CITATION: Pedersen v. Advanced Bionics LLC, 2026 ONSC 2239
COURT FILE NO.: CV-23-00698642-00CP
DATE: 20260421

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SUPERIOR COURT OF JUSTICE - ONTARIO

RE: PAUL PEDERSEN, Plaintiff

– and –

ADVANCED BIONICS LLC, NATIONAL HEARING SERVICES INC. c.o.b. as CONNECT HEARING CANADA, ADVANCD BIONICS AG, and SONOVA CANADA INC., Defendants

BEFORE: Justice E.M. Morgan

COUNSEL: *Margaret L. Waddell, Jordan D. Assaraf, Michael Steven Rastin, Sumaiya Akhter, and Luca Bellisario*, for the Plaintiff

Sarah J. Armstrong, Paul J. Martin, Philippe L. Desrosiers and Adam Gilani, for the Defendants

HEARD: April 8-10, 2026

CERTIFICATION MOTION

[1] The Plaintiff moves to certify this proposed class action pursuant to section 5(1) of the *Class Proceedings Act, 1992*, SO 1992, c. 6.

[2] The Second Amended Statement of Claim alleges that the medical devices designed, manufactured, marketed, and sold by the Defendants – cochlear implants that are surgically implanted and that permit hearing impaired persons to experience sound – are risky, defective, and require users to undergo invasive revision surgery to have the device removed and replaced.

[3] The Defendants submit that while there have been some cases of failed devices that require replacement, each patient's medical situation is unique and that individual causation issues predominate over any common issues such that the action cannot be pursued on a class basis.

I. The devices and the allegations

[4] Cochlear implants are electronic devices that convert sound into electronic impulses and that, when surgically implanted and connected to the auditory nerve, provide an ability to hear for persons who are hearing impaired. Unlike other amplification hearing aids, which are used externally and are readily removed if necessary, an implanted electrode array is installed with an invasive surgical procedure and can only be removed by means of a painful and potentially dangerous surgical intervention. These internal implants are developed to last for the patient's entire lifetime.

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[5] The Plaintiff's claim alleges that due to a design defect the Defendants' devices are prone to seepage of bodily fluids into the electoral array, which subjects the device to short circuiting and degrades its effectiveness. When this happens, the patient must go through surgery to remove and replace the defective device, followed by a difficult period of adjustment to the new implant in an effort to restore the ability to hear. Evidence in the record indicates that, to date, up to 50% of the Defendants' cochlear implants have failed in this way.

[6] Plaintiff's expert, Dr. Richard Gurgel, a professor of Neurotology and Skull Base Surgery and Director of the Cochlear Implant Program at the University of Utah, has opined that all of the Defendants' devices will eventually fail prematurely. That said, Dr. Gurgel also indicates in his report that there would need to be a personal medical assessment of each individual patient in respect of the effectiveness of their implanted device before embarking on revision surgery.

[7] On February 18, 2020, the Defendant, Advanced Bionics LLC, the manufacturer, announced the voluntary removal from the market of all the devices that had not yet been implanted into patients. It disseminated a letter to all patients with their surgically implanted devices that a "device issue" had been discovered "that could possibly affect the performance of your device." This letter was the first notice that the Defendants gave about the defect. This was followed up by the Defendants on February 21, 2020 with an "Urgent Field Action Notification" to healthcare professionals stating that they had "detected an increase in the number of initial HiRes Ultra and HiRes Ultra 3D device explants or the potential to be explanted as a result of a performance issue."

[8] Two months later, on April 17, 2020, Health Canada posted a Type II Medical Device Recall for the Defendants' cochlear implants, effective from February 18, 2020. At the same time, on February 17, 2020, the FDA in the United States published a similar recall of the Defendants' cochlear implants as a result of "Device Design," and, specifically, to "hearing performance degradation due to body-fluid entering the device." The Health Canada recall notice specified that the recall came about as a result of the discovery of a manufacturer's defect "… discovered during the device failure analysis on an explanted device on March 26, 2019."

[9] The February 2020 recall notices and advisories to patients and physicians were the first notice the Defendants gave regarding the issue. This was despite knowing of the potential for failure of their cochlear implant devices since March 2019. Indeed, in the February 21, 2020 "Urgent Field Action Notification", the Defendants stated that they had already had time to have "developed several improvements to the devices to address the issue", and that they had "received regulatory approval from the FDA in the US and Health Canada for these improvements." As

counsel for the Plaintiff points out, the record in this motion contains no evidence of, or any cogent explanation for, this delay in giving notice to patients or to healthcare providers.

[10] The Plaintiff's claim relates to the cochlear implants designed, marketed, sold, and serviced by the Defendants in Canada, other than in Quebec (where there is a separate action already authorized) between 2016 and February 18, 2020. The Defendants' records show that there are approximately 250 members of the proposed class, of which 50 are (or were at the time of having the devices implanted) minors under 18 years old. The evidence is not controverted that the hearing loss, revision surgery, and re-adaptation period is painful and psychologically difficult for patients. It is especially difficult for children whose skulls have grown around the original implant, and who gained the ability to hear with the initial surgery only to lose it again with the degradation of the device.

[11] Dr. Gurgel has opined on behalf of the Plaintiff and proposed class that there are a wide range of physiological and psychological impacts caused by the failure of a cochlear implant. Principal among these is, of course, hearing loss. In addition, there are less common, but nevertheless observable effects such as painful electrical discharges from the device that can cause facial nerve stimulation, dizziness and imbalance issues. According to Dr. Gurgel outcomes for these patients can vary in conjunction with complications from revision surgery, such that some patients do not regain their hearing potential.

[12] The Defendants have produced a report by Dr. Jeffrey P. Harris, the Chair Emeritus and Distinguished Professor in the Department of Otolaryngology – Head and Neck Surgery at the University of California, San Diego, who explains that device performance varies in accordance with the patient's specific circumstances. Factors that may have an impact include the cause or type of the patient's deafness, the length of time the patient experienced deafness prior to the surgical implantation, age, and the patient's general state of health and medical condition. As Dr. Harris puts it, regardless of whether the device suffers from a design flaw, "cochlear implant performance is shaped by a complex interplay of patient-specific factors."

[13] The Plaintiff's motion for certification is supported by, *inter alia*, the affidavits of two putative class members: the Plaintiff, Paul Pedersen, and Patric Boone. Each of these individuals depose about their hearing impairment and the great benefit they initially derived from having undergone the cochlear implant surgery and adjusted to the devices. They also each depose as to the deterioration of their hearing some time after the devices were implanted and their eventual need for the surgical extraction and replacement of those devices. Likewise, they each describe the pain, suffering, and losses they say they incurred due to the difficulties of the revision surgery and re-adjustment process.

[14] While each of these witnesses relates a compelling personal story, they each present challenges for the case that the proposed class would seek to make. That is, each of them in their own way illustrates the causation problem that Defendants' counsel identify as being the main obstacle to certification.

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[15] For example, in cross-examination Mr. Boone testified about his unique facial and cranial anatomy that made the initial implant surgery particularly risky and difficult. After his cochlear device was implanted, he sought treatment for a variety of maladies, including sleep apnea, high cholesterol, high blood pressure, gastroesophageal reflux, renal issues, glaucoma, anxiety, depression, sarcoidosis with accompanying lung nodules, and cardiac issues including a heart murmur and aortic stenosis. Most of these issues are unconnected, or only questionably connected, with his cochlear implant; and even some symptoms that Mr. Boone is certain are related to his implant, such as a reversal of the improvements he had felt in dealing with his long term vestibular balance problems, have continued long after his revision surgery, thereby casting doubt on the failed implants as being the true cause.

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[16] Mr. Pedersen's medical situation is even more complicated. In cross-examination, he explained that during the relevant period when he was suffering from his malfunctioning cochlear implant and his revision surgery, he also had cancer. His overall poor health inevitably makes one skeptical of his claims that a host of symptoms he has experienced – including vertigo and balance issues, nausea, headaches, mental fogginess, and convulsions or seizures – are causally related to the defective implants and/or the revision surgery. He also apparently experienced numbness, weakness and tingling in his arms and legs, as well as pain in his neck and shoulders, all of which according to Mr. Pedersen may or may not be related to the problems with his cochlear implants and which may therefore form part of the present claim.

[17] As with Mr. Boone, it is generally very difficult to discern what Mr. Pedersen considers is related to his cochlear implant experience and what is unrelated. In fact, he relates in his affidavit that although he is convinced that the bouts of vertigo he has experienced over time were directly related to his cochlear implant experience, that view is not shared by his own doctor. Mr. Pedersen deposes:

> Although my doctor at Sunnybrook did not consider that these physical effects were related to my Cochlear Implant, I had never experienced any of these effects to any kind of significant degree prior to being implanted with my Cochlear Implant device. While these effects largely resolved by October 2020, my vertigo remained quite severe until my revision surgery. Although not completely gone, my vertigo is minor and much more manageable post-revision surgery. I now only experience vertigo in a few, limited circumstances. Given that these debilitating symptoms largely resolved after the revision surgery, I feel strongly that they were caused by the initial Cochlear Implant.

[18] It is this complex causation situation that lies at the heart of the Defendants' argument against certification. Given the individualized assessment that the Boone and Pedersen claims seem to demand before concluding which harms flow from the design defects and other faults alleged against the Defendants, it is Defendants' counsels' view that individual issues will inevitably predominate over common issues contrary to the new and important certification requirement set out in section 5(1.1) of the *CPA*.

II. The certification requirements

a) Cause of action – section 5(1)(a)

[19] The Second Amended Statement of Claim pleads a number of causes of action: negligence in design, failure to warn, and failure to recall. The Plaintiff originally pleaded negligent manufacturing as well, but has since abandoned that claim.

[20] The question for each of the causes of action being pursued is whether it is "plain and obvious" that the claim cannot succeed, or "has no reasonable prospect of success": *Wright v. Horizons ETFS Management (Canada) Inc.*, 2020 ONCA 337, at para 58(f); *R. v. Imperial Tobacco Canada Ltd.*, [2011] 3 SCR 45, at para. 17. No evidence is admissible at this stage of the analysis, and pleadings of fact can be taken to be true unless they are patently ridiculous, incapable of proof, or are merely bald conclusory statements unsupported by material facts: *Lipson v. Cassels Brock & Blackwell LLP* (2013), 114 OR (3d) 481, at para. 87; *R. v. Imperial Tobacco*, at paras. 21-22.

[21] The Plaintiff advances causes of action in negligence in design, failure to warn, and failure to recall. The Plaintiff initially proposed a cause of action in negligent manufacturing of the devices, but has advised the Defendants and the Court that that head of liability is no longer being pursued.

[22] With respect to the claim for negligent product design, Plaintiff's counsel distill the following material facts pleaded in the Second Amended Statement of Claim:

> a) The Defendants were responsible for the research, design, manufacturing, distribution, sale and post-market monitoring of the Cochlear Implants, as well as for making representations to regulators about their safety;
>
> b) By no later than the first quarter of 2019, the Defendants were aware of the defects in the Cochlear Implants.
>
> > i) Clinical studies found a significant number of medically significant vestibular effects;
> >
> > ii) The Cochlear Implants were based on the predecessor devices, with a well-known fluid ingress and hermeticity defect, mirroring problems in the Cochlear Implants;
> >
> > iii) That defects were being found in significant numbers would have become apparent to the Defendants as part of their after-market servicing business;
> >
> > iv) In or before April 2019, clinical trials revealed a high percentage of patients experienced device failures and required revision surgeries; and,
> >
> > v) Once the Defendants understood the cause of the Cochlear Implant failures, they began researching and developing a 'work around' in the V2

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devices, and obtained regulatory approval for those devices in December 2019;

c) Though the Defendants knew by no later than Q1 2019 that the Cochlear Implants were dangerously defective and prone to failure, they continued to market, sell and distribute them until February 18, 2020, all the while representing them to be safe and effective;

d) The Defendants knew or should have known that the Cochlear Implants' defects made them prone to fluid ingress around the casing into the electrodes array, causing degradation, failure, the need for corrective surgery, and thus significant risk of bodily injury.

[23] The Defendants concede that there is a viable claim for design negligence. That concession alone passes the section 5(1)(a) hurdle, since a single cause of action is sufficient for certification purposes.

[24] The Defendants argue that there are no material facts pleaded that can support a claim for failure to warn. They submit that there are two scenarios where a failure to warn may represent a cause of action not doomed to fail: a) where the product is designed for safety, but there are inherent risks that the designer/manufacturer is aware of and is obliged to share its "informational advantage" with the user of the product; and b) if, after the product has been sold, it is discovered that it was not designed for safety, the designer/manufacturer is obliged to warn of such the design defect so that the user of the product can take steps to avoid injury: see *Hollis v. Dow Corning Corp.*, [1995] 4 SCR 634, at paras. 20-23.

[25] The Defendants say that neither version of the duty to warn is applicable or sensible in the present context. In the first place, they contend that a duty to warn runs counter to the Plaintiff's primary claim of design flaw. That is, if the design really was intrinsically flawed a warning would not assist the Defendants, and that sending out warning messages rather than correcting the design flaw would be no answer to the Plaintiff's claim: see *Nicholson v. John Deere Ltd.*, [1986] O.J. No. 1320 (HCJ), aff'd [1989] O.J. No. 495 (CA).

[26] Moreover, in a scenario where the design flaw is discovered, a claim of failure to warn runs contrary to the Plaintiff's own evidence. That is, Mr. Pedersen deposes that if he had been warned he would not have had the devices implanted. The Defendants say that in doing so, the Plaintiff has in effect acknowledged there is nothing he could have done to avoid the harms he suffered had been given a warning after implantation.

[27] A similar pattern of argument accompanies the Plaintiff's assertion of a claim for breach of the duty to recall. Defendants' counsel sites *Vester v. Boston Scientific Ltd.*, 2015 ONSC 7950, at para. 5, for the proposition that there are four duties recognized in product liability law: a) duty to manufacture a safe product, b) duty to warn of inherent risks of a product, c) duty to design a safe product, and d) duty to compensate for the cost of repair of a flawed product. None of these, according to Defendants' counsel, speak to a duty to recall a product in any circumstance.

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[28] Furthermore, it is the Defendants' view that while it may be prudent to recall certain products there is no duty to recall. They contend that in the absence of a recall, any liability for injuries that may have been prevented flows from the original design negligence and not from an unrecognized legal obligation to recall a product.

[29] The Defendants' arguments suggest that the larger fault – design negligence – subsumes the related faults – failure to warn or recall – because the injurious product should not have been sold in the first place, and that nothing further can be done to minimize losses among the consuming public. But that does not accord with the material facts pleaded by the Plaintiff. It is apparent that a warning will alert patients and health professionals of the design issues and will assist them in early identification of the source of the problem with a gradually failing device that causes gradually diminishing hearing. The material facts in relation to the Plaintiff point to the preventative effect of early intervention with a defectively designed cochlear, which will prevent more harms than late intervention after the patient has suffered the prolonged impact of a failed device.

[30] Accordingly, while the failure to warn may not replace liability for the negligent design, it may in the right circumstances supplement it. This cause of action, which is premised on the Defendants' early knowledge of the defective design and potential for harm, may also provide the foundation for a punitive damages claim if the requisite level of malintent is found in respect of the Defendants' failure to go public and to warn the vulnerable consumers of their product: *Nicholson v. John Deere Ltd*. (1986) 68 OR (2d) 191 (HCJ).

[31] Justice Perell explained the logic of a duty to warn in *Vester*, at para. 5:

> The manufacturer's duty to alert consumers about dangers associated with the use of a product is a continuing duty, requiring manufacturers to warn not only of dangers known at the time of sale, but also dangers discovered after the product has been sold and delivered…In the case of medical products, given their substantial risk of harm from improper use, the standard of care is correspondingly high and there will almost always be a heavy onus on the manufacturer to provide clear, complete and current information concerning the dangers inherent in the ordinary use of its product…

[32] The same logic holds true for a duty to recall. If, as Defendants' counsel submit, it is prudent to recall a product known to be defective and harmful, it is by definition imprudent – i.e. negligent – not to implement a recall.

[33] While the pleading sets out that the Defendants knew of the harms that could be caused by their devices in March 2019, it was not until Health Canada issued its recall notice in February 2020 that the products were removed from the market. During that time, class members were implanted with the devices and likely suffered otherwise avoidable injury.

[34] The fact that a stand-alone duty to recall has never been specifically recognized in the case law is not a reason in itself to reject this cause of action at the present stage. It is well accepted that novel claims, or previously unrecognized causes of action, should be litigated on a full factual record and not rejected on a pleadings basis alone. As the Court of Appeal put it in *Sienna v. Duckett*, 2025 ONCA 867, at para. 12, quoting *Imperial Tobacco*, at para. 21, "A claim should not be struck just because it has not yet been recognized, because the underlying law is unsettled, or because the plaintiff's odds of success seem slim. Rather, the court 'must be generous and err on the side of permitting a novel but arguable claim to proceed to trial.'"

[35] All three of the causes of action pleaded by the Plaintiff – including negligent design, failure to warn, and failure to recall, but not including negligent manufacturing – qualify as viable claims. None of them is inevitably destined to fail or can be said to have no prospect of success. The pleading establishes that the Plaintiff's action passes the certification hurdle in section 5(1)(a) of the *CPA*.

b) Identifiable class – section 5(1)(b)

[36] Generally speaking, the identifiable class requirement is not difficult to satisfy: *Andersen v. St Jude Medical, Inc.*, 2012 ONSC 3660 at para 186, at para. 97. The class must be defined with reference to objective criteria, and membership can be determined without reference to the merits of the action: *Hollick v. Toronto (City)*, [2001] 3 SCR 158, at para. 17.

[37] The Plaintiff proposes the following class definition:

> All persons who were implanted in Canada (excluding Quebec) with the HiRes Ultra CI HiFocus MS Electrode, HiRes Ultra CI HiFocus SlimJ Electrode, HiRES Ultra 3D CI with HiFocus SlimJ Electrode, HiRes Ultra 3D CI with HiFocus MS Electrode and HiRes Ultra 3D CI with HiFocus SlimJ Electrode (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").

[38] Turning to the first paragraph of the definition, membership in the class is objectively defined and can be verified through medical records, hospital records, the Defendants' list of implanted patients, and by self-identification. It does not depend on the merits of the claim or the outcome of the litigation. The problem with the definition, however, is that it is overly broad. It includes every person who has been implanted with the relevant devices, whether the particular device has failed or not. That broad a definition inevitably encompasses individuals who do not have a cause of action.

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[39] In *Palmer v. Teva Canada Limited*, 2024 ONCA 220, at para. 45, citing *Atlantic Lottery Corp. Inc. v. Babstock*, [2020] 2 SCR 420, Justice Miller stated on behalf of a unanimous Court that, "the negligent conduct of a defendant can only ground an obligation for compensation to the extent that it causes damage or an actual materialized loss. It is the materialized loss that gives rise to a defendant's obligation to compensate the plaintiff for the injury."

[40] In *Atlantic Lottery*, Justice Brown (for the majority) made reference to the writings of Canadian tort law scholars, who in turn make Justice Cardozo's well-known comment that there is no negligence "in the air": *Palsgraf v. Long Island Railroad Co.*, 248 N.Y. 339, 162 N.E. 99 (1928). Justice Brown explained, at para. 33:

> As this Court has maintained, '[a] defendant in an action in negligence is not a wrongdoer at large: he is a wrongdoer only in respect of the damage which he actually causes to the plaintiff' (*Clements v. Clements*, 2012 SCC 32, [2012] 2 S.C.R. 181, at para. 16). There is no right to be free from the *prospect* of damage; there is only a right not to *suffer* damage that results from exposure to unreasonable risk (E. J. Weinrib, *The Idea of Private Law* (rev. ed. 2012), at pp. 153 and 157-58; R. Stevens, *Torts and Rights* (2007), at pp. 44-45 and 99). In other words, negligence 'in the air' — the mere creation of risk — is not wrongful conduct. [emphasis in the original]

[41] Since the creation of risk, without material harm ensuing, is not itself tortious conduct, the class of injured claimants cannot include all persons implanted with the impugned devices. While Dr. Gurgel has opined that all of the Defendants' devices may eventually fail, the evidence in the record is that roughly 50% of them have actually failed.

[42] The evidence shows that surgeons consider there to be three categories of cochlear implant failures: (a) hard failure, (b) medical (or non-device) failure, and (c) soft (unverified) failure. Hard failures entail a malfunction within the device itself and are objectively measurable. A cochlear implant undergoing hard failure can be tested for changes in impedance, open circuits, or other anomalies. Hard failures are not only objectively measurable, but as Dr. Gurgel reports, they correspond to a specific electronic signature that can be measured by testing at a radiological clinic.

[43] In fact, Dr. Gurgel explained in cross-examination that the cochlear implant manufacturers, including the Defendants, typically test explanted devices and report their analyses to surgeons. The Defendants are therefore expected to possess documentation for each extracted device showing whether it was a hard failure likely caused by the fluid ingress issue as alleged in this claim.

[44] The present action does not concern medical failures unrelated to a failure of the Defendants' devices. It is likewise not concerned with soft failures that, while felt subjectively by a cochlear implant patient, cannot be objectively verified. Plaintiff's counsel expressly state in their factum that, "This action is about hard failures in the Cochlear Implants." That statement must therefore define the boundaries of the class. I would add it as a necessary element in the first paragraph of the Plaintiff's proposed definition.

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[45] The *Family Law Act* ("*FLA*") class is a derivative class which is dependant on the Implant Patient Class for membership. This class is likewise objectively defined and is bounded by relevant legislation. Ontario courts have approved class definitions for derivative *FLA*-based claims in previous medical device class proceedings: see e.g., *Anderson, supra*, at paras 17-21; *O'Brien v. Bard Canada Inc.*, 2015 ONSC 2470, at paras 166-174; *Vester, supra*, 2015 ONSC 7950, at paras 104-107.

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[46] Accordingly, I would amend the class definition as follows in order for it to meet the requirement for certification set out in section 5(1)(b) of the *CPA*:

> All persons who were implanted in Canada (excluding Quebec) with the HiRes Ultra CI HiFocus MS Electrode, HiRes Ultra CI HiFocus SlimJ Electrode, HiRES Ultra 3D CI with HiFocus SlimJ Electrode, HiRes Ultra 3D CI with HiFocus MS Electrode and HiRes Ultra 3D CI with HiFocus SlimJ Electrode (collectively, the "Cochlear Implants"), or any of the Cochlear Implant components including electrode arrays, *whose Cochlear Implants have undergone a hard failure* (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").

c) Common issues – section 5(1)(c)

[47] The following are the common issues proposed by the Plaintiff:

Liability Issues

Defective Devices

1. Were the Cochlear Implants defective or unfit for their intended use?

    a. If so, how?

2. If the answer to Q. 1 is yes, were the defect(s) in the Cochlear Implants caused by the negligent research, design, manufacturing, and/or testing of the Cochlear Implants by either Advanced Bionics LLC and/or Advanced Bionics AG?

Duty of Care

3. Did any of the Defendants owe a duty of care to the Class members?

    a. If so, what duty of care was owed to the Class by which Defendants?

4. If the answer to Q. 1 is yes, did any of the Defendants know or ought they reasonably to have known that the Cochlear Implants were defective or unfit for their intended use?

a. If so, when did the Defendants know or ought they reasonably to have known that the Cochlear Implants were defective or unfit for their intended use?

b. Did any of the Defendants owe the Class a duty to warn them of the defect(s) when the defect(s) became known to the Defendants?

c. If so, when did the duty to warn arise?

5. Did any one or more of the Defendants breach the duty to warn the Class of the defect(s) in the Cochlear Implants?

6. Did Advanced Bionics LLC, Advanced Bionics AG and/or Sonova Canada Inc. owe a duty to the Class to promptly recall the Cochlear Implants when the defect(s) became known to them?

a. If so, did Advanced Bionics LLC, Advanced Bionics AG and/or Sonova Canada Inc. breach the duty to recall by failing to do so on a timely basis?

FLA claims

7. Are any of the Defendants liable to the Family Law Claimants within the meaning of the following statutes:

a. *Family Law Act*, R.S.O. 1990, c. F.3, s. 61;

b. *Tort-feasors Act*, R.S.A. 2000, c. T-5, s. 2.1;

c. Civil Code of Quebec, c, CCQ-1991, article 1457.

Statutory breaches

8. Did any of the Defendants fail to identify, eliminate and/or reduce the risks associated with the Cochlear Implants, and fail to provide information regarding any remaining risks posed by the Cochlear Implants contrary to s. 20(1) of the *Food and Drugs Act*, R.S.C. 1985, c. F- 27 and the *Medical Devices Regulations*, S.O.R./98-282, ss. 9-13, 15-18, 58-61.1, 64- 65.1, and

a. If so, who, when, and how?

Damages

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General Damages

9. Are any of the Defendants liable to pay general damages to the Class Members?

a. If so, which Defendant(s) are liable, and in what amounts?

b. If so, can any of the general damages be assessed in the aggregate?

Pecuniary loss

10. Do screening, monitoring, and testing procedures exist which make the early detection of fluid ingress associated with the Cochlear Implants possible and beneficial?

a. If so, do the Sub-Class Members who have not undergone revision surgery to remove the Cochlear Implants have an increased need for screening, medical care, and testing procedures for early detection and treatment of fluid ingress associated with the Cochlear Implants?

b. If so, are Advanced Bionics LLC and/or Advanced Bionics AG required to fund or compensate Class Members and the Provincial Health Insurers for the costs of screening, monitoring, and treating fluid ingress associated with the Cochlear Implants?

11. Can the value of the claims of the Class Members be assessed on an aggregate basis, in whole or in part?

12. Are the Class Members "insured persons" who are entitled to recovery from the Defendants, or any of them, for the cost of health care services provided by Provincial and Territorial Health Insurers who have a subrogated interest pursuant the statutes set out below, including all applicable insured services in the following Acts:

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;

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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.

Punitive damages

13. Should punitive damages be awarded against any of the Defendants?

a. If so, what sum ought to be awarded, and against which Defendants?

[48] Counsel for the Defendants voice a number of objections and make numerous comments on this proposed list, each of which can be briefly explored. In doing so, it must be kept in mind that "[t]he question at the certification stage is not whether the claim is likely to succeed, but whether the suit is appropriately prosecuted as a class action": *Hollick*, at para. 16. The task of a motion court at the certification stage is to assess whether there is some basis in fact for each of the proposed common issues, but not to decide any the common issues themselves: *Fehr v. Sun Life Assurance Company of Canada*, 2018 ONCA 718, at paras. 86-87. One must be careful not to confuse the issue of whether a common question should be asked with the merits of the question that the proposed common issue poses: *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, [2013] 3 SCR 477, at para. 99.

[49] Although they would frame the liability issues as a single question with somewhat different wording, counsel for the Defendants essentially agrees that proposed questions 1 and 2 represent a valid common issue. The question of whether the Defendants' cochlear implant devices were designed negligently is at the core of the Plaintiff's claim and is shared by all of the putative class members. The Plaintiff has combined the design question with the questions of negligent research and testing, which are little more than specific aspects of the overall design process.

[50] One qualification that the Defendant would make to the proposed liability questions is to eliminate the issue of "manufacturing" from question 2. I agree with the Defendants and would eliminate that word from the proposed question. As previously indicated, the Plaintiff is no longer pursuing a claim for negligent manufacturing; accordingly, there is no relevance, and no basis in the factual record, for including the question of negligent manufacturing in the common issues.

[51] Defendants' counsel objects to question 3 about whether the Defendants owe a duty of care to the class members because the answer is self-evident. I agree that it has been a foundational

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principle of tort law for nearly a century that a party who designs and puts ginger beer (or any other product) into the market owes a duty of care to downstream users with respect to a snail (or any other defect) in the product. That said, there is no harm in asking a question of trite law as a logical prelude to the questions that follow it. Given the sequence of issues presented by Plaintiff's counsel, I would approve question 3 as a proper common issue.

[52] The objections to questions 4, 5, and 6 put forward by Defendants' counsel repeat their objections to the Plaintiff's causes of action in duty to warn and duty to recall. For the reasons set out in Part II(a) above, those are valid causes of action. And since the Plaintiff has pleaded those claims, the common issues supporting them are valid common issues. Questions about when the Defendants learned of the alleged defects in their devices and whether they had had a duty to issue any warnings or recalls, or did issue any warnings or recalls, and when those duties arose, all have a basis in fact and are logical issues going to the causes of action that the Plaintiffs have pleaded.

[53] Defendants' counsel objects to common issue 7 with respect to *Family Law Act* claims based on their view that those claims cannot be answered in common. It is the Defendants' position that these claims raise "theoretical" questions about legislation in different provinces, and that they can only be answered after an individual assessment of whether the claiming family member actually suffered a loss.

[54] I do not understand what is "theoretical" about a legislative right to compensation. While the governing statutes may vary province to province, those legal differences are always present in national class actions. Having to look at another province's legislation is not an "individual" issue that runs contrary to the commonality needed for a class action. Further, the claims are derivative of the class members' claims, and while quantification may vary with the family circumstances, the qualification for liability of a family class is a valid common issue question: *Pugliese v. Chartwell*, 2024 ONSC 1135, at para. 172.

[55] Defendants' counsel raises an objection to common issue 8 with respect to whether the Defendants' conduct breached the *Food and Drugs Act* and/or the *Medical Devices Regulations*. They submit in their factum that, "Canadian law is clear that contravening a regulatory statute does not, in itself, give rise to any legal remedy, and complying with a regulatory statute is not, in itself, proof that the defendant has acted non-negligently [citations omitted]." While that is accurate, Canadian law is equally clear that, "Legislative standards are relevant to the common law standard of care, but the two are not necessarily co-extensive": *Ryan v. Victoria (City)*, [1999] 1 SCR 201, at para. 29. While regulatory measures are not conclusive proof of standard of care, they do provide some basis in fact on which to premise a common issue: *Dine v. Biomet*, 2015 ONSC 7050, at para. 50.

[56] Common issues 9, 11, and 13 deal with general damages, aggregate damages, and punitive damages, respectively. Defendants' counsel objects to them all on essentially the same basis – that they cannot be answered in common. As Defendants' counsel express it in their factum, damages are not a common issue and cannot be awarded collectively "[i]n a tort action, where liability is established only with proof of compensable loss by each class member…"

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[57] The Defendants, however, ignore the distinction between liability and quantification. As Justice Belobaba pointed out in *Dine*, at n. 37, "the *prima facie* entitlement issue can be litigated at the common issues trial…" While there may have to be individual damages assessments following the determination of the common issues, those can be kept to a minimum by limiting general damages to the direct and immediate medical and monitoring consequences of the device failure and ensuing surgery.

[58] As discussed in Part II(d) below, Plaintiff's counsel have indicated that they will be limiting the class' claim to only those losses directly related to the harm caused by a defective cochlear implant device. That will eliminate further consequential damages claims. And while that will not make all claimants' damages uniform, it will provide a base level of commonality on which damages could be considered without individual proof. The Court of Appeal expressly endorsed this approach in *Good v. Toronto (Police Services Board)*, 2016 ONCA 250, at para. 75:

> [I]t would be open to a common issues judge to determine that there was a base amount of damages that any member of the class (or subclass) was entitled to as compensation for breach of his or her rights. [Divisional Court] wrote, at para. 73 , that '[i]t does not require an individual assessment of each person's situation to determine that, if anyone is unlawfully detained in breach of their rights at common law or under s. 9 of the Charter, a minimum award of damages in a certain amount is justified'.

[59] Likewise, the question of punitive damages is directed far more to the Defendants' knowledge and conduct than to any individual evidence that the class members need to adduce. The requisite analysis will therefore be equally applicable across the class. Given the timing of the earliest device failure, there is at least some basis in fact to ask about punitive damages.

[60] Accordingly, the questions relating to general, aggregate, and punitive damages are all proper common issues.

[61] Finally, the Defendants object to common issues 10 and 12 with respect to health insurance claims. Question 10 address the specific question of whether increased testing and monitoring, and the costs thereof, are part of the harm caused by defective cochlear devices, while question 12 relates to whether such amounts are recoverable from provincial health insurers. As with the *Family Law Act* claims, Defendants' counsel submits that the varying legislative criteria for health cost coverage across the provinces makes these questions impossible to answer on a common basis.

[62] With respect, I disagree with the Defendants' position. National class actions can accommodate legislative differences without undermining commonality among the class members. Those differences raise distinctions of law and policy inherent to a federal constitutional structure; they do not raise individual differences that run counter to a common factual basis and common experience among class members. Increased testing, monitoring, and medical intervention may be billed slightly differently in Ontario and, say, Manitoba, but within the context of any one provincial health insurance scheme the class members' position can be addressed in

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common. I see no reason to exclude these questions from the common issues raised by the present claim.

[63] In sum, the common issues as proposed by Plaintiff and his counsel are all valid common issues. The one modification is that the word "manufacturing" is to be removed from question 2.

d) Preferable procedure – sections 5(1.1) and 5(1)(d)

[64] The preferable procedure requirement lies at the core of the Defendants' opposition to certification. That includes both the long established version in section 5(1)(d) of the *CPA*, and the more recently enacted requirement in section 5(1.1)(b) that "the questions of fact or law common to the class members predominate over any questions affecting only individual class members."

[65] The Defendants submit that the nature of the Plaintiff's claim, the extensive and varied types of harm that he alleges he has suffered, and the fact that causation cannot be determined on a class-wide basis, mean that individual issues will predominate over common issues. They argue that in that case, the action is not suitable for certification.

[66] In *Banman v. Ontario*, 2023 ONSC 6187, at para. 317, Justice Perell acknowledged that the section 5(1.1)(b) requirement was enacted with the intent to "raise the threshold, heighten the barrier, or make more rigorous the challenge of satisfying the preferable procedure criterion." He went on to explain, at para. 318, that "[t]he factor that the common issues taken as a whole must predominate is a test of anticipated productivity and a type of inferiority test. If the common issues do not predominate then a class action is not productive and is inferior (not superior) to the alternative of proceeding immediately to individual issues trials."

[67] Counsel for the Defendants submit that this explanation does little more than to paraphrase the statute. Justice Perell's primary characterization of the change introduced by section 5(1.1)(b) adds little specificity to an overall understanding of the statutory language: "There is a subtle but significant element in the emphasis in the new test that the common issues predominate over the individual issues. The subtle point is that it is the common issues – taken together – that must predominate over the individual issues": *Ibid*., at para. 322.

[68] Counsel for the Plaintiff submit that section 5(1.1)(b) adds virtually nothing new to the pre-existing analysis of preferability under section 5(1)(d). They submit that to satisfy both the new section and the pre-existing section on preferability, the Plaintiff must show some basis in fact that a class action would: (a) be a fair, efficient, and manageable method of advancing the claim; (b) be preferable to any other available means of resolving the claim; and (c) facilitate judicial economy, behaviour modification, and access to justice: *AIC Limited v. Fischer*, [2013] 3 SCR 949, at para. 22. At the hearing of the present motion, they cited a recent scholarly article for the proposition that, "Recourse to these varying sources of interpretation – from a plain language reading to Hansard to BC, and even, US precedent – suggests that Ontario's predominance requirement codifies, rather than changes, existing preferable procedure case law": Kalajdzic, Jasminka and Zimmerman, Adam S., *Local Reform or Legal Transplant: Ontario's Amended Certification Test* (April 26, 2024), SSRN: https://ssrn.com/abstract=4808628.

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[69] Counsel for the Defendants, on the other hand, submit that section 5(1.1)(b) represents a substantial rethinking of the preferability requirement, in that it adopts language from U.S. legislation that was specifically rejected by the Ontario legislature when the *CPA* was enacted in 1992. As the Supreme Court explained in *Hollick*, at para. 30:

> [T]he Act contemplates that class actions will be allowable even where there are substantial individual issues: see s. 5. It is also true that the drafters rejected a requirement, such as is contained in the American federal class action rule, that the common issues 'predominate' over the individual issues.

[70] Defendants' counsel submits that, following the relevant American jurisprudence, the analysis "predominance" must be a comparative exercise requiring the court to measure the significance, complexity, and number of common issues, and to compare that with the significance, complexity and number of individual issues that will remain after any common issues trial. In addition, the Court must compare the time and resources that will be required to adjudicate each set of issues. Citing the leading case of *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997), they point out that in the U.S. product liability personal injury class actions generally fail to meet the predominance requirement since even if the harmfulness of the product can be established on a common basis it typically does not predominate – in quantity, complexity, or resources – over the evaluation of individual medical histories and other idiosyncratic elements of the causation analysis.

[71] It frankly seems unlikely that the Ontario legislature, by adding a new provision to the *CPA* that contains a key phrase – predominate – that was specifically rejected when the statute was first enacted, intended to simply restate and codify the existing state of the law as Plaintiff's counsel suggest. It seems equally unlikely that in adding new and somewhat more strict language to the existing preferable procedure requirement that the Ontario legislature intended to import a large body of U.S. jurisprudence holus-bolus.

[72] While the explanation of section 5(1.1)(b) provided in *Banman* may be too subtle to perceive with the naked eye, the addition of a predominance requirement where there previously was none must be taken to impose some degree of stricter scrutiny on the preferability issue than has been the case up until now. The evidence provided by the Plaintiff's two affiants – Mr. Pedersen himself and Mr. Boon – illustrate why and how that new policy might play out.

[73] Defendants have created charts of medical issues gleaned from their review of personal medical records disclosed by Messrs. Pedersen and Boon. The charts contain lengthy lists of pre-existing medical conditions, medications, and treatments for each of those individuals, which go on for a number of pages. The affidavits of each affiant each detail a complex list of harms that they suffered either leading up to or in the wake of their revision surgery. These include physical ailments (sleeplessness, anxiety, hearing deficiencies, depression, vertigo, and pain) together with negative social and economic impacts (isolation, job loss, communication difficulties, personality changes).

[74] Defendants' counsel are of the view that the individual issues presented by these two class members – if, as we must at this stage – take them as representative or typical of the class as a whole – will substantially outweigh anything contained in the common issues. As presented by the Plaintiff, the claim suggests that there might be testimony not only from every claimant's treating doctor but from every claimant about her or his lifestyle, employment, family, social situation, recreation, etc., with whatever supporting evidence is needed to support that testimony. In that scenario, individual issues would certainly predominate over common ones on almost any rational interpretation of section 5(1.1)(b).

[75] The Plaintiff and his counsel have acknowledged this problem and taken steps to address it. As discussed in Part II(b) above, the class itself will be limited to individuals whose devices have experienced a hard failure and who have undergone revision surgery. In accordance with the methodology laid out by Dr. Gurgel, the defect in the class members' devices can be determined by examination of the extracted device itself and data collected by the surgeon and the Defendants regarding the device. This will place a workable limit on any individual medical issues that need to be canvassed.

[76] In addressing damages in their factum, Plaintiff's counsel have stated that the class's aggregate damages claim is limited to a commonly experienced base level. As they put it: "Aggregate damages can be assessed for the base level of harm suffered by all Class Members who have had to undergo revision surgery. All revised Class Members, by having these surgeries, suffered a common bodily injury ." As explained in Part II(b) above, the class definition will be limited to persons who have undergone revision surgery, and so this description applies to all certified class members.

[77] As discussed in Part II(b) above, punitive damages, if found to be applicable as a result of the Defendants' knowledge and conduct, can likewise be considered in common among the class. The only issue remaining for post-common issues consideration, therefore, is that of general damages.

[78] In their factum, Plaintiff's counsel indicate that one type of individualized, general damages heading can be singled out for special treatment. They identify this category as "pecuniary damages for additional monitoring, screening and treatment, as well as whether provincial health insurers are entitled to recover. These are standard questions about the scope of the damages that the Defendants will be liable for, and do not ask for the amounts to be fixed at the common issues trial."

[79] In order for individual issues not to predominate over common ones, and for a class action to be the preferable procedure for determining the class members' claims, this must be the limit and extent of any general damages claim. In that way, the entire action, including any post-trial individual considerations, will be focused on the direct medical consequences of the alleged design defects in the Defendants' cochlear implants. No socio-economic or lifestyle evidence will be required from the Plaintiffs.

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[80] When the claim is limited in this way, the common issues will represent the vast majority of the issues to be resolved in the class members' claims, with only minor medical-related costs to be determined on an individual basis. The extended health and socio-economic losses are eliminated from the post-common issues phase of the case, and the common issues damages are restricted to aggregate and, possibly, punitive damages that are restricted to the failed devices and medical care necessitated by that failure, and that can be considered uniformly across the class. The action, contained in this way, will satisfy the predominance/preferability requirement.

[81] With this limitation on the damage claims, I conclude that the requirements in sections 5(1.1) and 5(1)(d) of the *CPA* are satisfied.

e) Representative Plaintiff and litigation plan – section 5(1)(e)

[82] The Defendants take no issue with Paul Pedersen as representative Plaintiff. There is no suggestion that he has any conflict of interest with other class members. Counsel has indicated that he has been a full participant in the action thus far. His affidavit evidence shows him to be an intelligent and knowledgeable class member.

[83] I am satisfied that Mr. Pedersen will "vigorously and capably prosecute the interests of the class": *Western Canadian Shopping Centres Inc. v. Dutton*, [2001] 2 SCR 534, at para. 41.

[84] Defendants' counsel do raise significant objections to the proposed litigation plan. These objections are based on their view that the individual issues are of overwhelming importance to the action, and that abbreviated procedures implemented after a common issues trial will effectively deny due process to the Defendants for most of the issues they have to address. As Defendants' counsel put it in their factum:

> [T]he litigation plan does not recognize or make provision for the complexities that the parties will encounter in resolving the individual issues of causation and damages discussed above. For example, the individual assessment of damages does not contemplate the introduction of expert evidence; rather, class members will simply complete a 'claims form', and on that basis a referee will assess the compensable damages. The Defendants presumptively have no right to cross-examine the class member on the contents of the claims form, and if the Defendants seek to challenge the claim, they must provide the referee with 'supporting evidence'. The Defendants also have no right to discover the class members to explore the possibility of comorbidities to which the claimed losses might be attributable.

[85] Section 25 of the *CPA* provides that the parties and the court may devise summary procedures for resolving individual issues after a trial of common issues. As Justice Cullity pointed out in *Ragoonanan v. Imperial Tobacco Canada Ltd*. (2005), 78 OR (3d) 98, at para. 72, aff'd [2008] OJ No 1644 (Div Ct), "[t]his will ordinarily be the case where the issues raise questions of fact that can be resolved on the basis of documentary evidence, or can otherwise be readily determined."

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[86] What Defendants' counsel describe is, essentially, the state of the Plaintiff's claim as issued in the Statement of Claim and repeated in the motion record. What Justice Cullity describes is, essentially, the Plaintiff's claim as certified with the limitations set out in Parts II(a), (b), (c) and (d) above. In other words, by addressing the Defendants' predominance and preferable procedure arguments, the limitations imposed here on the certified action also address the Defendants' litigation plan arguments.

[87] To summarize, the limitations which collectively make the litigation plan workable are, in a nutshell: a) a class definition limited to persons who have experienced a hard failure of their cochlear implant device and have undergone revision surgery, b) liability issues that do not include a negligent manufacturing claim, c) compensatory damages restricted to a base level of aggregate damages of bodily injuries suffered in common by persons who have undergone revision surgery, d) potentially, punitive damages on a class-wide basis, and e) limited and strictly medical-related general damages on an individual basis.

[88] In *Cloud v. Canada (Attorney General)*, 2004 CanLII 45444, at para. 95 (ON CA), Justice Goudge stated that, "The litigation plan produced by the appellants is, like all litigation plans, something of a work in progress." If there are procedural issues that need to be addressed subsequent to the common issues trial and as a result of the findings therein, I am confident that the parties and the Court will be in a position to make the necessary adjustments keeping their eye on considerations of both efficiency and fairness.

[89] With this understanding, the action satisfies the requirement in section 5(1)(e) of the *CPA* that there be an appropriate representative Plaintiff and a workable litigation plan.

III. Disposition

[90] The action is hereby certified on the terms set out above. The Plaintiff is confirmed as representative Plaintiff for the class and his counsel are appointed class counsel.

[91] The causes of action are as described in paragraph 34 above. The class is as defined in paragraph 46 above, the common issues are as described in paragraph 47 above (with the small change described in paragraph 50 above), and the damages claimed by the class are limited as described in paragraphs 75-80 (and summarized in paragraph 87) above.

IV. Costs

[92] The parties may make written submissions on costs.

[93] I would ask Plaintiff's counsel to email my assistant with brief cost submissions within two weeks of today, and Defendants' counsel to email my assistant with brief cost submissions within two weeks of receiving the Plaintiff's submissions.

Morgan J.

Date: April 21, 2026

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