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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

COCHLEAR LTD., Plaintiff, v. OTICON MEDICAL AB, and OTICON MEDICAL LLC, Defendants.	CIVIL ACTION Case No. 3:18-cv-06684

MEMORANDUM IN SUPPORT OF PLAINTIFF'S APPLICATION FOR AN ORDER TO SHOW CAUSE WHY DEFENDANTS SHOULD NOT BE PRELIMINARILY ENJOINED FROM INFRINGING PLAINTIFF'S PATENT

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Pursuant to Federal Rule of Civil Procedure 65(a) and Local Civ. Rule 65.1, Plaintiff Cochlear Ltd. ("Cochlear") applies for an order to show cause why a preliminary injunction should not issue pending trial prohibiting Defendants Oticon Medical AB and Oticon Medical LLC (collectively "Oticon") from infringing Cochlear's recently issued U.S. Patent No. 9,838,807 ("the '807 patent") by selling, offering for sale, and/or importing Oticon's Ponto BHX implant.

I.
INTRODUCTION

Cochlear is the leading provider of bone conduction hearing systems, which transmit sound through a patient's skull bones to avoid a damaged outer or middle ear. Cochlear's BI300 implant – which anchors the bone conduction system to the skull – has been specially designed to promote the bonding of the implant and the bone.

Oticon is Cochlear's sole competitor for the type of bone conduction hearing systems at issue in this litigation. In order to compete with Cochlear, Oticon introduced its own implant – called the Ponto BHX implant – that also promotes the bonding of the implant and the bone. Among other things, Oticon's sales of the BHX implant are harming Cochlear's reputation as the technology leader in bone conduction hearing systems.

The U.S. Patent and Trademark Office recently issued the '807 patent to Cochlear, and numerous claims of the '807 patent directly cover the Oticon Ponto

BHX implant. As a result, Cochlear requests that the Court enjoin Oticon from infringing the '807 patent pending trial.

II.
STATEMENT OF FACTS

A. Cochlear's Bone Conduction Hearing System

Cochlear Ltd. subsidiary Cochlear Bone Anchored Solutions AB manufactures and sells bone conduction hearing systems. *See* Declaration Of Rom Mendel In Support Of Plaintiff's Application For An Order To Show Cause Why Defendants Should Not Be Preliminarily Enjoined From Infringing Plaintiff's Patent ("Mendel Decl."), ¶ 2. In the United States, those bone conduction hearing systems are sold through the Cochlear Ltd. subsidiary Cochlear Americas, located outside of Denver, Colorado. *Id.* Cochlear Ltd., Cochlear Bone Anchored Solutions AB and Cochlear Americas (collectively, "Cochlear") are all involved in providing quality bone conduction hearing systems to patients in the United States. *Id*.

Bone conduction hearing systems (also known as bone anchored hearing systems) conduct vibrations from a sound processor through a patient's skull bones to bypass a damaged outer and middle ear and send sound directly to the inner ear. *Id* at ¶ 3. Cochlear Americas distributes two types of implantable bone conduction hearing systems, both under the Baha® trademark: Baha® Connect and Baha® Attract. *Id* at ¶ 4.

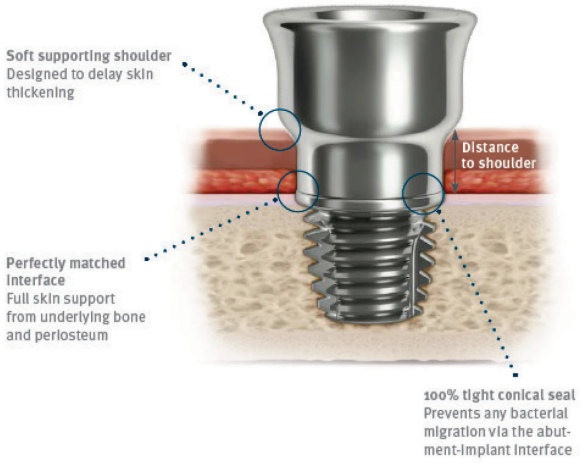
The Baha® Connect system is at issue in this litigation. *Id.* That system uses an implant secured to the skull that is connected to a skin penetrating abutment that is in turn connected to a sound processor that picks up sound and generates the vibrations that are to be transmitted through the bone to the inner ear. *Id* at ¶ 5.

B. Oticon's Bone Conduction Hearing System

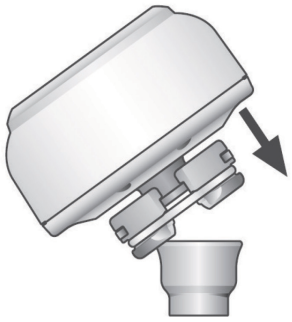
Cochlear and Oticon Medical are the only two entities distributing Baha® Connect-type bone conduction hearing systems (*i.e.*, systems having a skin penetrating abutment) in the United States. *Id* at ¶ 6. Oticon markets its system using the Ponto trademark. *See* Declaration of Mark E. Rentschler, Ph.D. In Support Of Plaintiff's Application For An Order To Show Cause Why Defendants Should Not Be Preliminarily Enjoined From Infringing Plaintiff's Patent ("Rentschler Decl."), ¶ 25.

The Ponto system includes an implant for anchoring the system in the skull:

Id. at ¶ 26. The implant is in turn connected to a skin penetrating abutment:

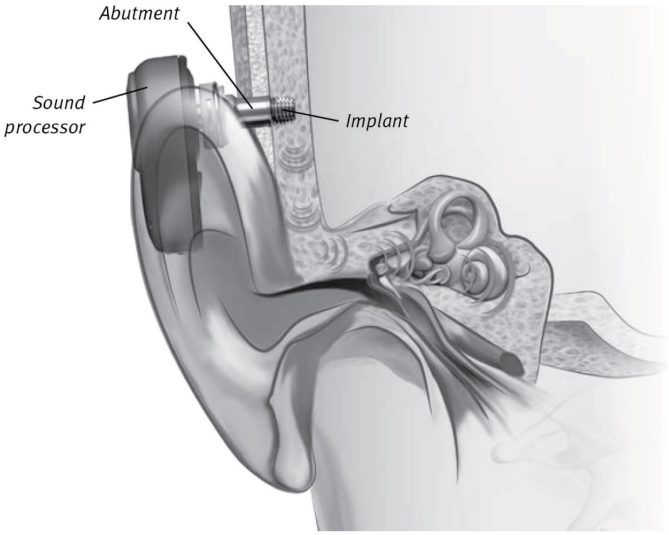


Id. at ¶ 27. A sound processor that creates vibrations can then be connected to the abutment by a snapping action:



Id. at ¶ 29.

With the parts of the Oticon Ponto system fully connected, the sound processor can transit vibrations through the skull bone directly to the inner ear, as shown below.



Id. at ¶ 28.

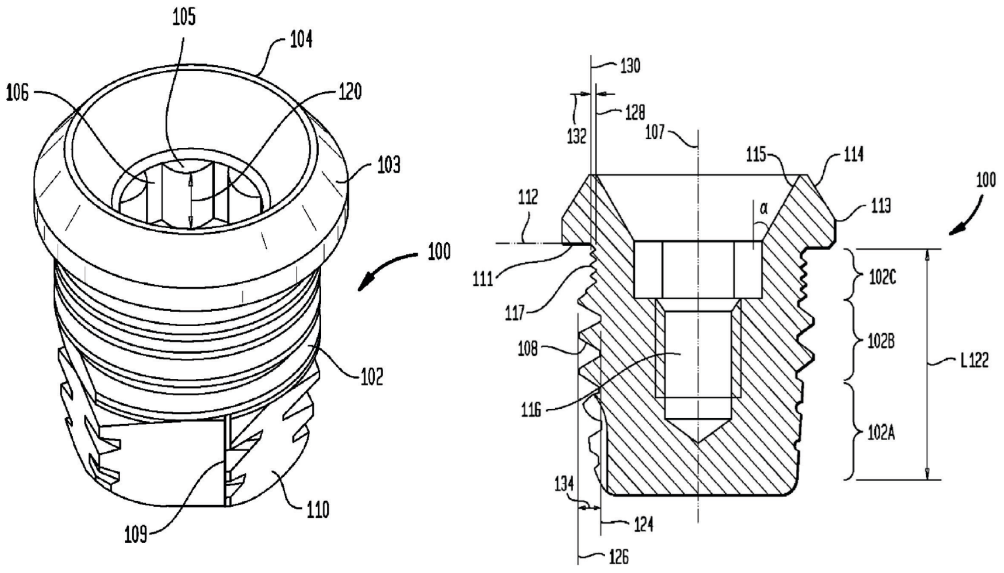
C. The '807 Patent

Cochlear's '807 patent is directed to the implant (bone anchoring element) in a bone conduction hearing system. Rentschler Decl. Ex. B ('807 patent col. 1, ll. 19-61). Specifically, the '807 patent teaches an improved implant that promotes "osseointegration." *Id.* ('807 patent col. 1, ll. 62-67).

Osseointegration is the process where new bone binds with the implant surface and the implant exhibits mechanical stability (*e.g.*, resistance to destabilization by mechanical or shear forces) that allows it to carry a load such as the rest of the bone conduction hearing system. Mendel Decl., ¶ 9. Improved osseointegration provides greater implant stability and allows the implant to be

loaded (attached to the rest of the system including the sound processor) sooner than was previously possible with bone conduction hearing systems. *Id.* at ¶ 9.

To achieve better osseointegration, the '807 patent discloses several novel features for a bone conduction implant, including a threaded tapered portion (108 in the drawing below) and a flange for providing a stop (103 in the drawings below), along with a circumferential groove between the flange and the threads (117 in the drawing below).



Rentschler Decl. Ex. B ('807 patent Figs. 1 & 2).

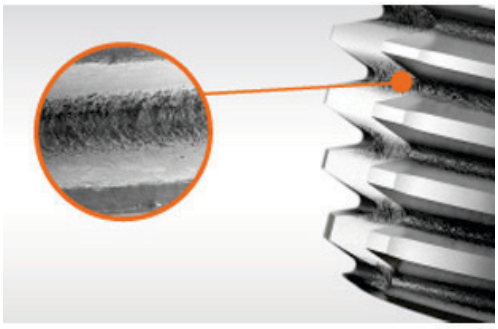
In addition to the particular thread arrangements for the implant, the '807 patent states that retention by the bone may also be improved by increasing the surface roughness of the bone contacting surfaces of the fixture. For example, the surfaces can be modified by an abrasive blasting process to increase surface roughness. *Id.* ('807 patent col. 5, ll. 7-14). The '807 patent contains numerous

claims that cover the many combinations of the specific features described in the '807 patent.

D. Oticon's Infringing BHX Implant

Oticon's current Ponto implant is called BHX. Rentschler Decl., ¶ 26. Oticon promotes the BHX implant as providing "the next level of osseointegration." Mendel Decl., ¶ 13. Like the '807 patent, the Oticon Ponto BHX implant is threaded, and includes a flange that serves as a stop and an annular groove between the flange and the threads:

Rentschler Decl., ¶ 30. Additionally, the Ponto BHX implant includes laser-ablated surfaces that increase the roughness of the surfaces:



Id. at ¶ 31.

Dr. Mark Rentschler, a professor at the University of Colorado at Boulder and Principal Investigator at the Advanced Medical Technologies Laboratory, has thoroughly reviewed information regarding the Oticon Ponto BHX implant and compared that product to the claims in the '807 patent. His analysis, as detailed in his declaration, led him to conclude that Oticon's Ponto BHX implant infringes numerous claims in that patent. Rentschler Decl., ¶ 33.

E. Cochlear Will Be Irreparably Harmed By Oticon's Infringement

Cochlear sells a BI300 implant, which was introduced in 2010, as part of the Baha® Connect system. Mendel Decl., ¶ 7. That implant, shown below, has a configuration and surface treatment (branded Tioblast™) that promotes osseointegration.

Id. at ¶ 8.

The improved osseointegration of the BI300 implant (with greater implant stability and earlier loading) has proven especially important to surgeons. *Id.* at ¶ 10. Significantly, the BI300 implant enhanced Cochlear's reputation as the technology leader for Baha® Connect-type bone conduction hearing systems among surgeons and audiologists. *Id.* at ¶ 11.

Oticon introduced the infringing Ponto BHX implant to compete with the Cochlear BI300 implant. *Id.* at ¶ 12. The introduction of the BHX implant is damaging Cochlear's reputation as the technology leader for Baha® Connect-type bone conduction hearing systems. *Id.* at ¶ 14. It is impossible to quantify the economic impact of this reputational harm. *Id.*

Additional harm from sales of the Ponto BHX implant – beyond the reputational harm – is also difficult to quantify. *Id.* at ¶ 15. Cochlear's underlying philosophy and business model is built upon a life-long relationship with the patients that receive its systems, captured by the saying that Cochlear uses "Hear now. And Always." *Id.* at ¶ 16. As a philosophy, Cochlear offers a lifetime of support for patients' hearing needs, with needed service and upgrades to ensure that the patients continue to hear well (if not better) as they age. *Id.* at ¶ 17.

As part of its business model, Cochlear depends not only on the sale of implants, but also on the sale of upgraded sound processors over a patient's lifetime. *Id.* at ¶ 18. The revenue from the sales of upgraded sound processors helps fund research and development that allows further performance enhancements as time goes on. *Id.*

When a patient chooses a Cochlear BI300 implant, Cochlear will generate revenue from the upgrades, because the BI300 implant and related abutments are only compatible with Cochlear sound processors. *Id.* at ¶ 19. On the other hand,

when a patient chooses an Oticon Ponto BHX implant, each time during a patient's lifetime that patient decides to upgrade, he or she can upgrade with either an Oticon or Cochlear sound processor, making it difficult to determine whether and to what extent Cochlear will lose revenue from, and a relationship with, that patient. *Id.*

Additionally, the timing of a patient's eligibility for an upgrade is largely governed by reimbursement rules, and can vary based on the organization providing reimbursement, such as an insurer or governmental entity. *Id.* at ¶ 20. It is difficult to project the amount and timing of potential future upgrades (and revenue from the upgrades) for any one patient. *Id.*

As a result, when Cochlear loses a patient – perhaps on a surgeon's recommendation of the Ponto BHX implant – Cochlear loses not just the sale of an implant, but possibly the lifelong relationship with that patient, including the revenue from upgraded sound processors. *Id.* at ¶ 21. Because of the many variables, the total economic harm from such a loss would be difficult to quantify. *Id.*

Taken together, the amount of reputational and downstream competitive harm to Cochlear from sales of the Ponto BHX implant is difficult, if not impossible, to quantify and goes far beyond lost revenue (and profits) from sales of Cochlear's BI300 implants. *Id.* at ¶ 22.

III.
COCHLEAR IS ENTITLED TO A PRELIMINARY INJUNCTION PREVENTING OTICON FROM SELLING ITS BHX IMPLANT

A. Legal Standards

District courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. The decision of whether to grant or deny a preliminary injunction in a patent case is committed to the discretion of the court. *See eBay v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).

A court considers four factors in deciding whether to preliminarily enjoin patent infringement: (1) a reasonable likelihood that the patent owner will succeed on the merits; (2) the likelihood that the patent owner will suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities between the parties; and (4) the injunction's impact on the public interest. *Murata Mach. USA, Inc. v. Daifuku Co.*, 830 F.3d 1357, 1363 (Fed. Cir. 2016) (*quoting Nat'l Steel Car, Ltd. v. Canadian Pac. Ry.*, 357 F.3d 1319, 1324-25 (Fed. Cir. 2004)). All of these factors weigh in favor of granting an injunction.

B. There Is More Than A Reasonable Likelihood That Cochlear Will Succeed On The Merits Of Its Patent Infringement Claim

"[T]o demonstrate likely success on the merits, [a patentee] must show that, in light of the presumptions and burdens applicable at trial, it will likely prove that [the accused infringer] infringes the asserted claims of the . . . patent and that the

patent will likely withstand [the accused infringer's] challenges to its validity." *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002). Both elements exist here.

1. Oticon Cannot Reasonably Dispute that Its BHX Implant Infringes the '807 Patent

Under 35 U.S.C. § 271(a), "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . infringes the patent." There are two steps to determine whether a product comes within the scope of the claims of a patent. First, the court construes the claims of the patent, and second, the court compares the construed claims to the accused product. *See Tate Access*, 279 F.3d at 1365. Step one is generally an issue of law for the court. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc). Step two is an issue of fact which requires a finding that each and every claim limitation or its equivalent is found in the accused product. *See Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003).

Here, the two steps lead to a conclusion of infringement. As shown in the Rentschler Decl., at least claims 1-12, 14, 16-17, 25, 28, 33-35, 37-41 and 45-47 of the '807 patent are infringed by the Oticon Ponto BHX implant. Rentschler Decl., ¶ 33.

2. Oticon Will Not Be Able To Raise a Substantial Question Concerning the Validity of the '807 Patent

The '807 patent is presumed to be valid, with "[t]he burden of establishing invalidity . . . on the party asserting such invalidity." 35 U.S.C. § 282; *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). "Because of this presumption, an alleged infringer who raises invalidity as an affirmative defense has the ultimate burden of persuasion to prove invalidity by clear and convincing evidence, as well as the initial burden of going forward with evidence to support its invalidity allegation." *Id*. As the Federal Circuit explained in *Titan Tire*:

> If . . . the alleged infringer responds to the preliminary injunction motion by launching an attack on the validity of the patent, the burden is on the challenger to come forward with evidence of invalidity, just as it would be at trial. The patentee, to avoid a conclusion that it is unable to show a likelihood of success, then has the burden of responding with contrary evidence, which of course may include analysis and argument.

Id. at 1377. "Thus, when analyzing the likelihood of success factor, the trial court, after considering all the evidence available at this early stage of the litigation, must determine whether it is more likely than not that the challenger will be able to

prove at trial, by clear and convincing evidence, that the patent is invalid." *Id*. at 1379.

Each patent claim constitutes a separate invention and must separately be proven invalid by clear and convincing evidence for Oticon to succeed. *See* 35 U.S.C. § 282 ("A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims…"); *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1220 (Fed. Cir. 1995) ("[E]ach claim is a separate statement of the patented invention"). Here Oticon infringes *twenty-eight* patent claims, each defining inventions of different scope. Additionally, the Patent Office allowed these twenty-eight claims after thorough examination and consideration of more than *eighty* prior art references. Rentschler Decl. Ex. B ('807 patent, first and second pages, References Cited). It is difficult to impossible to believe that Oticon would have a significant chance of invalidating all of the infringed claims.

C. Cochlear Will Suffer Irreparable Harm Unless Preliminary Injunctive Relief Is Granted

To show irreparable harm on a preliminary injunction in a patent infringement case, "a patentee must establish . . . : 1) that absent an injunction, it will suffer irreparable harm, and 2) that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." *Apple Inc. v. Samsung Electronics. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012).

"[T]he irreparable harm inquiry seeks to measure harms that no damages payment, however great, could address." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). "Price erosion, loss of goodwill, damages to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." *Id*. In *Celsis In Vitro*, the Federal Circuit recognized that the inability to accurately measure all lost sales or growth as a result of an infringing competitor is a factor to consider in the irreparable harm analysis. *See id*. (upholding the district court's finding of irreparable harm and noting that the "mere possibility of monetary damages does not defeat a motion for preliminary injunction"). Other factors to consider in the irreparable harm analysis include the size and structure of the market, the likelihood of losing customers and market share, and the degree to which the infringer competes with the plaintiff. *See Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1170-71 (Fed. Cir. 2014).

Here, allowing Oticon to continue promoting and selling its Ponto BHX implant will irreparably damage Cochlear's reputation in the marketplace. *C.f. Douglas Dynamics, LLC v. Buyers Products Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013) (reversing denial of injunction in view of reputational loss). Additionally, Oticon's promotion of its implant will likely lead to the loss of potentially lifelong patients. Such damages are difficult, if not impossible, to quantify. *See Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017) ("'it is

impossible to quantify the damages caused by the loss of a potentially lifelong customer.'"); *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) (loss of market opportunities cannot be quantified or adequately compensated, and is evidence of irreparable harm).

As the only players in the market, the relationship between Cochlear and Oticon is also an important factor in the Court's analysis of irreparable harm. Courts are more likely to grant an injunction in two-player markets where the parties are direct competitors. *See, e.g., Robert Bosch v. Pylon Mfg. Corp.,* 659 F.3d 1142, 1153 (Fed. Cir. 2011).

D. The Balance of Hardships Decidedly Favors The Grant Of Injunctive Relief

The balance of hardships tips sharply in favor of Cochlear. Cochlear will be irreparably harmed if Oticon continues to promote and sell its BHX implant. On the other hand, *Oticon could simply return to selling the implant it offered prior to the BHX implant*. Thus, notwithstanding this request for injunctive relief, Oticon will still be able to sell its products—it just won't be allowed to market a product that irreparably harms Cochlear. Thus, Oticon will not unreasonably suffer from such an injunction.

E. The Public Interest Favors Granting An Injunction To Preserve Cochlear's Patent Rights

The public interest favors protecting patent rights where, as here, a likelihood that the patent is valid and enforceable is demonstrated. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008). The Federal Circuit has also "long acknowledged the importance of the patent system in encouraging innovation. Indeed, the 'encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.'" *Patlex Corp. v. Mossinghof*, 758 F.2d 594, 599 (Fed. Cir. 1985). "[B]y shifting market benefits to the infringer while litigation is pending for patents that are likely to withstand the attack, the incentive for discovery and development of new products is adversely affected. The statutory period of exclusivity reflects the congressional balance of interests, and warrants weight in considering the public interest." *Abbott Labs*., 544 F.3d at 1362. Accordingly, the public interest weighs in favor of granting a preliminary injunction.

IV.
CONCLUSION

For the reasons set forth above, Cochlear is entitled to an order to show cause why a preliminary injunction should not issue preventing Oticon from promoting, selling, offering for sale, and/or importing its Ponto BHX implant.

Dated: April 13, 2018

Respectfully submitted,

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