IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO

Civil Acton No. 1:17-cv-00660-PAB-KMT
COCHLEAR LTD.,
Plaintiff,
v.
OTICON MEDICAL AB, and OTICON MEDICAL LLC,

Defendants.

AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND JURY DEMAND

Plaintiff Cochlear Ltd. (hereafter "Cochlear") states 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.
- 2. Cochlear, through its wholly-owned subsidiary Cochlear Bone Anchored Solutions AB, develops and manufactures bone anchored hearing systems. Cochlear Bone Anchored Solutions AB is a corporation organized under the laws of Sweden and has its principal place of business at Konstruktionsvägen 14, SE-435 33 Mölnlycke, Sweden.
- 3. Cochlear, through its wholly-owned subsidiary Cochlear Americas, markets and sells bone anchored hearing systems in the United States. Cochlear Americas is a Delaware corporation, with a principal place of business at 13059 East Peakview Avenue, Centennial, Colorado.
- 4. 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 Datavägen 37B, SE-436 33 Askim, Sweden.
- 5. 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 580 Howard Ave., Somerset, New Jersey.
- 6. On information and belief, Oticon Medical LLC is a wholly-owned subsidiary of William Demant USA, Inc., and William Demant USA, Inc. is in turn a wholly-owned subsidiary of William Demant Holding A/S.

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- 7. On information and belief, Oticon Medical AB is a wholly owned subsidiary of William Demant A/S.
- 8. On information and belief, Oticon Medical AB markets and sells products in the United States through Oticon Medical LLC.

JURISDICTION AND VENUE

- 9. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.
- 10. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.
- 11. 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 product 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.
- 12. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and (d), and 1400(b).

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THE PATENTS-IN-SUIT

- 13. Cochlear Ltd. is the lawful owner of U.S. Patent No. 9,596,550 ("the '550 patent") entitled "Prosthesis Adapter," a copy of which is attached as Exhibit A, that has been duly and legally issued by the United States Patent and Trademark Office.
- 14. Cochlear Ltd. holds all necessary rights and authority to enforce the '550 patent and seek all available remedies in connection with it.
- 15. Cochlear Ltd. is the lawful owner of U.S. Patent No. 9,602,936 ("the '936 patent") entitled "Prosthesis Adapter," a copy of which is attached as Exhibit B, that has been duly and legally issued by the United States Patent and Trademark Office.
- 16. Cochlear Ltd. holds all necessary rights and authority to enforce the '936 patent and seek all available remedies in connection with it.

BACKGROUND

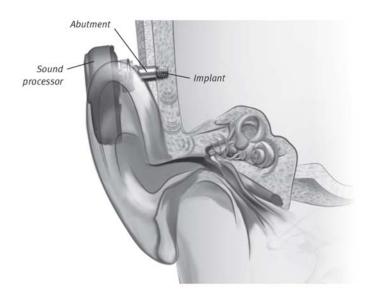
- 17. This case involves bone anchored hearing systems (also known as osseointegrated auditory implant systems), which require the recipient-user of such a system to undergo a surgical procedure to have an implant inserted into the recipient-user's skull. Sound can then be transmitted directly through the skull to the recipient-user's inner ear by bone conduction.
- 18. Cochlear sells bone anchored hearing systems in the United States, including in Colorado, using the Baha® trademark.
- 19. On information and belief, Oticon Medical AB, through Oticon Medical LLC, offers for sale and sells bone anchored hearing systems in the United States, including Colorado, using the Ponto trade name.

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20. On information and belief, the Ponto and Baha systems both include an implant that is connected or connectable to a conical skin-penetrating abutment. On information and belief, the figure below shows an implant and abutment for a bone anchored hearing system.



21. 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.



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22. 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.



23. On information and belief, Oticon Medical is offering 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.



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- 24. On information and belief, multiple fingers extend downward from the abutment extension and serve to lock the abutment extension into a Baha[®] abutment.
- 25. On information and belief, the abutment extension is connected to a Baha abutment in eights steps, as shown below.

Connecting the AE

Preparations

 Clean surrounding skin. Check that the abutment is correctly attached to the implant – see instructions in the surgical manual.

Connection

- Pick up the AE by connecting the counter torque wrench to the pre-mounted adapter on the AE.
- 2. Position the AE on the abutment and use your finger tips to slowly and carefully turn the counter torque wrench with the mounted AE until the AE is aligned with the abutment interface. The outer part of the AE will stop turning when the interfaces are aligned.
- Ensure that the AE is correctly positioned on the upper surface of the abutment.



- 5. Attach the Torque wrench to the screwdriver. Insert the screwdriver into the AE center screw through the center of the counter torque wrench and screw clockwise to tighten (20 Ncm). This prevents from over tightening the center screw.
- Check the AE is firmly attached to the abutment.
- Lift the counter torque wrench and adapter straight up from the AE.
- 8. Discard the adapter.







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- 26. On information and belief, Oticon Medical has offered the Ponto abutment extension and sound processor for connection with a Baha implant and abutment.
- 27. On information and belief, Oticon Medical's abutment extension permits a user to connect a Ponto sound processor to a Baha® abutment by providing an outer collar to which the female portion of the Ponto sound processor can connect.
- 28. On information and belief, as a result of Oticon Medical's offering, 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.
- 29. On information and belief, the Ponto abutment extension includes each element (or an equivalent of each element) of, for example, the following invention claimed in '550 patent:

Oticon Medical Abutment Extension

anchored hearing solution users providing access to the Ponto

Claim Language	Otton Medical Abutilent Extension
A percutaneous bone	On information and belief, the Oticon Medical abutment
conduction prosthesis	extension is a percutaneous bone conduction prosthesis
structural component,	structural component.
comprising:	On information and belief, the Oticon Medical website states, "[t]he Abutment extension can be used with most bone anchored hearing solution abutments on the market The Abutment Extension solution is suited for existing bone

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Claim Language

Oticon Medical Abutment Extension

System. The Abutment Extension is mounted noninvasively to the patient's abutment outside the operating theatre and fits seamlessly on the existing abutment."

an adapter configured to
indirectly couple a coupling
apparatus of an
operationally removable
component of a
percutaneous bone
conduction device to a
coupling apparatus of a
body interfacing prosthesis
configured to be attached to
a mastoid bone of a
recipient,

On information and belief, the female connector (a coupling apparatus) of a Cochlear Baha® abutment (a body interfacing prosthesis) can be connected to one end of the Oticon Medical abutment extension (an adapter). On information and belief, the female connector (a coupling apparatus) of an Oticon Medical sound processor (an operationally removable component of a percutaneous bone conduction device) can be releasably coupled to the other end of the Oticon Medical abutment extension.

the adapter is devoid of a snap-coupling component on a first longitudinal end thereof and is configured as a male snap coupling

On information and belief, the Oticon Medical abutment extension is devoid of a snap-coupling component on a first longitudinal end thereof and is configured as a male snap coupling component on an opposite longitudinal end thereof.

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component on an opposite longitudinal end thereof,

Oticon Medical Abutment Extension

On information and belief, on the Oticon Medical abutment extension, multiple fingers extend downward from the main body of the abutment extension.

On information and belief, instead of snap coupling to the Cochlear Baha® abutment, a center screw is used to connect the Oticon Medical abutment extension to the abutment by attaching a torque wrench to a screwdriver, inserting the screwdriver into the abutment extension screw through the center of the torque wrench and screwing clockwise to tighten.

On information and belief, as the center screw is tightened within the Oticon Medical abutment extension, the fingers are pushed outward away from the longitudinal axis of the abutment extension to extend beneath the inner collar of the Cochlear Baha® abutment, thereby connecting the Oticon Medical abutment extension to the Baha® abutment.

On information in and belief, the opposite longitudinal end of the Oticon Medical abutment extension is configured as a male snap coupling component.

wherein the opposite

On information and belief, the Oticon Medical abutment

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longitudinal end thereof has a maximum outer diameter greater than a maximum outer diameter of the first

longitudinal end.

Oticon Medical Abutment Extension

extension is tapered so that the opposite longitudinal end of the Oticon Medical abutment extension has a maximum outer diameter greater than a maximum outer diameter of the first longitudinal end.

30. On information and belief, the Ponto abutment extension is specially adapted for use in a product that includes each element (or an equivalent of each element) of, for example, the following invention claimed in the '936 patent, and has no substantial non-infringing uses:

Claim Language

A bone conduction prosthesis, comprising:

Product Made with Oticon Medical Abutment Extension

On information and belief, the Oticon Medical abutment extension is specially adapted for use in a bone conduction prosthesis.

On information and belief, the Oticon Medical website states, "[t]he Abutment extension can be used with most bone anchored hearing solution abutments on the market. ... The Abutment Extension solution is suited for existing bone anchored hearing solution users providing access to the Ponto System. The Abutment Extension is mounted noninvasively to the patient's abutment outside the operating theatre and fits

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Product Made with Oticon Medical Abutment Extension

seamlessly on the existing abutment."

an abutment;

On information and belief, the abutment extension is mounted

to a patient's abutment.

an adapter; and

On information and belief, the Oticon Medical abutment

extension is specially made so that the female portion of the

abutment can be connected to one end of the abutment

extension to allow it to serve as an adapter.

an operationally removable

component configured to

generate vibrations, the

operationally removable

component including a

coupling apparatus, wherein

the operationally removable

component is an

operationally removable

component of a bone

conduction device,

On information and belief, the Oticon Medical abutment extension is specially adapted to connect to a sound processor that generates vibrations (an operationally removable component). On information and belief, the sound processor to which the Oticon Medical abutment is adapted to connect contains a snap coupling (a coupling apparatus).

On information and belief, the sound processor is part of a bone conduction hearing system and has a vibrator that is connected to the snap coupling so as to transmit vibrations through the snap coupling.

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Product Made with Oticon Medical Abutment Extension

the operationally removable component includes a vibrator in vibrational communication with the coupling apparatus,

the abutment is directly connected to the adapter on one side,

a bone fixture is located on an opposite side of the abutment from the one side,

the bone fixture is fixed to

the abutment by an abutment screw extending through the abutment, the abutment screw having a head that secures the abutment to the bone fixture when the abutment screw is screwed

On information and belief, the Oticon Medical abutment extension is specially adapted to directly connect to the abutment.

On information and belief, the abutment is connected to a bone implant and attached to that bone implant by a screw that extends through the abutment.

On information and belief, the head of the screw in the abutment serves to physically secure the abutment to the bone implant.

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Product Made with Oticon Medical Abutment Extension

into the bone fixture,

the coupling apparatus is configured to be rigidly snap coupled to the abutment via the adapter for quick release and quick connect from and to, respectively, the adapter, while the adapter remains connected to the abutment,

On information and belief, the Oticon Medical abutment extension is specially adapted to snap couple to the sound processor, so that the sound processor can be quickly connected to and released from the Oticon Medical abutment extension.

On information and belief, the Oticon Medical abutment extension is specially adapted to remain connected to the abutment when the snap coupling to the sound processor is used.

the coupling apparatus includes a female component,

On information and belief, the snap coupling of the sound processor is a female component.

the adapter includes a male component at least partially received into the female component of the coupling apparatus,

On information and belief, a portion of the abutment extension is specially adapted to be a male component that fits within the female snap coupling component.

the adapter has a first end and a second end, the second end facing the abutment, the On information and belief, the Oticon Medical abutment extension has two ends, one of which (the first end) is specially

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Product Made with Oticon Medical Abutment Extension Claim Language first end facing the coupling adapted to face the snap coupling. apparatus, and the first end includes a On information and belief, the first end of the Oticon Medical surface extending in a flat abutment extension includes a flat planar surface that is specially adapted to fit into the female snap coupling plane, wherein the surface extends from one side of the component. adapter to an opposite side of the adapter, wherein the surface is encompassed by the female component of the coupling apparatus.

31. Cochlear has not licensed nor otherwise authorized Oticon Medical to import, make, use, sell or offer to sell products covered by the '550 or '936 patents.

COUNT I

(Infringement of the '550 Patent)

- 32. Cochlear refers to and incorporates herein the allegations of Paragraphs 1-31 above.
- 33. On information and belief, Oticon Medical's promotion, sale, offer for sale, and/or importation of its abutment extension, and the promotion of combination bone anchored

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hearing systems using that extension, has infringed and contributed to infringement of one or more claims of the '550 patent literally or under the doctrine of equivalents.

- 34. By reason of Oticon Medical's infringement, Cochlear is suffering damages, including impairment of the value of the '550 patent, in an amount yet to be determined.
- 35. Oticon Medical's acts of infringement are causing irreparable harm to Cochlear and will continue to cause irreparable harm unless enjoined by this Court.

COUNT II

(Infringement of the '936 Patent)

- 36. Cochlear refers to and incorporates herein the allegations of Paragraphs 1-35 above.
- 37. On information and belief, Oticon Medical's promotion, sale, offer for sale, and/or importation of its abutment extension, and the promotion of combination bone anchored hearing systems using that extension, has infringed and contributed to infringement of one or more claims of the '936 patent literally or under the doctrine of equivalents.
- 38. By reason of Oticon Medical's infringement, Cochlear is suffering damages, including impairment of the value of the '936 patent, in an amount yet to be determined.
- 39. Oticon Medical's acts of infringement are causing irreparable harm to Cochlear and will continue to cause irreparable harm unless enjoined by this Court.

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PRAYER FOR RELIEF

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

- (a) Awarding monetary damages sufficient to compensate Cochlear for infringement of the '550 and '936 patents;
- (b) Preliminarily and permanently 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 contribution to infringement of infringement of the '550 and '936 patents;
 - (c) Costs of suit; and
 - (d) Such other and further relief as the Court may deem just and proper.

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DEMAND FOR A JURY TRIAL

Cochlear Ltd. demands trial by jury on all issues so triable.

Dated: March 21, 2017

Respectfully submitted,

/s/ Bruce G. Chapman

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Attorneys for Plaintiff Cochlear Ltd.

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CERTIFICATE OF SERVICE

The undersigned certifies that counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system on March 21, 2017, per D.C.COLO.LCivR 5.1(d).

/s/ Bruce G. Chapman

Bruce G. Chapman

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