CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

Nº : 500-06-001254-230

SUPERIOR COURT
(Class Actions)

HERBERT "TROY" DINGWELL

Applicant

v.

ADVANCED BIONICS L.L.C., a legal person having its head office at 12740 San Fernando Road, Sylmar, California, 19808, USA

and

ADVANCED BIONICS CORPORATION, a legal person having its head office at 28515 Westinghouse Place, Valencia, California, 91355, USA

and

ADVANCED BIONICS AG, a legal person having its head office at Laubisrütistrasse, 28, Stäfa, 8712, Switzerland

and

SONOVA HOLDING AG, a legal person having its head office at Laubisrütistrasse, 28, Stäfa, 8712, Switzerland

and

SONOVA AG, a legal person having its head office at Laubisrütistrasse, 28, Stäfa, 8712, Switzerland

and

SONOVA CANADA INC., a legal person having an elected domicile at 3700-1, Place Ville-Marie, Montréal, Québec, H3B 3P4, Canada

and

NATIONAL HEARING SERVICES INC. c.o.b. as CONNECT HEARING, a legal person having its head office at 50 Queen Street North – Suite 1020, Kitchener, Ontario, N2H 6M2, Canada

Defendants

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVE
(Art 575 *C.C.P.*)

TO ONE OF THE HONOURABLE JUDGES OF THE SUPERIOR COURT OF QUÉBEC SITTING IN THE DISTRICT OF MONTREAL, THE APPLICANT RESPECTFULLY SUBMITS:

I- OVERVIEW

1. Cochlear implants are electronic devices that allow individuals who are severely to profoundly deaf to process sounds. These devices are surgically implanted in a part of the inner ear called the cochlea.

2. The defendants developed, manufactured and sold cochlear implants under the names “HiRes Ultra” and “HiRes Ultra 3D” - the initial “versions” of these implants (the “Cochlear Implants”) were sold and implanted in Canada between 2017 and 2020.

3. The Cochlear Implants are defective and were recalled by the defendants in February 2020. Fluid enters the surgically implanted electrode, causing degradation and/or loss of function. This defect can also cause physical symptoms such as pain, nausea, dizziness, and convulsions. An excessively high number of the Cochlear Implants have already required replacement surgery, and many more will require such surgery in the future.

4. The defendants knew that the Cochlear Implants posed major risks, as they were a “repackaging” of a previous model that had been recalled on several occasions for the same defect. Furthermore, once the defendants received confirmation that the

Cochlear Implants were failing, they neglected to recall the devices in a timely manner – instead, they developed a new "version" of the "HiRes Ultra" series, and only recalled the Cochlear Implants once this new version was ready to bring to market.

5. For these reasons, the applicant wishes to institute a class action against the defendants in order to recover damages for the injuries suffered by class members by reason of the defects of the Cochlear Implants, along with punitive damages.

II- THE NATURE OF THE CLASS ACTION AND THE GROUP THE APPLICANT WISHES TO REPRESENT

6. The applicant seeks to institute a class action based on the *Civil Code of Québec*,[1] the *Consumer Protection Act*,[2] and the *Charter of Human Rights and Freedoms*[3] on behalf of the following group:

> All persons who were implanted in Québec with a HiRes Ultra or HiRes Ultra 3D cochlear implant manufactured by Advanced Bionics, or any components of such cochlear implants including the electrode array.
>
> All persons who are the successor, spouse, parent, child, sibling, dependant or caregiver to a person described in the preceding paragraph.
>
> *Toutes les personnes qui se sont fait implanter, au Québec, un implant cochléaire de modèle «HiRes Ultra » ou « HiRes Ultra 3D » fabriqué par Advanced Bionics, ou toute composante d'un tel implant cochléaire incluant le porte-électrodes.*
>
> *Toutes les personnes qui sont l'héritier, le conjoint, le parent, l'enfant, le frère, la sœur, la personne à charge ou l'aidant naturel d'une personne visée par le paragraphe précédent.*

III- THE PARTIES

A. The Defendants

7. Advanced Bionics Corporation and Advanced Bionics LLC are companies incorporated in the state of Delaware, USA and headquartered in Valencia, California, USA. These two companies carry on the business of the design, testing, manufacturing, marketing, sale and post-sale monitoring of cochlear implants, including the HiRes Ultra and HiRes Ultra 3D Cochlear Implants. They are wholly owned subsidiaries of the defendant Sonova Holding AG. The applicant files in this

[1] CQLR c CCQ-1991.
[2] CQLR c P-40.1.
[3] CQLR c C-12.

regard an excerpt of the "Annual Report 2022-2023" for the Sonova Group as **Exhibit P-1.**

8. Advanced Bionics AG is incorporated and headquartered in Switzerland and was registered with Health Canada as the manufacturer of the Cochlear Implants. It is also a wholly owned subsidiary of Sonova Holding AG, as appears from Exhibit P-1.

9. Sonova Holding AG is incorporated in Switzerland. As appears from the Annual Report, Exhibit P-1, Sonova Holding AG is the ultimate parent company of the consolidated Sonova Group, and the only company in this group to be publicly traded (it is listed on the SIX Swiss Exchange). As also appears from Exhibit P-1, Sonova Holding AG holds 100% (directly or through subsidiaries) of the shares of all the other defendant corporations. Sonova Holding AG acquired Advanced Bionics Corporation in 2010, thereby entering the cochlear implant industry. At all relevant times, the Cochlear Implants were manufactured and brought to market under the Advanced Bionics brand name.

10. Sonova AG is incorporated in Switzerland. As appears from the Annual Report, Exhibit P-1, Sonova AG is involved in the holding/finance, sales, production and research of the Sonova Group. It is a wholly owned subsidiary of Sonova Holding AG.

11. Sonova Canada Inc. is a company incorporated under Ontario's *Business Corporations Act*[4] with a head office in Mississauga, Ontario, as appears from its information on the *Registre des entreprises du Québec*, **Exhibit P-2**. As appears from Exhibit P-1, this company is involved in sales and marketing activities.

12. National Hearing Services Inc. is a company incorporated under the *Canada Business Corporations Act*[5] with a head office in Kitchener, Ontario, as appears from its information on the *Registre des entreprises du Québec*, **Exhibit P-3.** It carries on business under the name "Connect Hearing", and provides sales, distribution, marketing and service functions for the other defendants, provides post-implant service to hospital clinics who implant their products, and provides post-implant service, monitoring and testing to patients.

13. The defendants committed all of the acts alleged below in concert, in pursuit of a common business plan. They conducted their operations as a single global business organization, in order to promote the business of cochlear implants carried out under the Advanced Bionics brand name ("Advanced Bionics" is used hereafter interchangeably with "the defendants"). They shared officers and directors and issued joint annual reports and consolidated financial statements.

[4] RSO 1990, c B.16.
[5] R.S.C., 1985, c. C-44.

B. The Applicant

14. The applicant, Herbert “Troy” Dingwell, who is 77 years old, lived in Lac-Saguay, Québec between 2015 and 2020. He currently resides in London, Ontario.

15. The applicant was implanted with a Cochlear Implant on his left side in 2017 at the CHU de Québec – Université Laval.

16. The applicant was recently informed by his treating audiologist at the London Health Sciences Centre that his implant has failed.

IV- THE FACTS GIVING RISE TO AN ACTION FOR THE APPLICANT AND EACH MEMBER OF THE GROUP

A. Cochlear implants

17. Cochlear implants are devices that provide hearing to deaf or hard-of-hearing individuals. They are designed for patients who have severe hearing loss from inner-ear damage who are not able to benefit from hearing aids, as well as patients who are congenitally deaf.

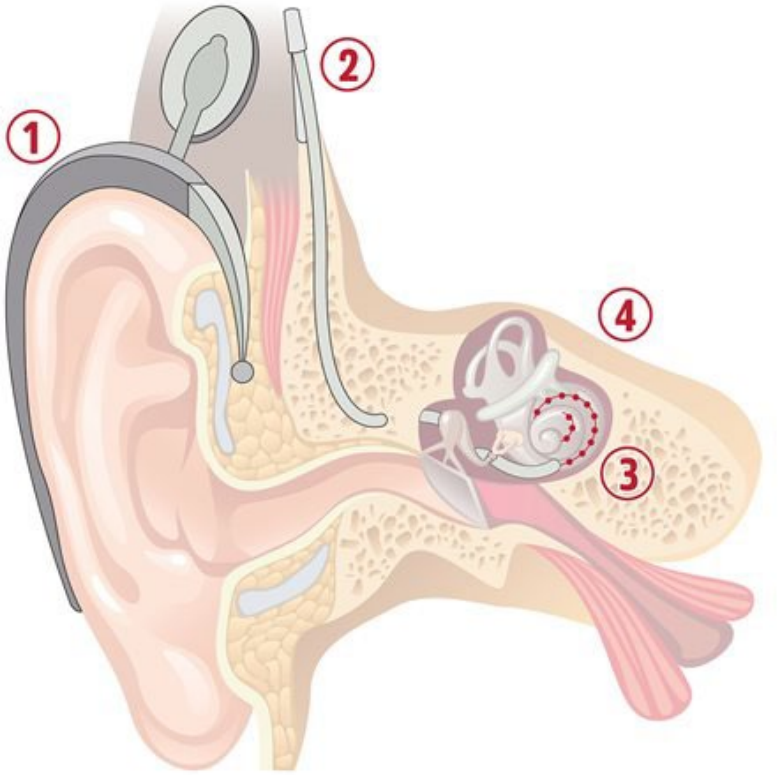
18. Both adults and infant children can receive cochlear implants. As pediatric patients are still developing their auditory cortex, a properly functioning cochlear implant is critical for higher-level linguistic and cognitive development and function.

19. Unlike a hearing aid, which amplifies sound, a cochlear implant delivers sound signals directly to the auditory nerve. A sound processor captures sound signals and digitally processes them, sending them to a receiver under the skin behind the ear. The receiver sends these signals to electrodes implanted in the snail-shell shaped inner ear (the cochlea), stimulating the acoustic (or cochlear) nerve.

20. While the external sound processor typically needs replacement every five to ten years, the internal implant is meant to last a lifetime.

21. Cochlear implant surgery is a major medical procedure, both physically and in terms of recovery time. Patients must undergo intensive functional rehabilitation – including follow-up with medical doctors, audiologists, psychosocial interveners and speech-language pathologists – in order to learn how to interpret the signals generated by the implant. Such rehabilitation typically lasts up to 10 weeks for adults and up to 12 weeks for children.

Fig. 1 – Basic functioning of cochlear implants



Fonctionnement de l'implant cochléaire

1. Le microphone capte les sons de l'environnement. Ensuite, les sons sont analysés par le processeur.
2. Les sons codés sont transmis à la partie interne. Celle-ci les transforme en impulsions électriques.
3. Les impulsions électriques sont dirigées vers les électrodes.
4. Les électrodes stimulent le nerf auditif qui envoie l'information au cerveau.

* Source: CHU de Québec – Université Laval; accessed on July 31, 2023 at: https://www.chudequebec.ca/patient/maladies-soins-et-services/specialites-et-specialistes/specialites/implant-cochleaire.aspx

B. The HiRes Ultra Cochlear Implants are defective.

22. The first versions, or "V1" models of the HiRes Ultra and HiRes Ultra 3D Cochlear Implants were introduced by Advanced Bionics in 2016.

23. The HiRes Ultra Cochlear Implant received approval from Health Canada on February 20, 2017, as detailed in a press release issued on Business Wire, **Exhibit P-4**. The device was promoted as featuring a low profile, making it ideal for recipients of all ages.

24. The HiRes Ultra 3D Cochlear Implant received approval from Health Canada on April 8, 2019, as detailed in a press release issued on Business Wire, **Exhibit P-5**.

25. Globally, Advanced Bionics reports that there have been 12,550 HiRes Ultra "V1" and 6,693 HiRes Ultra 3D "V1" Cochlear Implant surgeries, as detailed in Advanced Bionics' Reliability Report from June 2023, **Exhibit P-6**. It is estimated that several hundred implants were done in Québec.

26. On February 17, 2020, Advanced Bionics announced a recall of all non-implanted "V1" Cochlear Implant models, citing "hearing performance degradation due to body fluid entering the device", as appears from an entry in the United States Food and Drug Administration's ("FDA") database for medical devices, **Exhibit P-7**.

27. On April 17, 2020, Health Canada published a Medical Device Recall for the Cochlear implants – a copy of this publication is attached as **Exhibit P-8**.

28. In December 2022, a study published in the medical journal *The Laryngoscope* by world-renowned specialists Dr. Lutz Gärtner and Dr. Thomas Lenarz showed the dramatic extent of the defect affecting the Cochlear Implants. The article, titled "Advanced Bionics HiRes Ultra and Ultra 3D Series Cochlear Implant Recall: Time Course of Anomalies", is attached as **Exhibit P-9**.

29. Between September 2016 and October 2019, Drs. Gärtner and Lenarz implanted 349 Cochlear Implants at their clinic in Hannover, Germany, in the context of a clinical study conducted for Advanced Bionics. Representatives of Advanced Bionics were on site at the clinic, and tested devices suspected of malfunction using proprietary electrical field imaging ("EFI") software.

30. More specifically, implantation of the HiRes Ultra devices took place between September 2016 and November 2018, and implantation of the HiRes Ultra 3D devices took place between November 2018 and October 2019.

31. As detailed in their study, as of March 2022, more than 50% of the implanted Cochlear Implants showed anomalies, and nearly 35% of them had already required revision surgery to replace them. The study also concluded that the median survival time without anomalies of the devices – that is, the average time it took for the devices to fail – was 1,062 days.

32. The failure was caused by fluid ingress near the ring electrode of the Cochlear Implants. When fluid moves into the electrode pocket of the devices, the function of the electrodes is impeded, leading to decreased function. As a result, patients experienced distorted sound and impaired speech comprehension.

33. Each explanted Cochlear Implant was given by Drs. Gärtner and Lenarz's team to Advanced Bionics, who conducted individual device failure analyses ("DFA"). At the time of publishing their study, 76 of the 80 completed DFAs had revealed that the reason for the device failure was a short-circuit caused by fluid ingress in the electrode pocket.

34. Unfortunately, the defect of the Cochlear Implants has disproportionately impacted children. According to the Reliability Report issued by Advanced Bionics in June 2023, Exhibit P-6, 21% of HiRes Ultra 3D "V1" models in children have already been explanted. This figure is 24% of children for HiRes Ultra "V1" models.

35. As for adult patients, nearly 14% have required explants of the HiRes Ultra 3D "V1" Cochlear Implant, and nearly 20% have required explants of the HiRes Ultra "V1" Cochlear Implant.

36. Taking into account the mean time to detect a device failure, it is likely that the revision failure rate for the defendants' two Cochlear Implant models will be greater than 50%.

37. Indeed, at the time of writing, the "Cumulative Removal Percentage" for HiRes Ultra devices at Drs. Gärtner and Lenarz's clinic was 32.7% in adults and 59% in children.

C. The defect in the Cochlear Implants causes serious injuries

38. The defect in the Cochlear implants has had profound consequences on patients.

39. As noted by Drs. Gärtner and Lenarz, if the failure of a cochlear implant occurs early, or even immediately after implantation, adult patients may not perceive any distortions or impairment in sound quality, as they have not yet had the opportunity to experience the full potential of the devices. This can lead the patient to living with a malfunctioning Cochlear Implant for extended periods of time.

40. Indeed, sophisticated audiological tests are required in order to determine whether a Cochlear Implant is defective. Crucially, as Drs. Gärtner and Lenarz note, the most important of these tests – EFI – cannot be conducted in a normal clinical setting since Advanced Bionics has not made the required software available to healthcare professionals.

41. A malfunctioning cochlear implant can often have serious impacts on patients' emotional, psychological and social well-being. For instance, a reduction in performance of the device can lead to increased difficulties in maintaining conversations and socializing, which in turn can lead to social isolation or depression.

42. For pediatric patients, the defective Cochlear Implants present unique challenges. As discussed above, at such a young age, the auditory cortex is still under development, and the failure of a cochlear implant may normalize impairment. Revision surgery is required immediately to minimize damage to the language development process.

43. Conversely, lack of auditory stimulation in children can cause delay or deviations in neural development that have long-lasting harmful effects on auditory development, language acquisition and cognitive abilities.

44. 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 other ear.

45. In addition to risks related to hearing quality, the defect of the Cochlear Implants can cause loud noises in the inner ear, such as cracking or popping, as well as fever, pain or shocks throughout the face.

46. The defect can also cause vertigo, dizziness and convulsions as well as physical injuries related to these adverse effects, such as falls and motor vehicle accidents.

47. Patients whose implant fails also face the prospect of a second risky, invasive and time-consuming surgery, as detailed above. Indeed, Drs. Gärtner and Lenarz note that in their experience, adult patients hesitate to be reimplanted even when their speech comprehension has deteriorated. Risks and complications associated with revision surgery 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 the ear; and
- Inflammation and implant rejection.

48. As detailed above, patients who do proceed with revision surgery face a second long rehabilitation process to program their new cochlear implant. This process is associated to heightened stress due to the uncertainty surrounding the performance of the new implant. As with any invasive surgery, convalescence is often highly painful.

49. Further, all revision surgeries are associated with a higher risk of surgical failure. Indeed, implantation and removal of cochlear implants can cause structural damage to the inner ear complicating subsequent implantation.

50. Finally, many class members have suffered or will suffer loss of income. Their loved ones – who are also included in this class action - will suffer from this situation, in addition to suffering from loss of companionship and degradation of relationships, as well as the need to devote increased time and energy to care for class members suffering from a defective Cochlear Implant.

D. The Cochlear Implants were based on a flawed concept and improperly tested

51. When seeking regulatory approval, Advanced Bionics presented the HiRes Ultra series of implants as a "repackaging" of commercially available devices that it had previously brought to market, namely the "HiRes 90K" and "HiRes 90K Advantage" (the "90K Implant"). This "repackaging" involved, according to Advanced Bionics, incorporating the device "into new housing to reduce the size of the implanted components and to simplify the surgical procedure", as appears from a copy of the "Instructions for Use – HiResolution™ Bionic Ear System" distributed by Advanced Bionics in the United States, **Exhibit P-10**.

52. This was a highly risky decision, given that the 90K Implant had itself been subject to three distinct recalls, namely:

    a. In September 2004, all 90K Implants were recalled due to the potential presence of moisture in the internal circuitry, as appears from an entry in the FDA's database for medical devices dated September 27, 2004, **Exhibit P-11**. Patients, including children, suffered symptoms including sudden pain, loud noises, popping sounds and intermittent functioning. The 90K Implants were subsequently re-introduced to the market.

    b. In March 2006, certain 90K Implants were recalled again for elevated moisture levels, which could cause "intermittent function, complete loss of sound, sudden discomfort, pain, noise, or popping", as appears from an entry in the

FDA database for medical devices dated March 8, 2006, **Exhibit P-12**. Advanced Bionics claimed that these problems were caused by a component in the device that was manufactured by a new and unauthorized supplier. In July 2008, Advanced Bionics paid a $1.1 million civil penalty to the FDA for its failure to notify the agency of this new supplier, as appears from an article published in *Medical Device and Diagnostic Industry* on July 18, 2008, **Exhibit P-13.**

c. In November 2010, Advanced Bionics issued a full recall of all unimplanted HiRes 90K devices, after patients "experienced severe pain, overly loud sounds and/or shocking sensations" following the initial activation of the device, as appears from an entry in the FDA database dated November 23, 2010, **Exhibit P-14**. Certain 90K devices were again subsequently re-introduced into the market.

53. As can be seen, two of these recalls explicitly cited the exact same defect as that affecting the HiRes Ultra Cochlear Implants, namely excessive moisture in their components.

54. Despite the clear shortcomings of the 90K Implants, Advanced Bionics relied only on the clinical studies conducted on these devices or their components – or used in order to obtain regulatory approval for them – to obtain regulatory approval for the HiRes Ultra Cochlear Implants.

55. Indeed, as appears from the HiRes Ultra Instructions for Use, Exhibit P-10, the fact that the HiRes Ultra was a "repackaging" of the 90K device was used to justify the fact that no clinical studies whatsoever were conducted on the HiRes Ultra Cochlear Implants before their introduction to the market.

56. Advanced Bionics did this despite the fact that the studied 90K Implants were implanted with different models of electrodes – namely the "HiFocus" and the "HiFocus Helix" – whereas the HiRes Ultra Cochlear Implants were implanted with newly developed models, the "HiFocus SlimJ" and the "HiFocus Mid-Scala" electrodes.

57. Finally, the 90K Implant itself was not even the subject of a clinical trial, whereby special status is granted to a device in order to allow its implantation in a select group of participants in a pre-market study. Instead, Advanced Bionics relied on the clinical trials conducted for previously marketed devices (the "Clarion" and "Clarion CII", the "Clarion Implant") in order to obtain authorization to bring the 90K Implant to market.

58. It is noteworthy that a significant number of patients (5 out of 80, or 6,3%) who took part in the Clarion Implant clinical trial had reported vestibular symptoms, namely dizziness and/or spinning sensations.

E. Advanced Bionics wrongfully delayed its recall of the Cochlear Implants

59. In their article, Drs. Gärtner and Lenarz noted that a new pattern of anomalies, specific to the defect in the Cochlear Implant, was first detected in April 2019.

60. However, given the periods of implantation of the devices, as well as observed periods for the first appearances of anomalies, it is certain that cases highly indicative of device failure were observed by Drs. Gärtner and Lenarz well before April 2019.

61. Given that Drs. Gärtner and Lenarz were conducting a clinical study for Advanced Bionics and that the latter was on-site at their clinic, Advanced Bionics was informed of all instances of possible device failures.

62. Despite being made aware that the Cochlear Implants were defective, Advanced Bionics chose to leave these devices on the market while they developed new, supposedly non-defective versions of the devices.

63. As Advanced Bionics stated in an "update", **Exhibit P-15**, on the recall of the Cochlear Implants published on October 31, 2022:

> *In response to early indications of the original Ultra / Ultra 3D implant performance issue, AB made device improvements to protect against fluid impacting the electrode.*
>
> [emphasis added]

64. In June 2019 at the latest, Advanced Bionics undertook steps to obtain regulatory approval from the FDA of the new, "Version 2" of the Cochlear Implants, as appears from an excerpt of the FDA's database for medical devices, **Exhibit P-16**.

65. The FDA approved the "V2" models on December 23, 2019, as appears from an excerpt of the FDA's database for medical devices, **Exhibit P-17**.

66. Nevertheless, Advanced Bionics continued to market and sell the defective "V1" Cochlear Implants until February 2020, whereupon it finally issued a recall of the devices as detailed above.

67. Even when it did issue this recall, Advanced Bionics downplayed the risks of the Cochlear Implants, maintaining that the performance was observed in "a limited number" of devices, that the recall was being made with "an abundance of caution" and that the "situation does not present a device-related safety issue", as appears in the Advanced Bionics media release dated February 18, 2020, **Exhibit P-18**.

F. The Liability of the Defendants

68. As appears from the above, the Cochlear Implants contain a safety defect. The defendants are thus liable to repair the injuries caused to class members by this safety defect pursuant to art. 1468 of the *Civil Code of Québec*[6] ("*C.C.Q.*") and art. 53 of the *Consumer Protection Act*[7] ("*C.P.A.*").

69. Furthermore, and as detailed above, the defendants marketed a medical device that is crucial to the health and well-being of class members despite knowing that this device presented unreasonable risks. In so doing, the defendants acted with callous disregard for the safety and well-being of class members with a view to maximizing their profits. More specifically, the defendants:

    a. Brought the Cochlear Implants to market despite the fact that their predecessor devices had been recalled for numerous and identical defects;

    b. Conducted insufficient studies in order to adequately determine whether the Cochlear Implants were safe and effective, particularly in light of the failings of their predecessor devices;

    c. Failed to warn healthcare professionals and patients of the risks of failure and physical harm posed by the Cochlear Implants, namely by reason of the defects of their predecessor devices and the insufficient studies conducted upon them;

    d. Failed to immediately remove the Cochlear Implants from the market, and failed to immediately notify healthcare professionals, patients and public health authorities, upon receiving confirmation that the Cochlear Implants were defective.

70. This conduct constitutes an illicit and intentional violation of class members' right to personal security protected by the *Charter of Human Rights and Freedoms*.[8] The defendants are thus liable to pay compensatory and punitive damages to class members pursuant to art. 49 of said *Charter*.

71. Finally, for the reasons mentioned above, the defendants have also violated arts. 219 and 228 of the *C.P.A.* They are thus liable to pay compensatory and punitive damages to class members pursuant to art. 272 of the *C.P.A*.

[6] S.Q. 1991, c. 64.
[7] CQLR, c. P-40.1
[8] CQLR c C-12.

G. The Case of the Applicant

72. The applicant served in the Canadian Armed Forces in Germany. He lost his hearing due to prolonged proximity to outgoing machine gun fire.

73. As mentioned, the applicant was implanted with a Cochlear Implant on his left side in Québec City in 2017. He wears a hearing aid on his right side meant to complement the Cochlear Implant through a Bluetooth connection.

74. The applicant experienced severe pain at the incision site during his recovery from his cochlear implant surgery.

75. The activation and programming portion of his recovery was frustrating and highly stressful. The applicant frequently could not understand what was being asked of him by healthcare professionals. He felt fear at the prospect of recovering only limited hearing.

76. After the surgery, the applicant noticed that his hearing had partially improved: it was better in some areas, but not in others. Not knowing what to expect and not having a benchmark for how well a cochlear implant was supposed to work, he assumed that this level of improvement was normal. He underwent regular follow-ups for his Cochlear Implant with an audiologist at the Polyclinique de l'Oreille in Mont-Laurier.

77. However, after a while, the applicant noticed problems with his hearing. For instance, at the church he attended in Rivière-Rouge, he noticed that it was very difficult for him to maintain a conversation in a room with background noise.

78. The applicant moved to northern Ontario in December 2020, and more recently to London, Ontario.

79. For approximately two years, the applicant has noticed severe degradation of the performance of his cochlear implant. He finds it very difficult to distinguish between different sounds, and some sounds appear to him as shrill for no reason. It is also exceedingly difficult for him to maintain conversations in any location with background noise.

80. The applicant is an extremely social person. He is a pastor and a counselor at his local legion. He has lost his ability to socialize and finds this extremely distressing. His poor hearing leads to frequent miscommunications with people who seek his counselling, which he finds embarrassing and frustrating.

81. As a result, the applicant's quality of life has dramatically declined. He feels that any semblance of a good lifestyle has been lost. He has isolated himself, he seeks out silence, and he spends his days watching television with closed captioning.

82. He also has great difficulty communicating with his loved ones. For instance, he finds it very difficult to understand his son – who lives in Shefford, Québec – over the phone.

83. In addition to the decline in his hearing, the applicant has experienced many vestibular symptoms such as loss of balance, vertigo and dizziness. These symptoms were particularly pronounced immediately following the implant surgery, but he still experiences them on a regular basis. On one occasion, they led him to fall off his toilet and crash through the door of his shower. He suffered many cuts as a result.

84. The applicant is followed by an audiologist at the London Health Sciences Centre, Laura Hopkins. Ms. Hopkins has informed him that the decline in performance in his implant has likely been caused by fluid ingress.

85. Ms. Hopkins informed the applicant of the recall of the Cochlear Implants last June. He had received no communication on this topic from the defendants, and had no knowledge of the recall prior to this. He was contacted by representatives of the defendants last May and given a new processor by them, but this processor has had no impact on the quality of his hearing.

86. Ms. Hopkins has attempted many adjustments to the applicant's Cochlear Implant, to no avail. She has thus informed him that revision surgery will be required for him to experience any improvement in his hearing.

87. The applicant is extremely reluctant to undergo this revision surgery. He does not want to experience the painful, frustrating and fear-inducing rehabilitation process for a second time. He is also worried about the risks of revision surgery associated with his age (77).

V- CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

88. The composition of the class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings, for the following reasons:

    a. Class members are dispersed across Québec and Canada;

    b. Due to the confidentiality of medical records, it is impossible to know the identity of the individuals who have been implanted with the Cochlear Implants;

    c. Given the costs and risks inherent in litigation of this nature, many class members will hesitate to institute an individual action against the defendants. Even if class members themselves could afford such individual litigation, the judicial system could not as it would be overloaded;

d. Individual litigation of the factual and legal issues raised by the conduct of the defendants would increase delays and expenses for all parties and the judicial system;

e. In these circumstances, a class action is the only procedure that will allow class members to effectively pursue their respective rights and seek justice.

89. The claims of class members raise identical, similar or related questions of fact and law, namely:

a. Do the HiRes Ultra and HiRes Ultra 3D Cochlear Implants contain a safety defect? If so, can the defendants avoid liability by reason of one of the means of defence found at art. 1473 *C.C.Q.*?

b. Did the defendants breach class members' right to personal security protected by the *Charter of Human Rights and Freedoms* in the context of the manufacturing, pre-market testing, marketing and/or post-market surveillance of the Cochlear Implants? If so, was this breach illicit and intentional?

c. Did the defendants breach their obligations under arts. 218 and/or 228 of the *Consumer Protection Act*?

d. Can the Court order collective recovery of the non-pecuniary and punitive damages due to class members?

90. The questions of fact and law specific to each member consist of:

a. The nature and extent of the injuries suffered by each class member;

b. The amount of damages due to each class member.

VI- CONCLUSIONS SOUGHT

91. The conclusions that the applicant seeks are the following:

GRANT the class action against the defendants;

ORDER the defendants, solidarily, to pay class members an amount to be determined by the Court in compensation of their bodily, moral and material injuries;

ORDER collective recovery of the non-pecuniary damages due to class members;

ORDER individual recovery of the pecuniary damages due to class members;

ORDER the defendants to pay punitive damages in the amount of $5,000,000.00 (five million dollars);

ORDER collective recovery of the punitive damages due to class members;

THE WHOLE with interest, legal indemnity and costs, including but not limited to expert fees, notice fees and fees relating to administration of recovery.

VII- THE STATUS OF THE REPRESENTATIVE

92. The applicant requests that he be ascribed the status of representative.

93. He is in a position to represent the class members adequately, for the following reasons:

    a. He was implanted with a Cochlear Implant in Québec;

    b. He suffered injuries after having been surgically implanted with the Cochlear Implant;

    c. He is willing and able to devote the time required in order to fulfill his role as class representative.

    d. He is in a position to provide his lawyers with information relevant to this class action.

    e. He is acting in good faith with the sole purpose of obtaining justice for himself and each of the class members; and

    f. He understands the nature of the action.

VIII- JUDICIAL DISTRICT

94. The applicant requests that the present class action be brought before the Superior Court in the district of Montreal for the following reasons:

    a. A large portion of class members reside in Montreal or its surroundings;

    b. The offices of the applicant's Québec-based co-counsel, Trudel Johnston & Lespérance, are located in Montreal.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the application;

AUTHORIZE the bringing of a class action in the form of an action to recover compensatory and punitive damages pursuant to the *Civil Code of Québec*, the *Consumer Protection Act* and the *Charter of Human Rights and Freedoms*;

APPOINT the applicant as representative of the persons included in the group herein described as:

> All persons who were implanted in Québec with a HiRes Ultra or HiRes Ultra 3D cochlear implant manufactured by Advanced Bionics, or any components of such cochlear implants including the electrode array.
>
> All persons who are the successor, spouse, parent, child, sibling, dependant or caregiver to a person described in the preceding paragraph.
>
> *Toutes les personnes qui se sont fait implanter, au Québec, un implant cochléaire de modèle «HiRes Ultra » ou « HiRes Ultra 3D » fabriqué par Advanced Bionics, ou toute composante d'un tel implant cochléaire incluant le porte-électrodes.*
>
> *Toutes les personnes qui sont l'héritier, le conjoint, le parent, l'enfant, le frère, la sœur, la personne à charge ou l'aidant naturel d'une personne visée par le paragraphe précédent.*

IDENTIFY the principal questions of fact and law to be treated collectively as the following:

a. Do the HiRes Ultra and HiRes Ultra 3D Cochlear Implants contain a safety defect? If so, can the defendants avoid liability by reason of one of the means of defence found at art. 1473 *C.C.Q.*?

b. Did the defendants breach class members' right to personal security protected by the *Charter of Human Rights and Freedoms* in the context of the manufacturing, pre-market testing, marketing and/or post-market surveillance of the Cochlear Implants? If so, was this breach illicit and intentional?

c. Did the defendants breach their obligations under arts. 218 and/or 228 of the *Consumer Protection Act*?

d. Can the Court order collective recovery of the non-pecuniary and punitive damages due to class members?

IDENTIFY the conclusions sought by the class action to be instituted as being the following:

> **GRANT** the class action against the defendants;

ORDER the defendants, solidarily, to pay class members an amount to be determined by the Court in compensation of their bodily, moral and material injuries;

ORDER collective recovery of the non-pecuniary damages due to class members;

ORDER individual recovery of the pecuniary damages due to class members;

ORDER the defendants to pay punitive damages in the amount of $5,000,000.00 (five million dollars);

ORDER collective recovery of the punitive damages due to class members;

THE WHOLE with interest, legal indemnity and costs, including but not limited to expert fees, notice fees and fees relating to administration of recovery.

SET the deadline for opting out of the class action at 30 days from the date of the publication of the notice to class members;

DECLARE that all class members that have not opted out of the class action in the prescribed delay will be bound by any judgment to be rendered on the class action;

ORDER the publication of a notice to class members in accordance with article 579 of the *Code of Civil Procedure*, pursuant to a further order of the Court;

THE WHOLE with costs, including the costs of all publication of notices.

Montreal, August 3, 2023

Montreal, August 3, 2023

TRUDEL JOHNSTON & LESPÉRANCE
CO-COUNSEL FOR THE APPLICANT
Mtre André Lespérance
andre@tjl.quebec
Mtre Jean-Marc Lacourcière
jean-marc@tjl.quebec
Mtre Zoë Christmas
zoe@tjl.quebec
750, côte de la Place-d'Armes, suite 90
Montréal, QC H2Y 2X8
Tel. (514) 871-8385
Fax. (514) 871-8800

GLUCKSTEIN LAWYERS
CO-COUNSEL FOR THE APPLICANT
Mtre James Newland
newland@gluckstein.com
Mtre Brian Moher
moher@gluckstein.com
301-595 Bay Street, P.O. Box 53
Toronto, ON M5G 2C2
Tel: (416) 408-4252
Fax: (416) 408-4235

SUMMONS
(articles 145 and following C.C.P.)

Filing of a judicial application

Take notice that the plaintiff has filed this *Application for Authorization to Institute a Class Action and to Obtain the Status of Representative* in the office of the court of Montreal in the judicial district of Montreal.

Exhibits supporting the application

In support of the originating application, the plaintiff intends to use the following exhibits:

EXHIBIT P-1: Excerpts from the Sonova Group's Financial Report, 2022-2023

EXHIBIT P-2: Information sheet on the *Registre des entreprises* for Sonova Canada Inc.

EXHIBIT P-3: Information sheet on the *Registre des entreprises* for National Hearing Services Inc.

EXHIBIT P-4: Press release issued on Business Wire by Advanced Bionics on February 20, 2017

EXHIBIT P-5: Press release issued on Business Wire by Advanced Bionics on April 8, 2019

EXHIBIT P-6: Advanced Bionics Reliability Report, June 2023

EXHIBIT P-7: Entry in the United States Food and Drug Administration's ("FDA") database for medical devices regarding the recall of the HiRes Ultra Cochlear Implants dated February 17, 2020

EXHIBIT P-8: Medical Device Recall for the HiRes Ultra Cochlear Implants published by Health Canada on April 17, 2020

EXHIBIT P-9: Journal article entitled "Advanced Bionics HiRes Ultra and Ultra 3D Series Cochlear Implant Recall: Time Course of Anomalies" by Dr. Lutz Gärtner and Dr. Thomas Lenarz published in the *The Laryngoscope* in December 2022

EXHIBIT P-10: "Instructions for Use – HiResolution™ Bionic Ear System" distributed by Advanced Bionics in the United States

EXHIBIT P-11: Entry in the FDA's database for medical devices regarding the recall of the 90K HiRes Cochlear Implants dated September 27, 2004

EXHIBIT P-12: Entry in the FDA's database for medical devices regarding the recall of the 90K HiRes Cochlear Implants dated March 8, 2006

EXHIBIT P-13: Article published in *Medical Device and Diagnostic Industry* on July 18, 2008

EXHIBIT P-14: Entry in the FDA's database for medical devices regarding the recall of the 90K HiRes Cochlear Implants dated November 23, 2010, also available at the following link:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=95924

EXHIBIT P-15: Advanced Bionics Update on the Recall of the HiRes Ultra Cochlear Implants dated October 31, 2022

EXHIBIT P-16: Entry in the FDA's database for medical devices regarding the pre-market approval of V2 of the Cochlear Implants dated July 3, 2019

EXHIBIT P-17: Entry in the FDA's database for medical devices regarding the pre-market approval of V2 of the Cochlear Implants dated December 23, 2019

EXHIBIT P-18: Advanced Bionics media release regarding the recall of the Cochlear Implants, February 18, 2020.

Defendant's answer

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal situated at 1 Notre-Dame St. E. Montréal, H2Y 1B6 within 15 days of service of the application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the plaintiff's lawyer or, if the plaintiff is not represented, to the plaintiff.

Failure to answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgement may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of answer

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the cases required by the Code, cooperate with the plaintiff in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of the summons or, in family matters or if you have no domicile, residence or establishment in Québec, within 3 months after service; or
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Where to file the judicial application

Unless otherwise provided, the judicial application is heard in the judicial district where your domicile is located, or failing that, where your residence or the domicile you elected or agreed to with plaintiff is located. If it was not filed in the district where it can be heard and you want it to be transferred there, you may file an application to that effect with the court.

However, if the application pertains to an employment, consumer or insurance contract or to the exercise of a hypothecary right on the immovable serving as your main residence, it is heard in the district where the employee’s, consumer’s or insured’s domicile or residence is located, whether that person is the plaintiff or the defendant, in the district where the immovable is located or, in the case of property insurance, in the district where the loss occurred. If it was not filed in the district where it can be heard and you want it to be transferred there, you may file an application to that effect with the special clerk of that district and no contrary agreement may be urged against you.

Transfer of the application to the Small Claims Division

If you qualify to act as a plaintiff under the rules governing the recovery of small claims, you may contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Convening a case management conference

Within 20 days after the case protocol mentioned above is filed, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing that, the protocol is presumed to be accepted.

Application accompanied by a notice of presentation

Applications filed in the course of a proceeding and applications under Book III or V of the Code of Civil Procedure—excluding applications pertaining to family matters under article 409 and applications pertaining to securities under article 480—as well as certain applications under Book VI of the Code of Civil Procedure, including applications for judicial review, must be accompanied by a notice of presentation, not by a summons. In such circumstances, the establishment of a case protocol is not required.

Montreal, August 3, 2023

TRUDEL JOHNSTON & LESPÉRANCE
CO-COUNSEL FOR THE APPLICANT
Mtre André Lespérance
andre@tjl.quebec
Mtre Jean-Marc Lacourcière
jean-marc@tjl.quebec
Mtre Zoë Christmas
zoe@tjl.quebec
750, côte de la Place-d'Armes, suite 90
Montréal, QC H2Y 2X8
Tel. (514) 871-8385
Fax. (514) 871-8800

Montreal, August 3, 2023

GLUCKSTEIN LAWYERS
CO-COUNSEL FOR THE APPLICANT
Mtre James Newland
newland@gluckstein.com
Mtre Brian Moher
moher@gluckstein.com
301-595 Bay Street, P.O. Box 53
Toronto, ON M5G 2C2
Tel: (416) 408-4252
Fax: (416) 408-4235

NOTICE OF PRESENTATION
(Article 574 C.C.P.)

TO :

ADVANCED BIONICS L.L.C., a legal person having its head office at 12740 San Fernando Road, Sylmar, California, 19808, USA

ADVANCED BIONICS AG, a legal person having its head office at Laubisrütistrasse, 28, Stäfa, 8712, Switzerland

SONOVA AG, a legal person having its head office at Laubisrütistrasse, 28, Stäfa, 8712, Switzerland

NATIONAL HEARING SERVICES INC. c.o.b. as CONNECT HEARING, a legal person having its head office at 50 Queen Street North – Suite 1020, Kitchener, Ontario, N2H 6M2, Canada

ADVANCED BIONICS CORPORATION, a legal person having its head office at 28515 Westinghouse Place, Valencia, California, 91355, USA

SONOVA HOLDING AG, a legal person having its head office at Laubisrütistrasse, 28, Stäfa, 8712, Switzerland

SONOVA CANADA INC., a legal person having an elected domicile at 3700-1, Place Ville-Marie, Montréal, Québec, H3B 3P4, Canada

TAKE NOTICE that the present *Application for Authorization to Institute a Class Action and to Obtain the Status of Representative*, dated August 3, 2023, will be presented at the Superior Court at the Courthouse of Montréal, located at 1 Notre-Dame Street East, at a date and time to be determined by the Coordinating Judge for the Class Action Division.

DO ACT ACCORDINGLY.

Montreal, August 3, 2023

Montreal, August 3, 2023

TRUDEL JOHNSTON & LESPÉRANCE
CO-COUNSEL FOR THE APPLICANT
Mtre André Lespérance
andre@tjl.quebec
Mtre Jean-Marc Lacourcière
jean-marc@tjl.quebec
Mtre Zoë Christmas
zoe@tjl.quebec
750, côte de la Place-d'Armes, suite 90
Montréal, QC H2Y 2X8
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Mtre James Newland
newland@gluckstein.com
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Toronto, ON M5G 2C2
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ATTESTATION REGARDING THE NATIONAL CLASS ACTION REGISTER

I, undersigned, **MTRE JEAN-MARC LACOURCIÈRE**, one of the applicant's lawyers, certify that the present *Application for Authorization to Institute a Class Action and to Obtain the Status of Representative*, dated August 3, 2023, will be entered in the *National Class Action Register*.

Montreal, August 3, 2023

_____

MTRE JEAN-MARC LACOURCIÈRE

No.: 500-06-001254-230

DISTRICT OF MONTRÉAL
SUPERIOR COURT
(Class Actions)

HERBERT "TROY" DINGWELL

Applicant

c.

ADVANCED BIONICS L.L.C. et al.

Defendants

Our File: 1490-1

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVE

(Art. 575 *C.c.p.*)

O R I G I N A L

Mtre André Lespérance
andre@tjl.quebec
Mtre Jean-Marc Lacourcière
jean-marc@tjl.quebec
Mtre Zoë Christmas
zoe@tjl.quebec

TJL
750, côte de la Place
d'Armes, bureau 90
Montréal (Québec) H2Y 2X8
Tél. : 514 871-8385
Téléc. : 514 871-8800

Mtre James Newland
newland@gluckstein.com
Mtre Brian Moher
moher@gluckstein.com

GLUCKSTEIN LAWYERS
301-595 Bay Street,
P.O. Box 53
Toronto, ON M5G 2C2
Tel: (416) 408-4252
Fax: (416) 408-4235

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