UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COCHLEAR LTD., Plaintiff, v. MED-EL CORPORATION, USA, Defendant.	**Civil Action No.** **Jury Trial Demanded**

COMPLAINT

Plaintiff, Cochlear Ltd. ("Plaintiff" or "Cochlear"), by and through its counsel, files this Complaint for patent infringement against Defendant, MED-EL Corporation, USA ("Defendant" or "MED-EL"),[1] and alleges as follows:

NATURE OF THE ACTION

1. Cochlear is a global leader and innovator in the design and manufacture of medical and hearing implant technology. Since Cochlear's creation of the world's first multi-channel cochlear hearing implant in 1978, Cochlear has helped more than 450,000 people hear their children, friends, and families, and has maintained a high level of long-term implant reliability. Cochlear's invention from 40 years ago has evolved into its Cochlear™ Nucleus® System, and its hearing implant solutions have expanded, including the Cochlear Baha® System and the Cochlear Nucleus Hybrid™ Implant System. Today, Cochlear is one of the top 50 listed Australian companies, with a market capitalization of over US$7.2 billion.

[1]MED-EL Corporation, USA is sometimes referred to as "MED-EL Corporation" or "MED-EL USA."

2. Cochlear continues to significantly invest in research and development to advance medical and hearing technology. Cochlear invested more than US$109 million in research and development activities in its 2017 fiscal year, and increased its investment in research and development to US$120 million in its 2018 fiscal year. These substantial investments are reflected in a large portfolio of more than 500 U.S. patents, including U.S. Patent Nos. 9,144,676 (the "'676 Patent"), 9,884,141 (the "'141 Patent"), and 10,058,702 (the "'702 Patent"), which are asserted in this case. Copies of the '676 Patent, the '141 Patent, and the '702 Patent are attached hereto as Exhibits A through C, respectively.

3. Cochlear's hearing products address a world-wide problem – hearing impairment. The World Health Organization ("WHO") has estimated that approximately 466 million people worldwide have disabling hearing loss, of which 34 million are children. *See* Deafness and Hearing Loss, World Health Organization (Mar. 15, 2018), http://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss. The WHO estimates that unaddressed hearing loss poses an annual global cost of US$750 billion. *Id*.

4. Cochlear has made major breakthroughs in its research and development of various hearing devices, including cochlear hearing solutions, such as the Nucleus® System, and bone conduction hearing solutions, such as the Baha® System, that are covered and protected by Cochlear's intellectual property rights. Given its innovative efforts and substantial investments, Cochlear values its inventions and intellectual property rights.

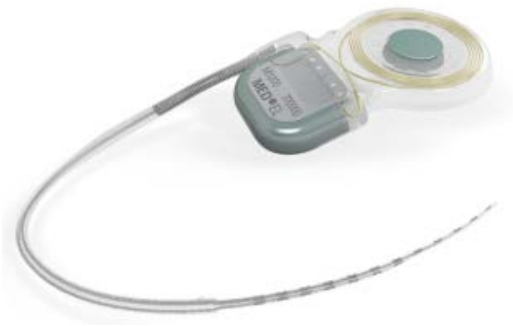
5. As further detailed below, MED-EL has decided to pursue products that violate Cochlear's patent-protected inventions.

6. MED-EL makes, uses, offers for sale, sells, and/or imports its own competing cochlear implant solution—the SYNCHRONY cochlear implant system that includes, without

limitation, an implant (e.g., Synchrony Implant) and an external audio processor (e.g., SONNET audio processor, RONDO audio processor, RONDO 2 audio processor) (collectively, "SYNCHRONY Implant System")—in the United States, undermining the value of Cochlear's substantial investments in its innovative technologies by infringing at least the '676, '141, and '702 Patents.

7. On January 23, 2015, MED-EL published a press release announcing that it has obtained an FDA clearance for the Synchrony Implant. (Ex. D, FDA Approves MED-EL's SYNCHRONY Cochlear Implant (Jan. 23, 2015), https://s3-eu-west-1.amazonaws.com/s3.medel.com/pdf/US/SYNCHRONY-FDA-Approval.pdf.) The press release states that "SYNCHRONY will be available in spring 2015." (*Id*. at 1.)

8. According to the press release, "[d]uring an MRI, SYNCHRONY's magnet freely rotates and self-aligns within its titanium housing," allegedly "reducing implant torque and the risk of demagnetization during MRI scans," and thereby enabling "MRI scans without the need for magnet removal." (Ex. D at 1.) Further, the "implant features a polymer stiffening ring within the silicone implant body to further secure the magnet housing," where the magnet can "be removed from the bottom side of the implant." (*Id*.) An image of the Synchrony Implant is provided as follows:



(*Id*.)

9. The press release further states that the "removable magnet housing features a protective coating to prevent unwanted cellular adhesion, simplifying the removal and replacement of the implant magnet." (Ex. D at 1-2.) "The incision for magnet exchange is made beside the implant, rather than directly over the implant." (*Id*. at 2.) The press release also provides that the Synchrony Implant uses titanium fixation pins for securing the placement of the implant and incorporates MED-EL's electrode arrays. (*Id*.) Further, "SYNCHRONY is compatible with all current MED-EL audio processors, including the recently approved SONNET." (*Id*. at 1.)

10. Further, upon information and belief, MED-EL's RONDO, SONNET, and RONDO 2 audio processors are made, used, sold, offered for sale, and/or imported in or into the United States. (*See, e.g.*, Ex. E, MED-EL Announces Limited-Time Offer: New Recipients to Receive Both the OPUS 2 BTE and RONDO Single-Unit Processors (May 23, 2013), https://www.medel.com/data/editor/file/press_releases_US/23962-Limited-Time-Offer-USA.pdf; Ex. F, FDA Approves New SONNET Audio Processor and MAESTRO 6.0 Software from MED-EL (Dec. 11, 2014), https://s3.medel.com/pdf/US/24967_r10_SONNET_FDA%20Approval-Press-Release.pdf; Ex. G, FDA Approves Industry's First Off-the-Ear Audio Processor with Wireless Charging: MED-EL's RONDO 2 (May 17, 2018), https://s3.medel.com/downloadmanager/downloads/us_research/en-US/RONDO%202%20FDA%20Approval%20Press%20Release.pdf.) These audio processors can be utilized with the SYNCHRONY Implant to comprise a working SYNCHRONY Implant System.

11. On March 24, 2015, MED-EL published another press release announcing "that the first SYNCHRONY cochlear implant has successfully been implanted at the University of North Carolina Hospitals," which was "the first facility in the country to offer SYNCHRONY." (Ex. H,

First U.S. Patient Receives MED-EL's SYNCHRONY Cochlear Implant (Mar. 24, 2015), https://s3.medel.com/pdf/US/SYNCHRONY_First_Surgery_3.24.15.pdf.)

12. No later than December 5, 2018, Cochlear informed MED-EL that certain MED-EL products, including the Synchrony Implant, infringe Cochlear's patents, including the '676 and '702 Patents. On information and belief, MED-EL has been aware of the '676, '141, and '702 Patents even before Cochlear's December 5, 2018 notice to MED-EL.

13. MED-EL's continued manufacture, use, offers for sale, sale, and/or importation of the SYNCHRONY Implant Systems in or into the United States directly and indirectly infringe one or more of the claims of the '676, '141, and '702 Patents, resulting in Cochlear's filing of this Complaint in order to defend its investments and to protect its innovative technologies and patent rights.

PARTIES

14. Cochlear is a corporation organized and existing under the laws of Australia, with a principal place of business at 1 University Avenue, Macquarie University, New South Wales 2109, Australia.

15. Cochlear develops and manufactures cochlear implant hearing solutions.

16. Cochlear, through its wholly-owned subsidiary, Cochlear Americas, markets, sells, and conduct clinical trials for cochlear implant solutions in the United States. Cochlear Americas is a corporation organized and existing under the laws of Delaware, with a principal place of business at 13059 E. Peakview Avenue, Centennial, Colorado 80111.

17. On information and belief, MED-EL Corporation, USA is a corporation organized and existing under the laws of Massachusetts, with a principal place of business at 2645 Meridian Parkway, Durham, North Carolina 27713.

18. On information and belief, MED-EL Corporation, USA is a wholly-owned subsidiary of MED-EL Elektromedizinische Geräte Ges.m.b.H., which is a company, a *Gesellschaft mit beschränkter Haftung* ("GmbH"), organized and existing under the laws of Austria, with a principal place of business at Fürstenweg 77a 6020 Innsbruck, Austria.

JURISDICTION AND VENUE

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

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

21. The Court has personal jurisdiction over MED-EL because it is incorporated and resides in the District of Massachusetts.

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because MED-EL is subject to personal jurisdiction in this District and is incorporated and resides in this District.

PATENTS-IN-SUIT

23. Cochlear is the owner and assignee of all rights, title, and interest in and under U.S. Patent Nos. 9,144,676 (the "'676 Patent"), 9,884,141 (the "'141 Patent"), and 10,058,702 (the "'702 Patent").

U.S. Patent No. 9,144,676 (the "'676 Patent")

24. Cochlear is the owner and assignee of all rights, title, and interest in and under the '676 Patent, titled "Implant Magnet System," which was duly and legally issued by the USPTO on September 29, 2015. (*See* Ex. A, the '676 Patent.) The '676 Patent is a lawfully issued, valid,

and enforceable United States Patent. The listed inventors of the ’676 Patent are Peter Gibson, Charles Roger Aaron Leigh, Frank Risi, and David Walker. (*Id*.)

25. The ’676 Patent generally relates to, without limitation, cochlear implant systems. (*See* Ex. A, the ’676 Patent 1:27.) For example, without limitation, the ’676 Patent is directed to a cochlear implant system comprising “essentially two components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a stimulator/receiver unit,” where the external and internal components would work together “to provide the sound sensation to a user.” (*Id*. at 1:27-32.) Further, for example, without limitation, the ’676 Patent is directed to a cochlear implant system with a magnetic alignment system that “prevents substantial movement of a magnet of an implanted component during an MRI procedure or allows for easy removal of the magnet to facilitate the MRI procedure.” (*Id*. at Abstract.)

26. Further, for example, without limitation, the ’676 Patent is directed to a “medical device comprising” “an external component having a first magnet” and “an internal component having a second magnet, wherein the first and second magnet provide magnetic alignment between the external component and the implantable component, wherein the implantable component includes a mounting for the second magnet, the mounting including a body having a plurality of recesses arrayed about the second magnet, and wherein the implantable component includes a silicone body, wherein the mounting sits at least partially within the silicone body of the implantable component, and wherein silicone of the silicone body extends into recesses, thereby securing the mounting to the silicone body.” (*Id*. at cl. 15.)

U.S. Patent No. 9,884,141 (the "'141 Patent")

27. Cochlear is also the owner and assignee of all rights, title, and interest in and under the '141 Patent, titled "Implantable Device Having Osseointegrating Protuberances," which was duly and legally issued by the USPTO on February 6, 2018. (*See* Ex. B, the '141 Patent.) The '141 Patent is a lawfully issued, valid, and enforceable United States Patent. The sole listed inventor of the '141 Patent is Peter Gibson. (*Id*.)

28. The '141 Patent generally relates to, without limitation, an implantable device (or an implantable component) and a method for implanting an implantable device. (*See* Ex. B, the '141 Patent 2:7-8, 2:18-19, 2:30-31.) For example, without limitation, the '141 Patent is directed to an "implantable device for mounting to a patient's bone," the device comprising "a housing including a surface having an abutting portion configured to abut the bone when the device is implanted in the patient, the abutting portion defining a housing axis orthogonal to the surface," "at least one stud extending from the surface of the housing," "the at least one stud being adapted to abut the patient's bone," and "the at least one stud having a substantially smooth shaft." (*Id*. at cl. 1.)

U.S. Patent No. 10,058,702 (the "'702 Patent")

29. Cochlear is also the owner and assignee of all rights, title, and interest in and under the '702 Patent, titled "Implant Magnet System," which was duly and legally issued by the USPTO on August 28, 2018. (*See* Ex. C, the '702 Patent.) The '702 Patent is a lawfully issued, valid, and enforceable United States Patent. The listed inventors of the '702 Patent are Peter Gibson, Charles Roger Aaron Leigh, Frank Risi, and David Walker. (*Id*.)

30. The '702 Patent generally relates to, without limitation, cochlear implant systems and methods for removing magnets of internal component of cochlear implant systems. (*See* Ex.

C, the ’702 Patent 1:23, 6:5-13.) For example, without limitation, the ’702 Patent is directed to “[a]rrangements for preventing any or at least reducing substantial movement of the magnet of a transcutaneous transmitter/receiver system, such as a cochlear implant system, while a recipient is undergoing MRI scans of relatively low field strengths and arrangements that allow removal of the magnet from within the implantee if necessary.” (*Id*. at 6:5-11.) Further, for example, without limitation, the ’702 Patent is directed to a method comprising “accessing an implanted component of a medical device implanted in a recipient through an incision in skin of the recipient, the implanted component including a magnet apparatus,” “inserting a tool through the incision in the skin towards the magnet apparatus,” “positioning a portion of the tool underneath a skull facing side of the magnet apparatus,” and “removing the magnet apparatus while the implanted component remains implanted in the recipient.” (*Id*. at cl. 1.)

COUNT I
Infringement of U.S. Patent No. 9,144,676

31. Cochlear incorporates by reference the allegations set forth in paragraphs 1-30 of this Complaint as though fully set forth herein.

32. MED-EL has directly infringed and continues to directly infringe one or more claims of the ’676 Patent, including, but not limited to, claims 1-3, 8-9, 11, and 13-21 of the ’676 Patent, under 35 U.S.C. § 271 by having made, used, sold, offered for sale, and/or imported, and/or continuing to make, use, sell, offer for sale, and/or import in or into the United States, without authority, cochlear implant devices, including, but not limited to, the SYNCHRONY Implant System. For example, without limitation, the SYNCHRONY Implant System meets and practices each and every limitation of at least one claim of the ’676 Patent, including, but not limited to, claims 1-3, 8-9, 11, and 13-21 of the ’676 Patent, either literally or equivalently.

33. MED-EL has indirectly infringed and continues to indirectly infringe one or more claims of the ’676 Patent, including, but not limited to, claims 1-3, 8-9, 11, and 13-21 of the ’676 Patent, under § 271(b) by having actively induced and/or continuing to actively induce customers and/or users to use, sell, offer for sale, and/or import in or into the United States, without authority, cochlear implant devices, including, but not limited to, the SYNCHRONY Implant System, which embody and/or practice the claims of the ’676 Patent. MED-EL has known about the ’676 Patent since at least December 5, 2018, when Cochlear notified MED-EL that MED-EL’s products, including the Synchrony Implant, now available in the United States, infringe the claims of the ’676 Patent. Since that date, MED-EL has continued to make, use, offer for sale, sell, and/or import in or into the United States the infringing SYNCHRONY Implant Systems. MED-EL knew or should have known that its continued sales of the SYNCHRONY Implant Systems would induce direct infringement by customers and/or users. MED-EL knew or should have known that its importation, use, offer for sale, and/or sale of the SYNCHRONY Implant Systems would infringe the ’676 Patent. Upon information and belief, MED-EL failed to redesign the SYNCHRONY Implant System to cease infringement.

34. MED-EL’s infringement of the ’676 Patent is and has been willful. MED-EL has known about the ’676 Patent since at least December 5, 2018, but has continued to make, use, sell, offer for sale, and/or import in or into the United States the infringing SYNCHRONY Implant Systems despite knowing that a risk of infringement of the ’676 Patent was significant.

35. MED-EL’s infringement of the ’676 Patent has caused damage to Cochlear, and Cochlear is entitled to recover from MED-EL the damages it has sustained as a result of MED-EL’s wrongful acts, including lost profits.

36. MED-EL's infringement of the '676 Patent will continue to damage Cochlear, causing irreparable harm for which there is no adequate remedy at law, unless enjoined by the Court.

COUNT II
Infringement of U.S. Patent No. 9,884,141

37. Cochlear incorporates by reference the allegations set forth in paragraphs 1-36 of this Complaint as though fully set forth herein.

38. MED-EL has directly infringed and continues to directly infringe one or more claims of the '141 Patent, including, but not limited to, claims 1, 8, and 16 of the '141 Patent, under 35 U.S.C. § 271 by having made, used, sold, offered for sale, and/or imported, and/or continuing to make, use, sell, offer for sale, and/or import in or into the United States, without authority, cochlear implant devices, including, but not limited to, the SYNCHRONY Implant System. For example, without limitation, the SYNCHRONY Implant System meets and practices each and every limitation of at least one claim of the '141 Patent, including, but not limited to, claims 1, 8, and 16 of the '141 Patent, either literally or equivalently.

39. MED-EL has indirectly infringed and continues to indirectly infringe one or more claims of the '141 Patent, including, but not limited to, claims 1, 8, and 16 of the '141 Patent, under § 271(b) by having actively induced and/or continuing to actively induce customers and/or users to use, sell, offer for sale, and/or import in or into the United States, without authority, cochlear implant hearing devices, including, but not limited to, the SYNCHRONY Implant System, which embody and/or practice the claims of the '141 Patent. Upon information and belief, MED-EL has known about the '114 Patent before the filing of this Complaint, and that its products, including the SYNCHRONY Implant Systems, likely infringed the claims of the '141 Patent. Despite such knowledge, MED-EL has continued to make, use, offer for sale, sell, and/or import

in or into the United States the infringing SYNCHRONY Implant Systems. MED-EL knew or should have known that its continued sales of the SYNCHRONY Implant Systems would induce direct infringement by customers and/or users. MED-EL knew or should have known that its importation, use, offer for sale, and/or sale of the SYNCHRONY Implant Systems would infringe the ’141 Patent. Upon information and belief, MED-EL failed to redesign the SYNCHRONY Implant System to cease infringement.

40. MED-EL’s infringement of the ’141 Patent is and has been willful. Upon information and belief, MED-EL has known about the ’141 Patent prior to the filing of this Complaint, but has continued to make, use, sell, offer for sale, and/or import in or into the United States the infringing SYNCHRONY Implant Systems despite knowing that a risk of infringement of the ’141 Patent was significant.

41. MED-EL’s infringement of the ’141 Patent has caused damage to Cochlear, and Cochlear is entitled to recover from MED-EL the damages it has sustained as a result of MED-EL’s wrongful acts, including lost profits.

42. MED-EL’s infringement of the ’141 Patent will continue to damage Cochlear, causing irreparable harm for which there is no adequate remedy at law, unless enjoined by the Court.

COUNT III
Infringement of U.S. Patent No. 10,058,702

43. Cochlear incorporates by reference the allegations set forth in paragraphs 1-42 of this Complaint as though fully set forth herein.

44. MED-EL has indirectly infringed and continues to indirectly infringe one or more claims of the ’702 Patent, including, but not limited to, claims 1-2, 6-8, and 10-12 of the ’702 Patent, under § 271(b) by having actively induced and/or continuing to actively induce customers

and/or users to use, sell, offer for sale, and/or import in or into the United States, without authority, cochlear implant devices, including, but not limited to, the SYNCHRONY Implant System, which embody and/or practice the claims of the ’702 Patent. MED-EL has known about the ’702 Patent since at least December 5, 2018, when Cochlear notified MED-EL that MED-EL’s products, including the Synchrony Implant, now available in the United States, infringe the claims of the ’702 Patent. Since that date, MED-EL has continued to make, use, offer for sale, sell, and/or import in or into the United States the infringing SYNCHRONY Implant Systems. MED-EL knew or should have known that its continued sales of the SYNCHRONY Implant Systems would induce direct infringement by customers and/or users. MED-EL knew or should have known that its importation, use, offer for sale, and/or sale of the SYNCHRONY Implant Systems would infringe the ’702 Patent. Upon information and belief, MED-EL failed to redesign the SYNCHRONY Implant System to cease infringement.

45. MED-EL’s infringement of the ’702 Patent is and has been willful. MED-EL has known about the ’702 Patent since at least December 5, 2018, but has continued to make, use, sell, offer for sale, and/or import in or into the United States the infringing SYNCHRONY Implant Systems despite knowing that a risk of infringement of the ’702 Patent was significant.

46. MED-EL’s infringement of the ’702 Patent has caused damage to Cochlear, and Cochlear is entitled to recover from MED-EL the damages it has sustained as a result of MED-EL’s wrongful acts, including lost profits.

47. MED-EL’s infringement of the ’702 Patent will continue to damage Cochlear, causing irreparable harm for which there is no adequate remedy at law, unless enjoined by the Court.

JURY DEMAND

48. Cochlear hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PRAYER FOR RELIEF

WHEREFORE, Cochlear respectfully requests that the Court enter judgment in its favor and against MED-EL as follows:

a. Enter judgment in favor of Cochlear on each of its claims;

b. Declare that MED-EL has infringed the ’676 Patent, the ’141 Patent, and the ’702 Patent;

c. Enter a permanent injunction enjoining MED-EL and its officers, agents, employees, and privies, from further infringement of the ’676 Patent, the ’141 Patent, and the ’702 Patent;

d. Award monetary damages sufficient to compensate Cochlear for MED-EL’s infringement of the ’676 Patent, the ’141 Patent, and the ’702 Patent, including lost profits and/or a reasonable royalty;

e. Grant Cochlear pre-judgment and post-judgment interest on the damages caused to it by reason of MED-EL’s infringement of the ’676 Patent, the ’141 Patent, and the ’702 Patent;

f. Declare that MED-EL’s infringement was willful and award enhanced damages and interest to Cochlear under 35 U.S.C. § 284;

g. Declare that this case is an exceptional case under 35 U.S.C. § 285 and award Cochlear its reasonable attorneys’ fees, costs, and expenses incurred in this action; and

h. Award such other and further relief to Cochlear as the Court deems just and proper.

Dated: February 18, 2019 Respectfully submitted,

/s/ *Kevin O'Connor*

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