

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Acton No. 1:16-cv-01700

COCHLEAR LTD., and
COCHLEAR BONE ANCHORED SOLUTIONS AB,

Plaintiffs,

v.

OTICON MEDICAL AB, and
OTICON MEDICAL LLC,

Defendants.

**AMENDED COMPLAINT FOR PATENT INFRINGEMENT
AND JURY DEMAND**

Plaintiffs Cochlear Ltd. and Cochlear Bone Anchored Solutions AB (collectively “Cochlear”) state as follows:

THE PARTIES

1. Cochlear Ltd. is a corporation organized and existing under the laws of Australia, having its principal place of business at 1 University Avenue, Macquarie University, New South Wales 2109, Australia. Cochlear Ltd. wholly-owns a U.S. subsidiary Cochlear Americas, a Delaware corporation, with a principal place of business at 13059 East Peakview Avenue, Centennial, Colorado.

2. Cochlear Bone Anchored Solutions AB is a corporation organized and existing under the laws of Sweden, having its principal place of business at Konstruktionsvägen 14, SE-435 33 Mölnlycke, Sweden.

3. On information and belief, Oticon Medical AB is a corporation organized and existing under the laws of Sweden, having its principal place of business at Ekonomivägen 2, SE-436 33 Askim, Sweden.

4. On information and belief, Oticon Medical LLC is a limited liability company organized and existing under the laws of New Jersey, having its principal place of business at 19 Schoolhouse Road, Somerset, New Jersey.

5. On information and belief, Oticon Medical LLC is a subsidiary of Oticon Medical AB through which Oticon Medical AB conducts operations in the United States.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

7. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

8. On information and belief, personal jurisdiction over Oticon Medical AB and Oticon Medical LLC (collectively “Oticon Medical”) is proper because the infringement has occurred in, and the products at issue have been offered for sale and sold by Oticon Medical within, the state of Colorado and this District, including through clinics in Colorado promoted on the website oticonmedical.com operated by defendant Oticon Medical AB.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and (d), and 1400(b).

THE PATENT-IN-SUIT

10. Cochlear Bone Anchored Solutions AB is the lawful owner, and Cochlear Ltd. is an exclusive licensee, of the U.S. Patent No. 7,043,040 (“the ‘040 patent”) entitled “Hearing Aid Apparatus,” a copy of which is attached as Exhibit A, which has been duly and legally issued by the United States Patent and Trademark Office.

11. Cochlear Bone Anchored Solutions AB and Cochlear Ltd. together hold all necessary rights and authority to enforce the ‘040 patent and seek all available remedies in connection with it.

BACKGROUND

12. This case involves osseointegrated auditory implant systems (also known as and hereinafter referred to as “bone anchored hearing systems”), which require the recipient-user of such a system to undergo a surgical procedure to have an implant inserted into the recipient-user’s skull. Sound can then be transmitted directly through the skull to the recipient-user’s inner ear by bone conduction.

13. Cochlear sells bone anchored hearing systems to Cochlear Americas in Colorado, and Cochlear Americas sells these systems in the United States, including in Colorado, using the Baha[®] trademark.

14. On information and belief, the company now known as Oticon Medical AB was founded by Patrik Westerkull in 2004. On information and belief, that company was originally known as Otorix AB until after it was purchased by William Demant Holding A/S, which also owns Oticon A/S.

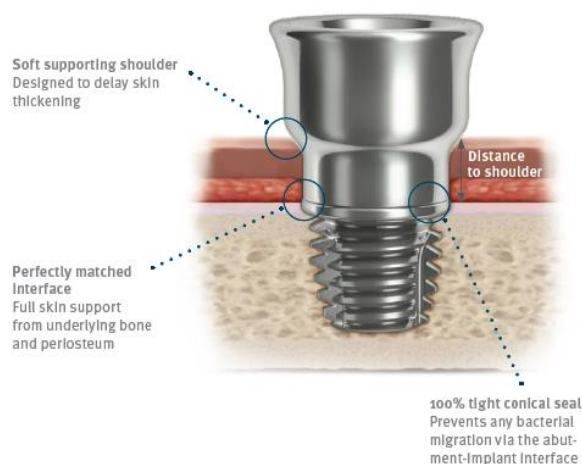
15. On information and belief, Oticon Medical AB, through its subsidiary Oticon Medical LLC, sells bone anchored hearing systems in the United States, including Colorado, using the Ponto trade name.

16. Until 2002, Mr. Westerkull was a Vice President at Entific Medical Systems AB (now known as Cochlear Bone Anchored Solutions AB), and is the sole named inventor on the ‘040 patent. Upon assignment of the ‘040 patent, Mr. Westerkull agreed that he would:

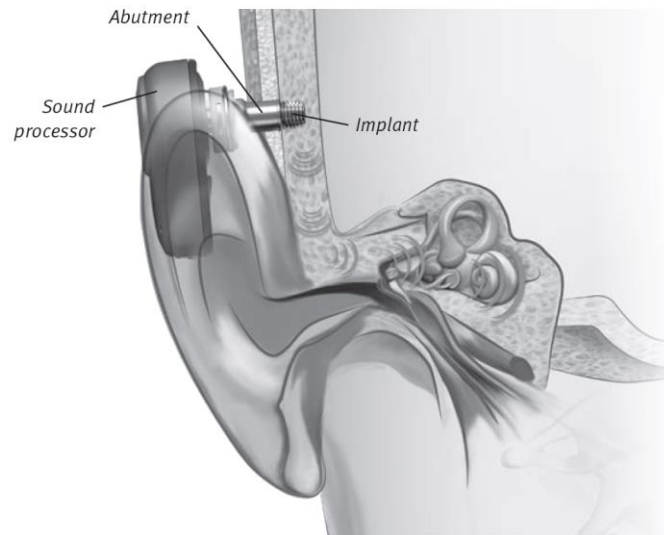
generally do everything possible to aid the ASSIGNEE, its successors, legal representatives and assigns, to obtain and enforce proper patent protection for said invention or discovery in all countries, all without further compensation, but at the expense of the ASSIGNEE, its successors, legal representatives and assigns.

17. On information and belief, Oticon Medical filed an application with the U.S. Food and Drug Administration (“FDA”) for the Ponto bone anchored hearing system (“Ponto system”), stating that the use, function and procedure for the Ponto system is substantially equivalent to Cochlear’s Baha[®] Divino device already approved by the FDA. On information and belief, Oticon Medical’s testing confirmed that the Ponto system was functionally equivalent to Cochlear’s Baha[®] Divino device.

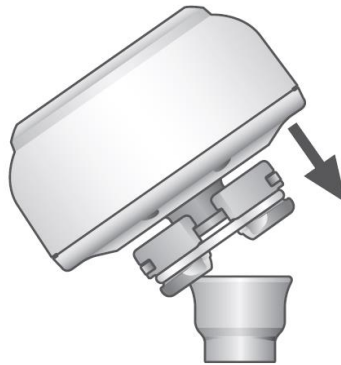
18. On information and belief, the Ponto and Baha systems both include an implant that is self-tapping and connected or connectable to a conical skin-penetrating abutment. On information and belief, the figure below shows the Ponto implant and abutment.



19. On information and belief, the Ponto and Baha systems both include a sound processor for creating vibrations that connects to the conical skin-penetrating abutment, as shown in the figure below.



20. On information and belief, in the Ponto system, the sound processor connects to the abutment by a snapping action, as illustrated in the figure below.



21. On information and belief, Oticon Medical has offered an abutment extension, as shown below, that is designed to connect a Ponto sound processor to Cochlear's Baha[®] abutment. On information and belief, Oticon Medical filed an application with the FDA for the abutment extension, indicating that the use and function is substantially equivalent to Cochlear's Baha[®] device.



22. On information and belief, Oticon Medical has promoted the Ponto system, as well as the Ponto abutment extension and sound processor working in connection with a Baha implant and abutment, to help patients with single-sided deafness using an arrangement where the sound processor is placed on the deaf side for picking up sound and transferring the sound to a functioning cochlea on the other side of the head.

23. On information and belief, as a result of Oticon Medical's promotion, marketing, advertisements and instructions, recipients, audiologists and/or physicians have created combination bone anchored hearing systems including a Baha implant, a Baha abutment, a Ponto abutment extension and a Ponto sound processor for use in single-sided deafness using an

arrangement where the sound processor is placed on the deaf side for picking up sound and transferring the sound to a functioning cochlea on the other side of the head.

24. On information and belief, these combination bone anchored hearing systems, when implanted, have included each element (or an equivalent of each element) of, for example, claim 1 of the '040 patent, as shown below:

<u>7,043,040 Claim Language</u>	<u>Oticon Medical Product</u>
1. A bone-conducting bone- anchored hearing aid apparatus for sound transmission from one side of a patient's head to the patient's cochlea on another side of the patient's head for rehabilitation of unilateral hearing loss, the hearing aid apparatus comprising:	On information and belief, Oticon Medical promotes combinations of its Ponto sound processor with Baha implants and abutments for pickup of sound on the deaf side of a recipient and transfer that sound to the recipient's functioning cochlea.
a vibratory generating part arranged to generate vibrations that are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient;	On information and belief, the sound processor in the Ponto system has a vibrator that, for single-sided deafness, is placed on the deaf side and transfers vibration to the functioning cochlea.

7,043,040 Claim Language

Oticon Medical Product

and

an implantable part operative to mechanically anchor the vibratory generating part, the implantable part being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient.

On information and belief, the Ponto sound processor has been combined with Baha implants and abutments that include an implanted screw portion that becomes osseointegrated into the patient's skull.

25. In 2010, Cochlear Ltd. and William Demant Holding A/S executed a license regarding certain bone anchored hearing systems.

26. The license grant was limited to products sold entirely under a brand name of William Demant Holding A/S. The license prohibited advertising, marketing or promoting cross-compatibility with Baha[®] products.

27. Cochlear has never licensed recipients, audiologist or physicians to make or use combination Baha and Ponto systems.

28. The making and use of combination bone anchored hearing systems is not licensed by Cochlear.

29. On information and belief, Oticon Medical knew that such unlicensed systems would infringe the '040 patent.

COUNT I

(Infringement of the '040 Patent)

30. Cochlear refers to and incorporates herein the allegations of Paragraphs 1-29 above.

31. On information and belief, Oticon Medical's promotion, sale, offer for sale, and/or importation of its abutment extender, and the promotion of combination bone anchored hearing systems for single sided deafness, has induced the infringement of one or more claims of the '040 patent literally or under the doctrine of equivalents.

32. On information and belief, Oticon Medical is estopped from challenging the validity of any claim of the '040 patent under the doctrine of assignor estoppel.

33. On information and belief, Oticon Medical's inducement of infringement of the '040 patent was willful.

PRAYER FOR RELIEF

WHEREFORE, Cochlear requests entry of judgment in its favor and against Oticon Medical as follows:

- (a) Declaring that Oticon Medical has induced infringement of the '040 patent;
 - (b) Awarding monetary damages sufficient to compensate Cochlear for past infringement of the '040 patent;
 - (c) Enjoining Oticon Medical and their officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from further infringement or inducement of infringement of the '040 patent;
 - (d) Declaring that this litigation is exceptional and awarding Cochlear their attorneys' fees, as well as enhanced damages;
 - (e) Costs of suit; and
 - (f) Such other and further relief as the Court may deem just and proper.
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DEMAND FOR A JURY TRIAL

Cochlear Ltd. and Cochlear Bone Anchored Solutions AB demand trial by jury on all issues so triable.

Dated: September 13, 2016

Respectfully submitted,

/s/ Bruce G. Chapman

Bruce G. Chapman - Lead Attorney

Bridgette A. Agness

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