, which was designed, manufactured, marketed, and sold by the Defendants. The product was defective, required revision surgery to replace it, and the Plaintiff has suffered and continues to suffer severe, chronic, and debilitating injuries as a result.

3. The fundamental defect with the Defendants' product is that it is subject to fluid ingress around the casing and electrodes, causing degradation of function, fluctuating volume and acuity, loss of speech recognition, vertigo, convulsions, and the need for revision and replacement surgery.

4. The Defendants sell and service the Cochlear Implants under the brand names "HiRes Ultra" and "HiRes Ultra 3D". These products were marketed, sold and implanted in patients in Europe, Canada, the United States of America, and elsewhere between 2016 and 2020. An unacceptably high percentage of these devices implanted have already failed and required surgery to remove and replace them.

5. On February 18, 2020, the Defendant, Advanced Bionics Corp., announced the removal from the market of its HiRes Ultra and HiRes Ultra 3D Cochlear Implants that had not yet been implanted, citing concern for "fluid ingress at the electrode ... leading to interruption of stimulation". In simple terms, the fluid caused partial or total loss of

impedance in some of the 16 circuits connected to the auditory nerve. On April 17, 2020, Health Canada posted a Medical Device Recall for the Cochlear Implants.

6. The problems with the Defendants' Cochlear Implants, however, are more extensive than the Defendants have so far been prepared to admit.

7. The Plaintiff brings this action on his own behalf, and on behalf of the proposed Class.

THE PLAINTIFF AND THE CLASS

8. The Plaintiff, Paul, is a resident of the Region of Niagara, Ontario. As described further below, he was implanted with a Cochlear Implant, specifically, a HiRes Ultra.

9. As a result of a disease process, Paul lost his ability to hear, bilaterally, while in his early 40's, and is disabled by virtue of his profound deafness. The Class he seeks to represent are all vulnerable by virtue of their disability. In addition, many of the class members are minors.

10. The Plaintiff brings this action on his own behalf, and on behalf of the Class, defined as follows:

All persons who were implanted in Canada with the HiRes Ultra or the HiRes Ultra 3D Cochlear Implant (collectively, the "Cochlear Implants"), or any of the Cochlear Implant components including electrode arrays (the "Implant Patients"); and

All other persons who by reason of his or her relationship to an Implant Patient have standing pursuant to s. 61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3, or equivalent legislation in other provinces and territories (the "Family Law Claimants").

11. The Plaintiff also brings this action on behalf of all provincial and territorial health insurers who are entitled to assert a claim for the recovery of the cost of insured services provided to members of the Class, pursuant to provincial or territorial legislation.

THE DEFENDANTS

12. The Defendant, Advanced Bionics Corporation and/or Advanced Bionics LLC (“Advanced Bionics”) is incorporated in the state of Delaware, USA, and is headquartered in Valencia, California, USA. Advanced Bionics carries on the business of the design, testing, manufacturing, marketing, sale, and post-sale monitoring and service of Cochlear Implants, including the HiRes Ultra and HiRes Ultra 3D Cochlear Implants. It is a wholly owned subsidiary of Sonova Holding AG.

13. The Defendant, Sonova Holding AG (“Sonova”), is incorporated in Switzerland, and is the parent company of Advanced Bionics and Sonova USA Inc.

14. The Defendant, National Hearing Services Inc., carrying on business as Connect Hearing (“Connect Hearing”), is a federally incorporated company in Canada and is owned by Sonova. It provides sales, distribution, marketing and service functions for Advanced Bionics and Sonova, provides post-implant service to the hospital clinics which implant their products, and provides post-implant service, monitoring and testing of the Implant Patients.

15. The Defendants are inter-related corporations with one being the parent, subsidiary, or affiliate of the other. The Defendants, individually and/or collectively, participated in one or more of the following: the development, testing, manufacturing, distribution, marketing, promotion, sale, post-sale monitoring, and servicing of the Implant Patients in Canada.

16. By virtue of the acts and omissions described herein, the Defendants are liable in damages or other compensation to the Class and each Defendant is responsible for the acts and omissions of the other Defendant for the following reasons:

- 7 -

- (a) each was the agent of the other;
- (b) each company's business was operated so that it was inextricably interwoven with the business of the other;
- (c) each company entered into a common advertising and business plan to research, design, test, manufacture, distribute, market, sell, and service its Cochlear Implants in Canada;
- (d) the companies issued joint annual reports and consolidated financial statements, which included the statements of the Advanced Bionics, Sonova, and Connect Hearing and their wholly owned subsidiaries;
- (e) the Defendants shared certain executive officers and directors;
- (f) the Defendants had a common business plan and intended that their businesses be run as one global business organization; and
- (g) they carried out the improper acts as pleaded below.

17. The Defendants are joint tortfeasors. They each knew, or ought to have known, that the Cochlear Implants were defective, and they each were in such a close and proximate relationship to the Plaintiff and Class members as to owe them a duty of care.

18. The Defendants each could have, but failed to, take reasonable steps to have prevented injury to the Plaintiff and Class members, including ensuring that the Cochlear Implants were properly designed, tested, and manufactured before marketing them, promptly recalling the Cochlear Implants, and properly warning patients of the risk of harm.

THE IMPLANTED DEVICES

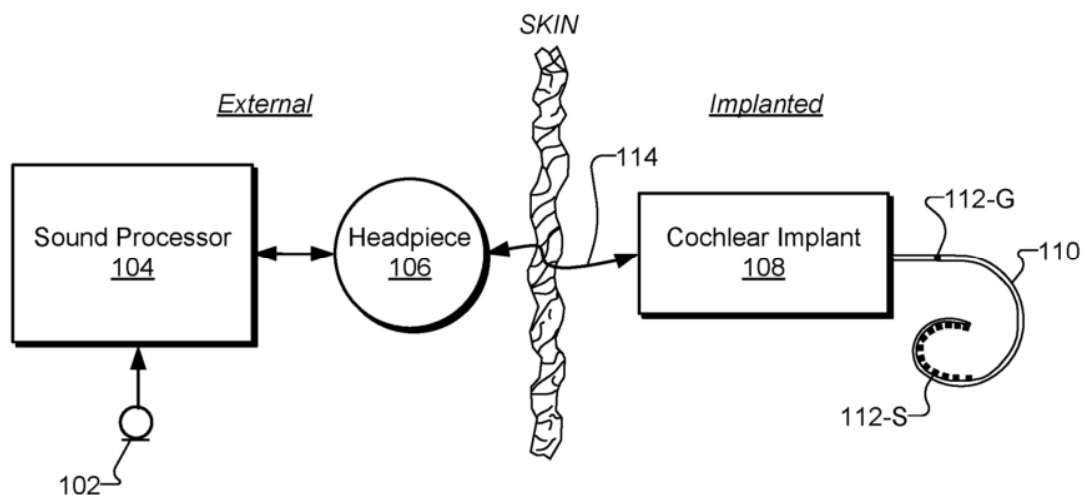
i. Cochlear Implants

19. A cochlear implant is an electronic device that enables patients to process sounds despite being severely to profoundly deaf. It can be an option for patients like Paul who have severe hearing loss from inner-ear damage who are not able to hear well with hearing aids, or for patients who are congenitally deaf.

20. Unlike hearing aids, which amplify sound, a cochlear implant bypasses damaged portions of the ear to deliver sound signals to the hearing (auditory) nerve.

21. Cochlear implants use a sound processor that fits behind the ear. The processor captures sound signals and digitally processes them, sending them to a receiver implanted under the skin behind the ear. The receiver sends the signals to electrodes implanted in the snail shell-shaped inner ear (cochlea), stimulating the acoustic (or cochlear) nerve.

Fig. 1 – Cochlear Implant Components – internal and external components



22. The signals stimulate the cochlear nerve, which then directs the signals to the auditory cortex of the brain. The brain interprets those signals as sounds, though these sounds would not be like natural hearing.

23. It takes time and training to learn to interpret the signals received from a cochlear implant. Within 3 to 6 months of use, people with cochlear implants generally make gains in understanding speech, provided that the device functions properly.

24. A portion of the patient population who receive cochlear implants are minors, many between the ages of 1 to 5 years old, with profound congenital deafness. For these patients, who are called pre-lingual because their auditory cortex is in the process of formation and development, a properly functioning cochlear implant is critical to higher level linguistic and cognitive function.

ii. The Advanced Bionics Cochlear Implants

25. The Advanced Bionics Cochlear Implants received market approval from Health Canada in February 2017.

26. Approximately 18,300 HiRes Ultra and HiRes Ultra 3D implants manufactured by the company were implanted worldwide, with about 6,000 being implanted into children.

27. The Cochlear Implants were essentially a smaller repackaging of the commercially available HiRes 90K and HiRes 90K Advantage cochlear implants (the “predecessor Cochlear Implants” or “predecessor devices”), which had been on the market since the mid-2000’s.

28. These predecessor devices had been recalled several times. The first time was in 2004 for symptoms that included sudden pain, loud noises, popping sounds, and intermittent functioning.

- 10 -

29. The second time was in 2006, when the FDA discovered that Advanced Bionics had changed components in the device without notifying the FDA and obtaining the regulator's approval. Advanced Bionics was required to pay the U.S. government \$1.1 million in 2008 to settle penalties resulting from that recall.

30. A third recall was in November 2010 after reports of patients experiencing malfunctions that resulted in severe pain, overly loud sounds, and shocking sensations after the cochlear implants were activated.

31. The FDA's MAUDE database, which records device failures and their root causes, contains over 500 instances of device failures in the HR 90K devices, many for loss of hermeticity.

32. The internal components of the HiRes Ultra and HiRes Ultra 3D include either a HiFocus SlimJ electrode array or a HiFocus Mid-Scala electrode (the "electrodes"). These electrodes are implanted surgically under the skin behind the ear. The electrodes used in the HiRes Ultra and HiRes Ultra 3D are of the same or substantially similar design to the electrodes used in the HiRes 90K predecessor devices.

Fig. 2 – HiRes Ultra 3D with SlimJ and Mid-Scala Electrode Arrays

(over)



33. Advanced Bionics performed minimal studies of the electrodes in the HiRes Ultra and HiRes Ultra 3D Cochlear Implants before bringing these electrodes to market. In the limited number of clinical studies it did perform, it found a significant number of incidences of vestibular effects, including imbalance, dizziness, spinning sensations, vertigo, and related outcomes. Despite these numerous and medically significant adverse events, Advanced Bionics proceeded to seek and obtain market approval in Europe, Canada and the USA on the basis that the Cochlear Implants were safe and effective for use and substantially equivalent to the predecessor devices.

34. The Cochlear Implants, like the predecessor devices, were prone to fluid ingress at the components implanted under the skin. This resulted in outcomes that include prolonged hearing degradation due to bodily fluids entering into the electrode, interruption of stimulation that negatively affects device performance, loud noises inside the inner ear, complete device failure, intermittent functioning, cracking or popping noises, pain throughout the face or subtle shocks to the face, reduced hearing in

patients, vertigo, dizziness, convulsions, and ultimately the need for surgery to remove and replace the device.

35. In 2016, Dr. Thomas Lenarz (“Dr. Lenarz”), a world-renowned otolaryngologist with a subspecialty in cochlear implants, and his colleagues at a clinic in Hannover, Germany, began implanting Advanced Bionics HiRes Ultra Cochlear Implants as part of a clinical trial. By early 2019, he and colleagues had implanted 349 patients, of whom 181 had experienced a device failure, and of those, 120 had already required surgery to remove and replace them.

36. Throughout the course of the clinical trial, and as late as April 2019, Dr. Lenarz had communicated with the Defendants and advised them of the unique type of failure mode, the number of failures, the likely cause of the failures, and had provided them with the numerous devices which had been explanted so that Advanced Bionics could analyse the root cause of the failures.

37. Once the Defendants understood the cause of the failures, which was as early as the first quarter of 2019, they began research and development of a “work-around” to rectify the problem, while at the same time continuing to market and sell these defective devices for implantation, representing them to be safe and effective.

38. The Defendants also began preparation of regulatory submissions to the FDA and other regulators by August 2019 or earlier, in order to obtain regulatory approval for replacement devices, which it called the HiRes Ultra “V2” and HiRes Ultra 3D “V2”, notwithstanding that they continued to market, sell and implant the “V1” models, which they now knew to be defective and unsafe.

39. The FDA granted 510K regulatory approval for the V2 model on December 28, 2019, but it was only on February 18, 2020, that the Defendants took corrective action with respect to the V1 devices. For almost 1 year, the Defendants marketed its V1 Cochlear Implant as being safe and effective, and promoting it to be implanted into

patients, knowing that these patients would likely require revision surgery because the device was defective.

40. The Plaintiff states and the fact is that Paul, prior to his original implant surgery, communicated directly with the Defendants' representatives, and was assured by them that the device they knew to be unsafe and defective was safe and effective. Based on those representations, Paul agreed to be implanted with a Cochlear Implant on August 23, 2019.

41. The failure of a cochlear implant is a serious medical event. Medical and device-related complications can cause physical discomfort (for example, fever and pain), as well as problems in personal functioning (for example, in speech discrimination, social behaviour, and mood).

42. In children, early access to hearing is critical and a lack of auditory stimulation can cause delay or deviations in neural development that have long-lasting harmful effects on auditory development, language acquisition, and even higher-level cognitive abilities. Similarly, for prelingual patients, unilateral auditory input can cause asymmetrical development of the auditory cortex, which can compromise the way that the auditory system responds to stimulation from a subsequent implant in the contralateral ear.

43. In cases where the cochlear implant causes adverse effects such as vertigo, dizziness, or convulsions, the outcomes in both children and adults can be associated with serious risks *unrelated to hearing*, such as falls, motor vehicle accidents, and other physical injuries caused by vertigo, dizziness, or convulsions. Episodes of vertigo, dizziness, or convulsions secondary to cochlear implant malfunctions can also be emotionally, psychologically, and socially impactful and disabling.

44. Revision surgery (with or without re-implantation) is also a serious medical event. Risks and complications associated with these surgeries include:

- Total hearing loss;
- Bacterial meningitis (causing swelling of the brain and spine);
- Tissue death;
- Facial nerve damage;
- Cerebrospinal fluid leakage;
- Perilymph fluid leakage;
- Skin wound infection;
- Blood or fluid collection at the surgical site;
- Dizziness or vertigo;
- Tinnitus (ringing in the ears);
- Sensory trouble (i.e., taste is affected);
- Numbness around ear; and
- Inflammation and implant rejection.

THE PLAINTIFF'S EXPERIENCE

45. Paul was implanted with the Advanced Bionics Ultra HiRes Cochlear Implant on August 23, 2019, at Sunnybrook Health Sciences Centre ("Sunnybrook") in Toronto, Ontario.

46. Following that implant surgery, Paul began suffering from infections and episodes of significant vertigo, dizziness, and convulsions. Paul suffered multiple episodes of vertigo and convulsions, accompanied with nausea.

47. Paul also suffered a degradation in device functionality, fluctuating volume, and loss of acuity, including a loss of speech recognition. He became socially isolated and depressed. He would re-attend often at Sunnybrook to meet with his audiologists for reprogramming because of the fluctuating losses of volume, acuity, and quality.

48. During the entire time that Paul was implanted with the Cochlear Implant, he was treated, monitored, assessed by one or more of the Defendants, its agents and employees, and his Cochlear Implant was serviced and assessed by the Defendants'

agents and employees, who periodically reprogrammed and replaced parts or components of his Cochlear Implant.

49. As a consequence of the Cochlear Implant's malfunctions and failure, Paul was disabled from working for a significant period of time.

50. Particulars of the damage sustained by Paul include:

- (a) Infection;
- (b) Loss of hearing and speech recognition;
- (c) Depression and social isolation;
- (d) Debilitating convulsions, vertigo, and attacks of dizziness;
- (e) Income loss; and
- (f) The need for unnecessary and invasive surgeries.

51. Prior to his implant, Paul was a full-time machine operator, and also operated a small business providing building contractor services. Since the implantation of the defective Cochlear Implant, Paul has suffered lost employment and business income as a result of the Defendants' negligence.

52. Paul will require extensive medical monitoring as a result of the defective implant and the Defendants' negligence. In addition, Paul has been put to a significantly higher risk of future medical complications.

53. Paul required a replacement Cochlear Implant. An Advanced Bionics company representative contacted him and urged him to agree to be implanted with another Advanced Bionics Cochlear Implant (a HiRes Ultra 3D "V2"). She represented that the replacement device was free from those defects which had caused the failure of his first device. In October 2022, Paul underwent the replacement surgery at Sunnybrook. If that cochlear implant also fails, he will need to undergo further surgery at greatly increased

risks, provided that the 2-prior implant/revision surgeries have not already caused too much structural damage to the inner ear and cochlea to allow for further surgeries.

54. Paul was not warned by the Defendants of the true risks and adverse events associated with the use of the Cochlear Implant. Had he been so advised before its implant, he would have refused this medical product and insisted on a safer alternative treatment. Had he been advised after its implant, he would have insisted on revision surgery earlier, thereby avoiding further injuries and damages. But for the Defendants' negligence and unlawful conduct, he would not have suffered his injuries and incurred his damages.

55. Paul's family and other Family Law Claimants have suffered and continue to suffer damages, including loss of income due to work absences required to attend to, care for and provide services to Class members, loss of care, guidance and companionship and expenses and special damages from loss of services formerly provided by Class members.

THE DEFENDANT'S NEGLIGENCE

(A) The Duty of Care

56. The Plaintiff states and the fact is that the Defendants, to further their business model and enhance profitability, actively encouraged a quasi-fiduciary relationship with Paul and other Cochlear Implant patients, actively monitoring their medical status, providing specialized testing unavailable to Paul's physicians and care providers, sharing Paul's medical and device-related information with one another, and providing medical advice on whether the device should be retained or revised. As a result, the Defendants owed the Paul and the Plaintiff Class a duty of care:

- (a) to properly design, manufacture, and test the Cochlear Implants;
- (b) to label, market, distribute and sell the Cochlear Implants

- 17 -

- (c) to ensure they were safe and free from defects prior to labelling, marketing, distributing and selling the Cochlear Implants;
- (d) to ensure that the Cochlear Implants were fit for their intended or reasonably foreseeable use prior to labelling, marketing, distributing and/or selling the Cochlear Implants;
- (e) to properly supervise its employees and consultants;
- (f) to monitor, investigate, evaluate and follow up on adverse events from the use of the Cochlear Implants throughout the world;
- (g) to warn the Plaintiffs and the Class that the Cochlear Implants carried a significant risk of malfunction, including shock causing convulsions, dizziness, and vertigo;
- (h) to ensure that audiologists, physicians, surgeons and implant recipients were kept fully and completely informed of all risks associated with using the Cochlear Implants, including the excessive risk of fluid ingress and the excessive risk that the implant would have to be replaced earlier than expected;
- (i) to disclose all risks to implant recipients in retaining the Cochlear Implants;
- (j) to properly and promptly inform Health Canada and other regulatory agencies of the changing and increasing risks associated with using the Cochlear Implants; and
- (k) to provide clear and proper communications to audiologists, physicians and patients, including how to carefully monitor patients, and precautions to be taken, so as to avoid injury or damage from the Cochlear Implants.

(B) Breach of Standard of Care

(i) Defective Design and Insufficient Testing

57. The Defendants fell below the standard of care to be expected of a fiduciary and a manufacturer of safe and effective devices intended for a vulnerable and disabled patient population, including Paul and the Plaintiff Class, as follows:

- (a) they improperly designed the Cochlear Implants, causing them to fail well before the natural life cycle of cochlear implants;
- (b) they failed to properly train and supervise their employees who were responsible for the assembly, servicing, and manufacturing of the Cochlear Implants;
- (c) they failed to conduct adequate tests and clinical trials initially and on an ongoing basis to determine whether the design of the Cochlear Implants was defective, thereby increasing the risks of injury and harm associated with the use of the Cochlear Implants;
- (d) they failed to conduct adequate tests and clinical trials initially and on an ongoing basis to determine the long-term effects and degree of risk associated with using the Cochlear Implants;
- (e) they were aware or ought to have been aware that the Cochlear Implants were unfit and defective and ought not to have been introduced into the market place;
- (f) they failed to provide proper long-term investigations of the effects and risks of continued use of the Cochlear Implants; and
- (g) they failed to fix the defects in the Cochlear Implants as soon as possible after they became aware of the defects and the injuries and risks associated with their use, or to withdraw the Cochlear Implants from the marketplace as soon as possible after they became aware of the defects and the injuries and risks associated with their use.

(ii) Defective Manufacturing

58. The Defendants' conduct fell below the expected standard of care with respect to the manufacturing and assembly of the Cochlear Implants as follows:

- (a) they failed to assemble and manufacture the Cochlear Implants so they would operate safely and effectively without exposing their consumers to undue risks;
- (b) they used inappropriate materials to manufacture the Cochlear Implants;
- (c) they failed to properly train and supervise their employees who were responsible for the assembly and manufacturing of the Cochlear Implants; and
- (d) they failed to properly supervise their employees and consultants involved in the assembly and manufacture of the Cochlear Implants.

(iii) Failure to Warn

59. The Defendants conduct fell below the expected standard of care owed to the Paul and the Plaintiff Class with respect to their duty to warn of the defects in the design and manufacturing of the Cochlear Implants as follows:

- (a) they failed to properly label, distribute, market and sell the Cochlear Implants and failed to ensure they were safe and free from defects prior to selling or distributing them;
- (b) they failed to ensure that the Cochlear Implants were fit for their intended or reasonably foreseeable use prior to labelling, marketing, distributing and selling them;
- (c) they failed to properly train and supervise their employees and consultants involved in labelling, marketing, distributing and selling the Cochlear Implants;

- 20 -

- (d) they were aware or ought to have been aware that the Cochlear Implants were unfit and defective and ought not to have been introduced into the marketplace;
- (e) When they became aware from field reports that the Cochlear Implants were unfit and defective, they continued to market the devices as safe and effective, and failed to warn patients;
- (f) they labelled, marketed, distributed and sold the Cochlear Implants without adequately disclosing the risks associated with using the Cochlear Implants;
- (g) they failed to give Health Canada or other regulatory agencies complete and accurate information concerning the Cochlear Implants by failing to disclose the problems with the Cochlear Implants on a timely basis or at all;
- (h) they failed to properly and promptly inform Health Canada and other regulatory agencies of the changing and increasing risks associated with using the Cochlear Implants;
- (i) they failed to adequately warn the Plaintiff, the Class, and their physicians and surgeons of all the risks then known or which were reasonably foreseeable in using the Cochlear Implants;
- (j) they knew or ought to have known that the Cochlear Implants posed significant risk of premature failure, fluid ingress, and associated adverse events, including vertigo, dizziness, and convulsions, and that the implants would have to be replaced in significantly fewer years than expected, and they failed to warn the Plaintiff and the Class but instead continued to sell, market and distribute the Cochlear Implants throughout Canada and the rest of the world;
- (k) they failed to warn the Plaintiff, the Class, and their audiologists, physicians, and surgeons about the need for comprehensive

regular medical monitoring to ensure early discovery of complications from the use of the Cochlear Implants set out above;

- (l) they failed to adequately monitor, evaluate, follow up and act promptly upon adverse reactions and high revision rates in the Cochlear Implants in Canada and throughout the world;
- (m) they failed to establish any adequate procedures to educate their sales representatives respecting the risks associated with the Cochlear Implants;
- (n) they continued to distribute and sell the Cochlear Implants notwithstanding that the FDA and Health Canada had received numerous complaints involving patients with Cochlear Implants;
- (o) they failed to promptly recall the Cochlear Implants; and
- (p) they failed to provide clear and proper instructions to audiologists, physicians, and patients, including patient monitoring and precautions to be taken so as to avoid injury or damage from the Cochlear Implants.

60. The defects and risks associated with the Cochlear Implants were in the Defendants' exclusive knowledge and control. The extent of the defects and risks were not known and could not have been known to the Plaintiff or the Class. The injuries of the Plaintiff and the Class would not have occurred but for the negligence of the Defendants in failing to ensure that the Cochlear Implants were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with the Cochlear Implants to the Plaintiff, the Class and to their audiologists and physicians.

61. The Defendants were aware or ought to have been aware of the high degree of complication and failure rates associated with the Cochlear Implants from the outset.

62. The Defendants were aware or ought to have been aware of the defects in the manufacture and design from the outset.

(C) Regulatory Duties

63. The Plaintiff pleads and relies upon the following statutes and regulations which were breached by the Defendants:

- (a) *Food and Drugs Act*, R.S.C. 1985, c. F-27, s. 20(1); and
- (b) the *Medical Devices Regulations*, SOR/98-282, ss. 9, 10-13, 15-18, 59- 61.1 and 64-65.1.

64. The Defendants' common law duties are informed by the *Medical Devices Regulations*, SOR/98-282. Pursuant to those regulations, each of the Defendants is a "manufacturer". They designed and assembled the Cochlear Implants, attached their trade name to it, labelled it and assigned it a purpose.

65. The regulations impose continuous obligations on the Defendants, commencing at licensing and continuing thereafter. They require the Defendants to ensure the safety of the Cochlear Implants before selling them, and to continuously monitor the safety of the Cochlear Implants 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 actions, including issuing a warning or recall, if new information becomes available which later alters the Cochlear Implants' risk profile.

66. Pursuant to s. 9 of the *Medical Devices Regulations*, the Defendants were required to maintain objective evidence to establish the safety of the Cochlear Implants. The Defendants breached this section. They failed to adequately obtain such information before licencing and to promptly update such information thereafter.

67. Pursuant to s. 10 of the *Medical Devices Regulations*, the Defendants were required to identify the risks of the Cochlear Implants, to eliminate or reduce those risks if possible, and to provide safety information with the Cochlear Implants concerning those risks which remained. The Defendants breached this section. They failed to eliminate the risk that the Cochlear Implants would prematurely fail and cause injury, and they failed to warn against this risk.

68. Pursuant to s. 11 of the *Medical Devices Regulations*, the Defendants were required to assess the risks of the Cochlear Implants against their benefit, and to not sell a product whose risks outweigh its benefits. The Defendants breached this section. The risk of the Cochlear Implants clearly outweighed their benefits.

69. Pursuant to s. 12 of the *Medical Devices Regulations*, the Defendants were required to ensure that the Cochlear Implants were effective for the uses for which they were represented. The Defendants breached this section. The Cochlear Implants were not effective.

(D) Causation

70. The Plaintiff pleads that he and the other Class members would not have had the Cochlear Implants implanted had they been aware of the true risks and defects. There were safer and economically feasible alternative implants available in the marketplace. The propensity of the Cochlear Implants to injure those who were implanted far outweighed any value to their use. In fact, there was no value to their use.

71. The Defendants' negligence in the design, manufacture and selling of the defective Cochlear Implants led to the damages sustained by the class.

(E) Damages

72. Paul and the Plaintiff Class have suffered and will continue to suffer damages as a direct result of the Defendants' negligence including, but not limited to:

- 24 -

- (a) enduring or having to endure painful medical procedures to implant the Cochlear Implants;
- (b) enduring or having to endure painful medical procedures to remove the Cochlear Implants;
- (c) enduring or having to endure painful medical procedures to implant cochlear implants that are free of defects;
- (d) personal injury, including dizziness, vertigo and convulsions and any associated accidents or injuries arising from those episodes, pain, inflammation, swelling, scarring, infection and other adverse effects and complications associated with the Cochlear Implants, corrective investigations and surgeries, and the adverse effects of the diseases which necessitated the implant of the Cochlear Implants in the first place;
- (e) severe emotional distress related to the pain and suffering associated with defective Cochlear Implants;
- (f) psychological injury and illness, including anxiety, social isolation, and depression;
- (g) the risk of death or other serious injuries;
- (h) costs associated with replacing the Cochlear Implants;
- (i) costs associated with monitoring the Cochlear Implants;
- (j) out-of-pocket expenses incurred by the Class Members or for their benefit; and
- (k) loss of income.

73. Members of the Class who may not require revision surgeries to remove their Cochlear Implants will nonetheless suffer damages from the cost of additional monitoring of their Cochlear Implants, including, but not limited to, frequent monitoring, diagnostic testing, and developmental issues in relation to auditory function, and will suffer physical, psychiatric, and psychological injuries as well.

74. Paul and the Plaintiff Class have suffered injuries which are permanent and lasting in nature, including diminished enjoyment of life as well as the need for lifelong medical treatment, monitoring and/or medications.

75. As a result of the Defendants' conduct described above, the Family Law Claimants have suffered damages, including, but not limited to:

- (a) actual expenses reasonably incurred for the benefit of Class Members;
- (b) travelling expenses incurred while visiting Class Members during treatment or recovery;
- (c) loss of income or the value of services provided for Class Members where services, including nursing and housekeeping, have been provided; and
- (d) compensation for loss of support, guidance, care and companionship that they might reasonably have expected to receive from Class Members.

76. All relevant provincial and territorial health insurers have incurred expenses with respect to the purchase of the Cochlear Implants and the medical treatment of the Plaintiff and the Class as a result of the Defendants' negligence. Consequently, the health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their direct right of action or right of subrogation in respect of all past and future insured services. This action is maintained on behalf of all provincial and territorial health insurers.

77. The above-described damages were foreseeable as a result of the Defendants' actions.

(F) Punitive Damages

78. Paul and the Plaintiff Class claim punitive damages as a result of the egregious, outrageous and unlawful conduct of the Defendants and, in particular, their callous disregard for the health and lives of vulnerable disabled adult and paediatric patients in Canada. In particular, the Defendants' conduct in continuing to manufacture, market, sell, and distribute the Cochlear Implants after obtaining knowledge the devices were defective, failing, and not performing as represented and intended showed complete indifference to or a conscious disregard for the safety of others justifying an award of punitive damages in a sum which will serve to deter the Defendants from similar conduct in the future.

79. Further, the Defendants, in the pursuit of profit, cultivated a close quasi-fiduciary relationship with disabled adult and paediatric implant patients, bypassing these patients' health care professionals, by providing monitoring, testing, and care. At the same time, the Defendants possessed far greater knowledge about the device's malfunctions, defects, failures rates, and the root causes of failure than the patients' physicians and audiologists.

80. Despite their superior knowledge, and their duty to disclose the risks of harm caused by their device, the Defendants, in order to protect their market share and profit, failed to make disclosure, delayed the inevitable corrective action until a replacement work around device was designed and manufactured, and allowed patients to be implanted with a device they knew to be defective.

REAL AND SUBSTANTIAL CONNECTION WITH ONTARIO

81. The Plaintiff and the Class plead that this action has a real and substantial connection with Ontario because, among other things:

- (a) the Defendants distribute and sell their products in Ontario and derive substantial revenue from such sales;

- 27 -

- (b) the application to Health Canada for permission to market the Cochlear Implants in Canada was made in Ottawa, Ontario;
- (c) the Defendants hold the licence to patents for the Cochlear Implants which patents are registered with the Canadian Intellectual Property Office in Ottawa;
- (d) the trademarks for the HiRes Ultra and HiRes Ultra 3D were registered with the Canadian Intellectual Property Office in Ottawa;
- (e) the Defendants advertised their products, including the Cochlear Implants, in Ontario;
- (f) the Defendants conducted research on their devices in Ontario;
- (g) the tort was committed in the province;
- (h) the Plaintiff and other Class members were implanted with their Cochlear Implants and sustained consequent damages in Ontario;
and
- (i) the Defendants are necessary and proper parties to the action.

82. The Plaintiffs plead and rely on s. 17.02(g), (h), (o) and (p) of the *Rules of Civil Procedure* permitting service outside Ontario in respect of the foreign Defendants.

83. The Plaintiff pleads and relies upon the following health care statutes with respect to those subrogated claims of Class members:

- (a) *Health Insurance Act*, R.S.O. 1990, c. H-6;
- (b) *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27;
- (c) *Alberta Health Care Insurance Act*, R.S.A. 2000, c. A-20;
- (d) *Health Administration Act*, R.S.S. 1978, D-17;
- (e) *Health Services Insurance Act*, C.C.S.M., c. H35;
- (f) *Manitoba Public Insurance Corporation Act*, C.C.S.M., c. P215
- (g) *Hospital Services Act*, R.S.N.B. 1973, c. H-9;

- (h) *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197;
- (i) *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8;
- (j) *Medical Care and Hospital Insurance Act*, S.N.L. 2016, c. M-5.01;
- (k) *Health Insurance Act*, R.S.Q., c. A-29;
- (l) *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3; and
- (m) *Hospital Insurance Services Act*, R.S.Y. 2002, c. 112.

84. The Plaintiff pleads and relies upon the following provincial statutes with respect to family member claims of the Plaintiff Class:

- (a) *Family Law Act*, R.S.O. 1990, c. F.3;
- (b) *Tort-feasors Act*, R.S.A. 2000, c. T-5;
- (c) *Family Law Act*, R.S.A. 2003, c. F-4.5;
- (d) *Fatal Accidents Act*, R.S.A. 2000, c. F-8;
- (e) *The Fatal Accidents Act*, R.S.S. 1978, c. F-11;
- (f) *The Fatal Accidents Act*, C.C.S.M., c. F50;
- (g) *Fatal Accidents Act*, R.S.N.B. 2012, c. 104;
- (h) *Fatal Injuries Act*, R.S.N.S. 1989, c. 163;
- (i) *Fatal Accidents Act*, R.S.P.E.I. 1988, c. F-5;
- (j) *Fatal Accidents Act*, R.S.N.L. 1990, c. F-6;
- (k) *Fatal Accidents Act*, R.S.Y. 2002, c. 86;
- (l) *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3; and
- (m) *Civil Code of Québec*, c. CCQ-1991.

- 29 -

April 27, 2023

GLUCKSTEIN LAWYERS

301-595 Bay Street
P.O. Box 53
Toronto, ON M5G 2C2

James M. Newland (23502M)

newland@gluckstein.com
Tel: (416) 408-4252 ext. 329
Fax: (416) 408-4235

Brian Moher (51095S)

moher@gluckstein.com
Tel: (416) 408-4252 ext. 292
Fax: (416) 408-4235

Lawyers for the Plaintiff

PAUL PEDERSEN

Plaintiff

- and -

ADVANCED BIONICS CORPORATION et al

Defendants

Court File No.

**ONTARIO
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at Toronto

Proceedings under the *Class Proceedings Act*, 1992

STATEMENT OF CLAIM

GLUCKSTEIN LAWYERS

301-595 Bay Street
P.O. Box 53
Toronto, ON M5G 2C2

James M. Newland (23502M)

newland@gluckstein.com
Tel: (416) 408-4252 ext. 329
Fax: (416) 408-4235

Brian Moher (51095S)

moher@gluckstein.com
Tel: (416) 408-4252 ext. 292
Fax: (416) 408-4235

Lawyers for the Plaintiff