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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

ALFRED E. MANN FOUNDATION FOR SCIENTIFIC RESEARCH,

Plaintiff,

vs.

COCHLEAR CORPORATION and COCHLEAR LTD.,

Defendants.

AND RELATED COUNTERCLAIMS.

Case No. **CV 07-08108 GHK (CTX)**

JOINT MEMORANDUM OF POINTS AND AUTHORITIES RE SUMMARY JUDGMENT MOTIONS

Date: June 15, 2009
Time: 9:30 a.m.
Courtroom: Hon. George H. King
Rm. 650, Roybal Bldg.

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PLAINTIFF'S MOTIONS FOR SUMMARY JUDGMENT

Plaintiff Alfred E. Mann Foundation for Scientific Research ("AMF") moves for partial summary judgment that three of the affirmative defenses raised by defendants Cochlear Corp. and Cochlear Ltd. (collectively "Cochlear") lack evidentiary support. The Court should grant summary judgment on Cochlear's laches, estoppel, and inequitable conduct defenses.

I. PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT RE LACHES

A. Cochlear's Laches Defense Fails

The Court should grant summary judgment against Cochlear's affirmative defense of laches. Cochlear cannot prove that AMF delayed filing suit for an unreasonable and inexcusable length of time from when it knew or reasonably should have known of its claim against Cochlear, and that the delay materially prejudiced Cochlear. *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1032, 1045 (Fed. Cir. 1992).

Cochlear asserts that a presumption of laches applies by claiming that AMF knew or should have known of Cochlear's infringement prior to December 13, 2001, or more than six years before filing suit. *Wanlass v. GE*, 148 F.3d 1334, 1339 (Fed. Cir. 1998), cited by Cochlear is inapposite because it involved devices that were "easily testable." There is no evidence that Cochlear devices (which are highly regulated FDA Class 3 medical devices available to qualified cochlear implant patient candidates) were readily available for AMF to test. Certainly, Cochlear's Freedom line of implants, introduced in 2005, were not available for AMF to test prior to December 13, 2001. Thus, as a matter of law, no presumption of laches attaches to the Freedom line of implants. Cochlear's evidence that AMF knew or should have known that Cochlear had a "telemetry" feature does not prove that AMF knew or should have known of infringement, which requires proof that all elements of the claimed invention be present. Cochlear does not and cannot contend that "telemetry" by itself infringes any claim of any patent in suit.

Infringement damages alone do not prove economic prejudice. *Aukerman, 960 F.2d.* at 1033; *State Contracting & Eng'g Corp. v. Condotte Am., Inc.*, 346 F.3d 1057, 1066-67 (Fed. Cir. 2003). Cochlear must explicitly prove a nexus between the economic loss and the alleged delay. *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 1294 (Fed. Cir. 1992) ("The change must be because of and as a result of the delay, not simply a business decision to capitalize on a marketing opportunity."). The infringer "must prove that the change in economic position would not have occurred had the patentee sued earlier." *Gasser Chair Co., Inc. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 775 (Fed. Cir. 1995). Failure to cease infringing sales after suit is evidence that no economic loss resulted from any delay. *Meyers v. Brooks Shoe, Inc.*, 912 F.2d 1459, 1463 (Fed. Cir. 1990), overruled on other grounds, Aukerman, 960 F.2d at 1038.

In its Third Amended Response to Interrogatory No. 5 (served approximately two weeks after the close of discovery), Cochlear identified the sole basis of its alleged prejudice: (1) AMF wrote a letter to Cochlear in 2003 stating that Cochlear's "Nucleus cochlear implants" "may infringe" U.S. Pat. No. 5,609,616; (2) Cochlear wrote a letter back to AMF in 2003 stating that Cochlear did not infringe; (3) AMF did not respond to the letter; and (4) "[Cochlear] relied on this silence in introducing a new generation product into the United States, namely the Nucleus® Freedom implant, in 2005." JA-131-32. Cochlear did not identify any nexus between its alleged economic prejudice and the alleged delay in filing.

Cochlear's Rule 30(b)(6) deposition witness, Tony Nygard, also failed to identify any economic prejudice. He only testified that Cochlear assumed that "AMF [was] satisfied with [Cochlear's] reply" to AMF's letter. JA-1408-09 (Nygard Dep. at 144:19 – 145:4). Nygard also could not identify any actions that Cochlear would have taken had AMF responded to O'Mahoney's letter differently. JA-1409 (Nygard Dep. at 145:5-12). Nygard also admitted that Cochlear did not cease any sales in response to this patent infringement lawsuit, but he refused to say

why, relying on attorney-client privilege. *Id.* (145:14-17). Another Cochlear witness, James Patrick, testified that Cochlear did not change any of its product development plans, either based AMF's letter or Cochlear's response. JA-1433, JA-1435 (Patrick Dep. at 178:1-15; 188:18-23).

There is simply no record evidence that Cochlear suffered any economic prejudice that has a specific nexus to the alleged delay by AMF in filing suit. *Hemstreet*, 972 F.2d at 1294; *Gasser*, 60 F.3d at 775. While the Janssen Declaration authenticates sales reports and provides the date of introduction of Cochlear's infringing Freedom line in 2005, it likewise fails to provide evidence linking the increased sales to the delay. *See* JA-714 (Janssen Decl. ¶¶ 2-3). Indeed, Cochlear has continued to sell the accused infringing devices after the lawsuit was filed, which is further proof that an earlier lawsuit would have had no effect on Cochlear's decision to introduce the Nucleus® Freedom implant in 2005. *Meyers*, 912 F.2d at 1463. Summary judgment should be granted against Cochlear's laches defense.

Cochlear now contends that it will suffer evidentiary prejudice because certain witnesses "can no longer remember" certain facts. Yet Cochlear made no mention of any evidentiary prejudice in its Third Supplemental Interrogatory response served after all fact depositions were taken. Thus, its new-found assertion should be ignored. In any event, Cochlear's assertion of evidentiary prejudice is conclusory and insufficient to establish nexus between the evidentiary loss and the delay. *See Unova Inc. v. Hewlett-Packard*, 2006 U.S. Dist. LEXIS 97400 *6-*7 (C.D. Cal. 2006). Here, Cochlear failed to present evidence that, before 2003, AMF knew or should have known of Cochlear's infringement because Cochlear's products are medical implants that are not readily available to inspect and analyze. There is no evidence suggesting that had AMF filed its lawsuit in 2003 that either Dr. Schulman or Mr. Gold would have remembered the supposed "key events" that Cochlear contends are lost because those "key events" occurred before the '616 patent issued on March 11, 1997. *See James River Corp. v. Hallmark Cards, Inc.*, 915 F. Supp.

968, 979-80 (E.D. Wisc. 1996); *Beam Laser Sys., Inc. v. Cox Commc'ns, Inc.*, 144 F. Supp. 2d 464, 472-73 (E.D. Va. 2001).

There are no genuine issues of material fact. Summary judgment should be granted.

B. Summary Judgment On Laches Should Be Denied

AMF delayed filing suit at least eight years since it learned of the alleged infringement. During that delay, Cochlear has introduced new products that are alleged to infringe (greatly increasing sales and potential damages). Memories and testimony have been lost. The resulting economic and evidentiary prejudice could have been avoided had AMF promptly filed suit.

1. AMF's Delay and Misleading Silence Prior to Suit

According to its President Joseph Schulman, AMF's belief that Cochlear was infringing arose "[w]hen I found out – when I discovered that they [Cochlear] were using telemetry."[1] In that regard, Schulman learned in 1994 or 1995 that "Nucleus [i.e. Cochlear] was reporting on impedance measurements …" based on telemetry.[2] In 1995, Schulman wrote about an industry meeting where a Cochlear PCIT (*i.e.* physician's cochlear implant tester) was among the topics covered.[3] Then, by 1996, Schulman reviewed an Advanced Bionics ("AB") document that stated that Cochlear had announced a new product that "meets the [AB] Clarion on back-telemetry …."[4]

Schulman was not the only one at AMF that knew early on that Cochlear's products had back telemetry. By 1999, AMF had employed Jon Phil Mobley as Technical Manager.[5] Mobley knew from his prior employment that "the Nucleus

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[1] **JA-1570-71** (Schulman 30(b)(6) 12/17/08 Depo. 29:23-30:20)
[2] **JA-1853** (Exh. 1075); **JA-1544-45** (Schulman 12/2/08 Depo. 128:23-129:24)
[3] **JA-1854-55** (Exh. 1076); **JA-1546-47** (Schulman 12/2/08 Depo. 130:4-131:8)
[4] **JA-1903-30** (Exhibit 1142, p. AMF010860); **JA-1565-66** (Schulman 30(b)(6) 12/17/08 Depo. 19:18-21:4)
[5] **JA-1380** (Mobley Depo. 8:3-8)

implant had back telemetry."[6]

Indeed, it is not surprising that Schulman and Mobley knew about Cochlear's use of back telemetry, because "it was apparently common knowledge …."[7] By December 2001, six years before this suit was filed, use of such telemetry was widely described in public documents.[8]

Despite long knowing about Cochlear's use of back telemetry, AMF waited until July 2003 to write Cochlear about the alleged infringement.[9] Cochlear promptly responded in writing, telling AMF that its products did not infringe.[10] AMF did not respond, and Cochlear concluded that AMF had dropped the matter.[11] In the next two years, Cochlear's new Nucleus Freedom product, implanted in thousands of patients, drove Cochlear's sales to a much higher level.[12]

AMF then filed suit in December 2007. In the interim, witnesses such as Schulman and patent attorney Bryant Gold have apparently lost their memories of key events.[13] AMF now seeks damages and an injunction, presumably including a

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[6] **JA-1383-84** (Mobley Depo. 39:21-40:12)

[7] **JA-1571** (Schulman 30(b)(6) 12/17/08 Depo. 30:14-20)

[8] E.g. **JA-1869-71** (Exh. 1128), **JA-1872-82** (Exh. 1132), **JA-1883-86** (Exh. 1135) and **JA-1887-1902** (Exh. 1140); **JA-1572** (Schulman Rule 30(b)(6) 12/17/08 Depo. 31:5-11 (representation that exhibits were from files of AMF's lawyers))

[9] **JA-1851** (Exh. 1071)

[10] **JA-1852** (Exh. 1072); **JA-1541** (Schulman 12/2/08 Depo. 125:2-12)

[11] **JA-715** (Janssen Decl. ¶ 3); **JA-1435** (Patrick Depo. 188:17-23 (Cochlear maintained its course on product development after denying infringement and receiving no response)); **JA-1408-09** (Nygard Depo. 144:13-145:4)

[12] **JA-714-1209** (Janssen Decl. ¶ 3 and Exhs. A-C (Nucleus Freedom implant released in the U.S. in 2005(*see* COC-5000242, -5000335); annual U.S. sales revenues of accused products increased by more than 50% after Freedom release, and more than 25% the following year (*see* COC-5000335, -5000448)))

[13] *E.g.*, Patent attorney Gold could not personally remember why the McDermott IEEE Article was withheld. **JA-1307-09** (Gold 30(b)(6) Depo. 35:9-19; 36:20-37:4). Schulman could not remember whether he had ever spoken with McDermott. **JA-1531-33** (Schulman 12/2/08 Depo., 113:22-115:2). *See also e.g.* **JA-1502, 1505, 1508, 1511, 1514-15, 1518, 1521, 1524-26, 1528, 1532, 1536, 1539, 1542-44, 1544 and 1546-48** (Schulman 12/2/08 Depo. 29:9-14; 33:5-23; 69:3-10; 76:9-14; 85:8-11; 86:18-25; 90:4-5; 94:3-25;

prohibition on testing, repairing and upgrading thousands of already implanted devices.

2. The Laches Factors Are Established

Laches arises from an unreasonable delay in filing suit, where the delay prejudices the defendant. *Aukerman,* 960 F.2d at 1032. "*Prima facie,* the underlying critical factors of laches are **presumed** upon proof that the patentee delayed filing suit for **more than six years** after actual or constructive knowledge of the defendant's alleged infringing activity." *Id.* at 1035-36 (emphasis added); *see also Wanlass,* 148 F.3d at 1338 (ignorance cannot overcome pervasive and open activities that should have been discovered more than six years before suit).

Here, AMF – through Schulman and Mobley – knew that Cochlear's products had the alleged infringing feature no later than 1999, *i.e.* at least eight years before the suit was filed. These facts, *prima facie*, establish laches.

Even apart from the presumption that applies here, Cochlear has suffered both economic and evidentiary prejudice. During AMF's delay, Cochlear has introduced new products, greatly increasing its sales and potential damages. Courts look to such "a *change* in the economic position" in finding laches. *Aukerman,* 960 F.2d at 1033 (emphasis in original). Had AMF promptly filed suit, the infringement issue would have been resolved before Cochlear introduced its new products, allowing the greatly increased sales and potential damages to be avoided. *See State Contracting*, 346 F.3d at 1066 ("Economic prejudice arises when a defendant … incurs damages that likely would have been prevented by earlier suit.").

Evidentiary prejudice arises when a defendant is unable "to present a full and fair defense on the merits due to … the unreliability of memories of long past events …." *Aukerman,* 960 F.2d at 1033. In this regard, "testimonial evidence is frequently critical to invalidity defenses and almost always so respecting

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103:12-15; 104:13-16; 105:9-19; 107:8-12; 114:1-11; 119:1-10; 123:3-13; 126:5-9; 127:15-18; 128:8-18; 130:20-22; 131:22-25; 132:17-20).

unenforceability." *Id.*, at 1035. Here, key AMF witnesses such as Schulman and Gold can no longer recall what they did, when they did it, or even if they did it. Evidence has been lost **because of** AMF's delay. *C.f. Hemstreet*, 972 F.2d at 1294 (prejudice must result from delay); *Gasser Chair*, 60 F.3d at 775 (same).

Presumptively and actually, AMF's unreasonable delay filing suit prejudiced Cochlear. The factors for laches are established and AMF's motion for partial summary judgment of no laches should be denied.

II. PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT RE ESTOPPEL

A. Cochlear's Estoppel Defense Fails

The Court should grant summary judgment againset Cochlear's affirmative defense of estoppel. Cochlear failed to produce evidence demonstrating that (1) AMF, through misleading conduct, led Cochlear to reasonably infer that AMF did not intend to enforce its patent against Cochlear; (2) Cochlear relied on that conduct; and (3) due to its reliance, Cochlear will be materially prejudiced. *Aukerman*, 960 F.2d at 1028.

Silence is not "misleading conduct" unless a party had a "clear duty to speak." *Id*. at 1043. "[S]ome evidence must exist to show that the silence was sufficiently misleading to amount to bad faith." *Hottel Corp. v. Seaman Corp.*, 833 F.2d 1570, 1573-74 (Fed. Cir. 1987) (silence of nearly five years was insufficient to establish estoppel in the absence of evidence of bad faith), overruled on other grounds, Aukerman, 960 F.2d at 1038. Silence in the absence of "threatened immediate or vigorous enforcement of its patent rights" is insufficient to establish the sort of misleading conduct that would be sufficient to establish estoppel. *Id at 1574.*

Cochlear must also show that "in fact, it substantially relied on the misleading conduct of the patentee in connection with taking some action." *Aukerman*, 960 F.2d at 1042-43. "To show reliance, the infringer must have had a relationship or communication with the plaintiff which lulls the infringer into a sense of security in

going ahead with [its investments]." *Gasser*, 60 F.3d at 776; *See also Hemstreet*, 972 F.2d at 1294-95; *James River*, 915 F. Supp. at 983.

Cochlear must also establish that it will suffer "material prejudice"—either economic or evidentiary if AMF proceeds with its claim. *Aukerman*, 960 F.2d at 1028, 1043.

There is no evidence of "misleading conduct" by AMF. Cochlear only cites the aforementioned exchange of letters between AMF and Cochlear. JA-131-31 (Cochlear's Third Amended Response to Interrogatory No. 4). AMF's July 2003 letter to Cochlear stated that "your Nucleus cochlear implants utilize features that ***may*** infringe" the '616 patent and that "Advanced Bionics has asked that we ***first explore a license agreement*** with Cochlear Pty Ltd. ***rather than undertake legal action*** . . . ." JA-1851 (emphasis added). This is not evidence of "misleading conduct." *Hottel*, 833 F.2d at 1574; *Meyers*, 912 F.2d at 1464. Further, the time between AMF's July 2003 letter and its lawsuit in December 2007 is not unduly lengthy to establish misleading conduct. *See, e.g., Hottel*, 833 F.2d at 1571-72 (four years and nine months "not unduly long").

There is also no evidence that Cochlear relied on AMF's alleged misleading conduct, and that it suffered "material prejudice." Cochlear's interrogatory response states that Cochlear "relied on this silence" by introducing the infringing Nucleus® Freedom implant in 2005. JA-130-31. Nygard testified that Cochlear assumed that "AMF [was] satisfied with [Cochlear's] reply" to AMF's letter, but could not identify any actions that Cochlear would have taken had AMF had responded differently. JA-1408-09 (Nygard Dep. at 144:19-145:12). Cochlear did not change any of its product development plans either based on AMF's letter or on Cochlear's response. JA-1420-21, 1433-35 (Patrick Dep. at 9:16-25; 10:1-6; 178:1-3; 187:23-25; 188:1-23). Cochlear did not stop producing the infringing products in response to this infringement lawsuit, JA-1409 (Nygard Dep. at 145:14-17); thus, Cochlear presents no basis for asserting that an earlier lawsuit would changed Cochlear's

business decision to introduce the Nucleus® Freedom implant in 2005. *See James River Corp.*, 915 F. Supp. at 978; *cf. Hemstreet*, 972 F.2d at 1294. Thus, there is no factual basis that Cochlear was materially prejudiced by AMF's conduct.

As discussed above, Cochlear also fails to show evidentiary prejudice. Its Third Amended Responses to Interrogatory No. 4, which was served after the close of discovery, makes no mention of evidentiary prejudice even though all of the fact depositions had been completed before the service of the response. As discussed above, Cochlear's evidence of evidentiary prejudice is conclusory and lacks a nexus with the alleged delay, and should be rejected.

There is no specific, admissible evidence demonstrating a genuine issue of material fact on whether AMF's conduct was misleading, much less that Cochlear relied on, and was materially prejudiced by such conduct. Summary judgment should be granted against Cochlear's estoppel defense.

B. Summary Judgment On Estoppel Should Be Denied

The facts regarding estoppel are discussed above at pp. 4-6 with regard to laches. In summary, AMF accused Cochlear of infringement and Cochlear promptly responded by denying any infringement. AMF then remained misleadingly silent, which was interpreted by Cochlear as an abandonment of AMF's claim. Cochlear thereafter proceeded to introduce a new product, greatly increasing its sales and the number of patients implanted.

Estoppel exists when a patentee misleadingly communicates – by words, conduct or silence – that it has abandoned its infringement claims and the defendant relies upon the communication to its prejudice. *Auckerman*, 960 F.2d at 1041.

Here, AMF told Cochlear that it "may be infringing" and Cochlear responded by telling AMF "Nucleus cochlear implants do not infringe …." AMF remained silent in the face of Cochlear's denial. Such silence reasonably raises an inference that AMF abandoned its claim. *Id.* at 1044; *Arctic Cat, Inc. v. Injection Research Specialists, Inc.*, 362 F. Supp. 2d 1113, 1122-23 (D. Minn. 2005).

Had AMF, rather than remaining silent, accurately stated that it intended to sue for infringement years later after the potential damages had increased exponentially, Cochlear would have been able to seek declaratory resolution much earlier, allowing it to avoid infringement liability that potentially exists for the Nucleus Freedom product. Cochlear's failure to take such affirmative action to protect itself is evidence of its reliance on AMF's silence. *Id.* at 1124. Indeed, Cochlear's launch of new allegedly infringing products is further evidence of Cochlear's reliance on AMF's silence. *Wafer Shave, Inc. v. Gillette Co.*, 857 F.Supp. 112, 121 (D. Mass. 1993), *aff'd*, 26 F.3d 140 (Fed. Cir. 1994). Furthermore, as discussed above at pp. 6-7. Cochlear suffered both economic and evidentiary prejudice while AMF remained misleadingly silent.

The factors of estoppel are satisfied. AMF's motion for partial summary judgment should be denied.

III. PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT RE INEQUITABLE CONDUCT

A. Cochlear's Inequitable Conduct Defense Fails

The Court should grant summary judgment against Cochlear's inequitable conduct defense, which asserts that during prosecution of claim 10 of the '616 patent, AMF failed to cite a July, 1989 article by McDermott, titled "An Advanced Multiple Channel Cochlear Implant," JA-1827-35 ("McDermott Article"). Cochlear cannot meet its burden of proving by clear and convincing evidence that the McDermott Article was both material to patentability and withheld by AMF with the intent to deceive. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). Therefore, the Court cannot find inequitable conduct. *See id.* at 1367.

1. The McDermott Article is Not Material Because it is Cumulative

Cochlear's patent law expert, Mr. Laurence Pretty, asserts that the McDermott Article is material because, unlike the "prior art cited by the examiner," the Article shows "a waveform display" that allows "the measuring of the electrode voltage for external display." *See* JA-693-94; JA-708-09 (Main Report of Lawrence H. Pretty ¶¶ 17 & 58-59 (hereinafter "Pretty Rpt."). But the McDermott Article is not material because it is cumulative of other references considered by the United States Patent and Trademark Office ("USPTO") during prosecution of the '616 patent. *See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 1000 (Fed. Cir. 2007); *see also* 37 C.F.R. § 1.56(b) (same).

Pretty candidly admits that he is "not a technical expert" and not qualified to make a comparison of the McDermott Article with other references already before the USPTO. JA-1457-58; JA-1460; JA-1476-77 (Pretty Dep. at 82:3-17; 83:20; 85:22; 116:3;122:3-6). Pretty never evaluated the other references of record in the '616 patent to compare them with the McDermott Article to determine whether it was cumulative. JA-1472-73; JA-1477-79, (Pretty Dep. at 110:2–113:8; 122:24–124:22). Pretty also failed to consider Dr. Choma's rebuttal expert report, JA-1477 (*id.* at 122:17-18), which concluded that the McDermott Article was cumulative of United States Patent No. 4,947,844 ("the McDermott patent"), and United States Patent No. 4,612,934 ("the Borkan patent"). *See* JA-507-29 (Choma Rebuttal Expert Report, § III, B, ¶¶ 1-2 & Appx. B (March 11, 2009) ("Choma Rpt.")). Both Dr. Choma and Dr. Loeb (Cochlear's technical expert) agree that the elements supposedly missing from the McDermott Article—"a waveform display" that allows "the measuring of the electrode voltage for external display"—are implicitly disclosed in both the McDermott and Borkan patents. JA-510-11; JA-514-29; JA-586-86; JA-1356-58 (Choma Rpt., § III, B, ¶¶ 1-4 & Appendix B; Loeb Rpt. at 23-24; Loeb Dep. at 87:17 – 89:1). Significantly, both the McDermott and Borkan

patents were cited to and considered by the examiner. *See* JA-1648-53; JA-9-10 (COC-0002195 - 2200; '616 patent, cover page).

Pretty supposedly relied on Dr. Loeb to establish materiality, but that assertion lacks evidentiary support. JA-708-09 (Pretty Rpt. ¶¶ 58-59). While Pretty testified that Loeb told him that the McDermott Article was "material" to claim 10, JA-709; JA-1449-50; 1473-75, (Pretty Rpt., ¶ 59; Pretty Dep. at 21:24–22:21; 111:12–113:8), Loeb did not remember that conversation. JA-1350; 1364-65 (Loeb Dep. at 81:3-10; 95:13–96:7). Loeb is not aware of what "materiality" means in this context and doubts that he has ever used that term. JA-1364 (Loeb Dep. at 95:20-22). During his deposition Loeb testified that "if you have a particular question about how [materiality] applies here, I would require your legal instruction about how you're using it." *Id.* (Loeb Dep. at 95:16-19). Pretty incorrectly assumed that Loeb knew and applied the correct legal standard . JA-1474 (Pretty Dep. at 112:8-14).

Even had Loeb opined that the McDermott Article was cumulative, Loeb never compared the McDermott Article to either the McDermott or Borkan patents. Loeb admits that the element in question—"a waveform display" that allows "the measuring of the electrode voltage for external display,"—***was*** disclosed in the McDermott and Borkan patents, either expressly or inherently. JA-638-39; JA-1461; JA-1470-71; JA-1473-74 (Loeb Rpt. at 23-24; Pretty Dep. at 86:1-11; 97:20–98:3; 111:8–113:8). Thus, the undisputed evidence of record demonstrates that the McDermott Article discloses no more than the McDermott or Borkan patents, which were before the USPTO. Thus, the Article is cumulative to those patents.

In its opposition, Cochlear relies entirely on the testimony of Mr. Gold, the patent attorney who prosecuted the '616 patent. Tellingly, Cochlear does not cite Loeb's testimony or his expert report, and Cochlear failed to provide any technical comparison between the Article and either the McDermott or Borkan patents, notwithstanding Dr. Choma's analysis demonstrating that the Article was not material. While Mr. Gold was a Rule 30(b)(6) designee, his testimony was limited

to facts relating to prosecution of AMF's patent applications. JA-1294; 1863-64 (Gold Dep. at 7:13-23 & Ex. 1082). He was not called upon to provide expert witness testimony. JA-1306-07; 1310-12; 1315 (Gold Dep. at 34:20–35:1; 38:21–39:2; 39:22–40:3; 43:5-7). Nor does Cochlear submit any evidence that Mr. Gold is one skilled in the art. The only evidence analyzing whether one skilled in the art would find the McDermott Article cumulative—and non-material—is Dr. Choma's expert witness testimony.

Because it failed to present evidence to contradict Dr. Choma's testimony, Cochlear failed to create an issue of fact concerning whether the McDermott Article is material. Summary judgment should be granted.

2. Cochlear Fails to Present Any Evidence of Intent to Deceive

There is no record evidence that AMF, Mr. Gold, or the inventors intended to deceive the USPTO. The failure to cite the Article to the USPTO, by itself, is insufficient to prove intent. To meet its burden of proof, Cochlear must present evidence of intent to deceive beyond the mere nondisclosure of the McDermott Article. "[M]ateriality does not presume intent, and nondisclosure, by itself, cannot satisfy the deceptive intent element." *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009). "Intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996). Because the McDermott Article is cumulative and therefore not material, there can be no intent to deceive.

Cochlear cites no evidence supporting the contention that AMF, Gold, or the named inventors specifically intended to deceive the USPTO. In an interrogatory response, Cochlear suggests that "the McDermott article directly contradicted the reasons for allowance provided by the examiner in the application that led to the '616 patent . . . ." Defendants' Third Amended Response to Interrogatory No. 6. JA-135. Cochlear's suggestion is simply an improper attempt to turn the

nondisclosure of the McDermott Article into an inference of deceptive intent. *See M. Eagles Tools Warehouse, Inc. v. Fischer Tooling Co.*, 439 F.3d 1335, 1340 (Fed. Cir. 2006).

Cochlear deposed all the living inventors, including Dr. Schulman, Dr. Strojnik, and Mr. Gord. Cochlear asked very few questions about the prosecution of the '616 patent and elicited no evidence showing an intent to deceive the PTO.[14] Similarly, Cochlear deposed Gold and found no evidence supporting its assertion of inequitable conduct.[15] Gold testified that his practice was to review references of which he was aware and "make a judgment call" to determine whether the reference was "merely cumulative" of other art already cited. JA-1296-97 (Gold Dep. at 21:21-22:3). Gold cited a number of references to the USPTO, including the McDermott and Borkan patents, thereby rendering the McDermott Article cumulative. *See* Section C. 1., *supra.* Moreover, while indicating that he did not remember why he did not cite the McDermott Article, Gold testified that "it must have been because I just felt my judgment call, that it was merely cumulative of something else that was already cited." JA-1301-02 (Gold Dep. at 28:24–29:7). Gold's testimony of his intent is consistent with the treatment of the McDermott patent and the McDermott Article in an office action in another case, JA-1934 (Gold Dep. Ex. 1147) (characterizing both as "illustrat[ing] back telemetry of FM data related to the monitoring of a voltage level in an implantable cochlear prosthesis"). There is no evidence that AMF, Gold, or any of the inventors intended to deceive the USPTO. Summary judgment should be granted.

B. <u>Summary Judgment On Inequitable Conduct Should Be Denied</u>

AMF's motion for summary judgment of no inequitable conduct rests on the

[14] Defendant's expert witness, Dr. Loeb, previously worked with the inventors named on the '616 patent and testified that "Schulman, Gord and Wolfe were scientists of integrity and honesty." JA-1346 (Loeb Dep. at 46:16-19).

[15] Dr. Loeb had also worked with Mr. Gold, who he characterized as "very competent and trustworthy." JA-1346 (Loeb Dep. at 46:20 – 47:3).

assertion (1) that the prior art that AMF withheld was not material and (2) that there is no evidence that AMF withheld prior art with the intention of deceiving the patent examiner. AMF's assertion is not correct.

1. Factual Background For Inequitable Conduct

AMF filed its original patent application on September 22, 1989.[16] That application was rejected based on U.S. Patent No. 4,947,844, naming Hugh McDermott as the inventor.[17] Indeed, the PTO found that the McDermott patent disclosed "everything claimed."[18] AMF then abandoned the original application.[19]

On August 29, 1991, AMF filed a continuation-in-part ("CIP") application.[20] U.S. Patent No. 5,609,616 ("the '616 patent) is based on that CIP application.[21] Claim 10 of the '616 patent (numbered claim 12 in the patent application) was initially rejected as unpatentable over the prior art.[22] AMF amended claim 12,[23] as a result of which the patent examiner allowed the claim, specifically stating that the claim was "allowable over the prior art of record since the prior art does not show or suggest the measuring of the electrode voltage for external display."[24]

At the time claim 10 of the '616 patent was allowed, AMF knew of – but withheld – the McDermott IEEE Article.[25] And the McDermott IEEE Article specifically discloses "a telemetry system that enables electrode voltage waveforms to be monitored externally in real time" using a "Waveform Display."[26]

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[16] Joint Appendix at **JA-1588**
[17] Joint Appendix at **JA-1639-43**
[18] Joint Appendix at **JA-1640**
[19] **JA-9** ('616 patent at face page)
[20] **JA-9** ('616 patent at face page)
[21] **JA-9** ('616 patent at face page)
[22] Joint Appendix at **JA-1654-60** (Office Action) & **JA-1681** (index of claims)
[23] **JA-1936-51** (Exhibit 1148)
[24] **JA-1952-55** (Exhibit 1149 (AMF001016))
[25] *E.g.* Reply and Counterclaims-in-Reply to Second Amended Counterclaims, ¶ 18 (AMF admits that it knew of the McDermott IEEE Article during the prosecution of the '616 patent)
[26] **JA-1827-35** (Exhibit 1039 (Abstract and Figure 4))

Not only did AMF know about the McDermott IEEE Article, but it had been generally following the work of Hugh McDermott. Schulman, a named inventor, wrote about a presentation by McDermott, who he knew was "a university based Australian auditory scientist," because McDermott's work potentially reflected future products from Cochlear.[27] Schulman apparently inquired about McDermott's work and McDermott contacted Schulman, offering "to send you some article or other information."[28]

Moreover, Gold, the attorney prosecuting the '616 patent application,[29] specifically knew about the McDermott IEEE Article when he was prosecuting the application.[30] Indeed, in 1995 – while the '616 patent application was being prosecuted – Gold disclosed the McDermott IEEE Article in a different patent application where it lacked relevance to the narrow patent claims limited to "a particular type of backtelemetry handshake signal."[31] But neither Gold nor anyone else at AMF ever disclosed the McDermott IEEE Article in connection with the '616 patent application.[32]

Gold withheld the McDermott IEEE Article even though he understood that it disclosed measurement of voltage for external display:

> Q: From figure 4, would you say that Exhibit 1039 [the McDermott IEEE Article] discloses monitoring of voltage for external display? …
>
> THE WITNESS: It is what it is, I mean the figure shows monitoring of voltage and sending it back with an FM signal.
>
> Q: And it shows the display of that voltage, correct?

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[27] **JA-1840-50** (Exhibit 1065)
[28] **JA-1836-39** (Exhibit 1064)
[29] *E.g.* **JA-1303** (Gold 30(b)(6) Depo. 30:4-8)
[30] **JA-1301** (Gold 30(b)(6) Depo. 28:21-23)
[31] **JA-1931-35** (Exhibit 1147)
[32] **JA-1299** (Gold 30(b)(6) Depo. 26:14-17)

A: Yeah, the waveform of the voltage, yes.[33]

The only reason that AMF (by its Rule 30(b)(6) witness Gold) could give for withholding the McDermott IEEE Article was that it was supposedly cumulative of the McDermott patent that was already before the patent examiner.[34] But, by Gold's admission, the McDermott patent does not disclose or inherently require an external display of voltage:

Q: Exhibit 1150 [the McDermott patent], though, does not show what happens on the outside, correct? …

A: I don't see it in the figures. …

Q: Can you point me to anything in the – in Exhibit 1150 that describes displaying voltage externally? …

A: … This doesn't refer explicitly to a display, but it is clear from reading that, to a person with skill in the art, that is what you are going to do. … You can't see what it looks like unless it is displayed.

…

Q: Could the voltage waveform be processed electronically without display?

A: Sure.

Q: And Exhibit 1150 [the McDermott patent] does not say either way how the voltage waveform is analyzed, correct?

A: I didn't see that.[35]

2. The 1989 Article Was Both Material And Withheld With An Intent To Deceive

"A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material

[33] **JA-1306-07** (Gold 30(b)(6) Depo. 34:20-35:8)
[34] **JA-1309** (Gold 30(b)(6) Depo. 37:22-38:10)
[35] **JA-1311-14** (Gold 30(b)(6) Depo. 39:22-42:13)

information …." *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007) (internal quotation omitted).

"The materiality of information withheld during the prosecution may be judged by the 'reasonable examiner' standard." *Id.* "That is, '[m]ateriality … embraces any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.'" *Id.* (*quoting Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998)).

Here, there is no need to guess what a reasonable examiner would likely consider important. Claim 10 of the '616 patent was allowed because "the prior art does not show or suggest the measuring of the electrode voltage for external display." Self evidently, the examiner would have considered prior art information important if it showed "measuring of the electrode voltage for external display." Both from the face of the withheld article and from Gold's binding Rule 30(b)(6) testimony, the McDermott IEEE Article shows exactly what the examiner found missing in the prior art.

Of course, if the withheld prior art is merely cumulative of other information that the examiner already has, it is not material. *McKesson*, 487 F.3d at 913. But here we know that the patent examiner had already determined that the McDermott and Borkan patents (alleged by AMF to be cumulative) lacked critical disclosure: After considering all of the prior art available to him including the McDermott and Borkan patents, the examiner stated that "the prior art does not show or suggest the measuring of the electrode voltage for external display."

Moreover, the examiner was correct that the prior art (including the McDermott and Borkan patents) failed to show "the measuring of the electrode voltage for external display." Gold's Rule 30(b)(6) testimony that the McDermott patent could function without an external display is fully consistent with the examiner's understanding. Likewise, AMF's statement that the Borkan patent

"implicitly" discloses external display of voltage is an admission that, consistent with the examiner's understanding, Borkan lacks any explicit disclosure of the external display of voltage. Indeed, when identifying items to be displayed, Borkan never mentions "voltage."[36] As such, the McDermott IEEE Article is the only prior art showing the measuring of the electrode voltage for external display. That article is thus both material and non-cumulative.

The intent element of inequitable conduct "is … in the main proven from facts, with a collection of inferences permitting a confident judgment that deceit has occurred." *Id.* (*quoting Akron Polymer*, 148 F.3d at 1385). Once a threshold level of materiality and intent are shown, "[t]he court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the level of materiality and intent, with a greater showing of one factor allowing a lesser showing of the other." *McKesson*, 487 F.3d at 913 (*quoting Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001) (internal quotation omitted)).

Here, AMF was following McDermott's work; AMF's original application had been rejected over a McDermott patent; and AMF knew the McDermott IEEE Article disclosed exactly what the examiner said was missing. Despite all that, AMF chose to submit the McDermott IEEE Article in an application where it was irrelevant, but withheld it from the '616 patent application where it would have resulted in rejection of claim 10. These facts lead to an inescapable inference that AMF withheld the McDermott IEEE Article in an intentional attempt to deceive the examiner into allowing the '616 patent. The elements of inequitable conduct are satisfied and AMF's partial summary judgment motion should be denied.

[36] **JA-1969-2004** (Exhibit 1152 at col. 25); **JA-1358-59** (Loeb Depo. 89:2-90:18)

DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

Defendant Cochlear Corporation (n/k/a Cochlear Americas) and Cochlear Ltd. (collectively "Cochlear) move for partial summary judgment that claims 1-14 of the U.S. Patent No. 5,938,691 ("the '691 patent") and claims 1-9 and 12-14 of U.S. Patent No, 5,609,616 ("the '616 patent") are invalid as indefinite; that claim 10 of the '616 patent is not infringed; and that claim 10 of the '616 patent is invalid in view of the prior art.

I. DEFENDANTS' MOTON FOR SUMMARY JUDGMENT RE INDEFFINITENESS

A. The System Claims Of The '691 And '616 Patents Are Invalid As Indefinite

Patent claims 1-14 of the '691 patent recite cochlea stimulation systems; claims 1-9 and 12-14 of the '616 patent recite systems for testing a cochlear implant/stimulator. All of these "system" claims include (either directly or through dependency on other claims) limitations written in "means plus function" ("MPF") format. Under 35 U.S.C. § 112, ¶ 6, such MPF claim limitations cover "the corresponding structure, material or acts described in the specification [of the patent] and equivalents thereof." "In a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." *WMS Gaming Inc. v. International Game Technology*, 184 F.3d 1339, 1349 (Fed. Cir. 1999).

To avoid purely functional claiming in cases involving inventions implemented with a computer or microprocessor, the Federal Circuit has "consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor." *Net MoneyIn, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1367 (Fed. Cir. 2008) (internal quotation omitted). *See also Finisar v. DirecTV Group*, 523 F.3d 1323, 1340-41 (Fed. Cir. 2008).

Failure to disclose the algorithm for the microprocessor renders the claim invalid as indefinite under 35 U.S.C. § 112, ¶ 2. *Aristocrat Techs. Austl. Pty. v. Int'l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008) ("control means" interpreted to be a microprocessor with no specific algorithm renders claims invalid).

1. The Asserted Claims of the '691 Patent are Invalid For Indefiniteness

Independent claims 1, 6, 9 and 14 of the '691 patent (as well as claims 2-5, 7-8 and 10-13 that depend from those claims) – encompassing all claims of the '691 patent asserted by AMF – contain the MPF limitation "means for generating data indicative of the audio signal." The parties stipulated that the structure corresponding to this MPF limitation is "an analog to digital converter and a microprocessor."[37]

The parties' stipulation has no algorithm associated with the microprocessor because none is disclosed in the '691 patent.[38] The lack of any such algorithm has been confirmed by AMF's technical expert Prof. John Choma when he fails to identify any such algorithm in his expert report[39], and further confirmed by his deposition testimony. *See* **JA-1145** (Choma Depo. 50:11-15):

> Q. So you would agree, would you not, Professor Choma, that the '691 Patent does not describe what steps the microprocessor (30) performs on the signal that's fed to it by A[nalog] to D[igital] converter (28)?
>
> A. There is no algorithm disclosed, yes.

See also **JA-1254-57** (Choma Depo. 159:5-162:2):

[37] Joint Appendix at **JA-99-104**
[38] **JA-1052-88** (Stevenson Decl., ¶¶ 20-22)
[39] Joint Appendix at **JA-454-470**

> … Q. Is – so is there any algorithm disclosed --- that is performed by the microprocessor in this particular --- to perform these particular steps. …
>
> A. No, other than …. Other than the definition of the inputs and outputs, there is no algorithm supplied in a software format or in some sort of an encoded format.
>
> Q. And what is the specification of the output of the microprocessor?
>
> A. Would be the pulses necessary to activate the gate array. The digital pulses, I should say.
>
> Q. And what information about those pulses is provided in this patent?
>
> A. Nothing explicit.

Thus, the '691 patent fails to disclose any algorithm for the MPF limitation in claims 1-14 that by stipulation includes a microprocessor. Under controlling Federal Circuit law, those claims are invalid as indefinite.

AMF's opposition rests on Choma's attempt to characterize the microprocessor as an "ASIC" or "DSP," as well as Choma's new identification of a supposed "algorithm" in the '691 patent. Choma's characterization of the microprocessor is irrelevant because it is undisputed (and indeed stipulated) that the applicable structure includes a microprocessor.[40] Moreover, Choma's opinion that he can divine an "algorithm" based on inputs and outputs is negated by his undisputed testimony, discussed above, that the '691 patent discloses "[n]othing explicit" about the outputs. *U.S. v. Various Slot Machines*, 658 F.2d 697, 701 (9th

[40] All of the cases cited by AMF to avoid binding Federal Circuit precedent regarding the insufficiency of a microprocessor alone as structure (*i.e.* district court and unpublished cases) are dated prior to *Aristocrat Techs.*, 521 F. 3d 1328.

Cir. 1981) (absent specific facts showing genuine issues for trial, expert opinion is irrelevant).

Even if Choma's ultimate opinion is credited, there is no genuine issue of material fact. Choma does not identify an algorithm; instead he merely recasts the function "generating data indicative of the audio signal" as the function "encoding the digital data … to generate an encoded, amplitude modulated signal." (Indeed, AMF's briefing at pp. 25-26 admits Choma merely identifies the function of the microprocessor.) Choma's additional opinion that published algorithms are available to persons in the art is irrelevant. *Aristocrat Techs.*, 521 F.3d at 1337. There is no genuine issue of material fact and partial summary judgment of invalidity of the claims of the '691 patent is appropriate.

2. The Asserted System Claims Of The '616 Patent are Invalid For Indefiniteness

Similar to the '691 patent, claim 1 of the '616 patent (as well claims 2-9 that depend from claim 1) contains the MPF limitation "external processing means coupled to the transmitting means of the external headpiece/transmitter for receiving and processing the status-indicating signals to derive information therefrom regarding the operation of the implanted stimulator and its plurality of tissue stimulating electrodes." The parties stipulated that the structure corresponding to this MPF limitation is an "antennae, receiver, and microprocessor."[41]

Likewise, claim 12 of the '616 patent (and claims 13-14 that depend from claim 12) contain the MPF limitation "external processing means for processing the received status-indicating signals to derive information therefrom regarding the operation of the ICS and its plurality of tissue stimulating electrodes." The parties stipulated that the structure corresponding to this MPF limitation is a "microprocessor."[42]

[41] Joint Appendix at **JA-99-104**
[42] Joint Appendix at **JA-99-104**

The '616 patent does not disclose any algorithm for the microprocessor for performing the function in either of the above identified MPF limitations of claim 1 and 12 of the '616 patent.[43] Indeed, the lack of disclosure is not disputed by Prof. Choma in his rebuttal report.[44]

AMF's opposition rests, however, on Choma's completely new and previously undisclosed opinion that the '616 patent includes an algorithm.[45] Choma's declaration testimony on this point should be precluded. Fed.R.Civ.P. 37(c)(1) (automatic preclusion of information not disclosed under Rule 26(a)). Even if not precluded, Choma's declaration merely says "that devising an algorithm to perform that function would be within the capability of one skilled in the art, and therefore it is not necessary for the patent to designate any particular algorithm to perform the claimed function." … [T]hat argument is contrary to [Federal Circuit] law." *Aristocrat Gaming*, 521 F.3d at 1334.

Under controlling Federal Circuit law, claims 1-9 and 12-14 of the '616 patent, all of which include a MPF limitation that by stipulation corresponds to a microprocessor, are invalid as indefinite. Partial summary judgment of invalidity is appropriate.

B. Issues of Fact Preclude Summary Judgment on Cochlear's Indefiniteness Defense

Cochlear fails to meet its burden of proving by clear and convincing evidence that claims in the '616 and '691 patents are indefinite. The Court should deny Cochlear's motion.

The cases cited by Cochlear requiring disclosure of an algorithm are inapplicable because the microprocessors at issue are not "general purpose

[43] **JA-1061-64** (Stevenson Decl., ¶¶ 34-38)
[44] Joint Appendix at **JA-454-470**
[45] *Compare* Stevenson Report at **JA-1030-51** (disclosing opinion re no algorithm) with Choma Rebuttal Report **JA-454-470** (lacking disclosure of algorithm)

computer[s]." *See Aristocrat Techs. Austl. Pty. Ltd. v. Int'l Gaming Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008). One skilled in the art would recognize that the microprocessors disclosed in the '691 and '616 patents are not general purpose computers or microprocessors, but instead are application specific integrated circuits ("ASICs") designed to perform specific functions. *See* JA-534-35 (Choma Decl. ¶¶ 17-20). ASICs are significantly faster and consume significantly less power than general purpose computers or microprocessors. *See* JA-536-38 (*id.* ¶¶ 22-26). The '691 and '616 patents use ASICs that include digital signal processors or "DSPs" that perform the specific functions required by the means-plus-function clauses at issue. *Id.* (¶¶ 22-23). These ASICs that include DSPs are not general purpose computers or microprocessors and are not generally programmable. *Id.* (¶ 21). Thus, disclosure of an algorithm is not required. *See Alt v. Medtronic, Inc.*, 2005 U.S. Dist. LEXIS 44928, at *15-*16 (E.D. Tex. 2005).

Even if an algorithm is required, the '691 and '616 patents adequately disclose structure to meet the definiteness requirement. The definiteness standard is not "lofty." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1341 (Fed. Cir. 2008). Indefiniteness cannot be found unless the claims are "quite vague" and where "one of skill simply cannot perceive the bounds of the invention." *Id.* Algorithms need not be disclosed in exact mathematical terms, particularly when suitable algorithms are known in the art. *See In re Dossel*, 115 F.3d 942, 946-47 (Fed. Cir. 1997); *see also Aristocrat Techs. Austl. Pty Ltd. v. Multimedia Games, Inc.*, 266 Fed. Appx. 942, 947 (Fed. Cir. 2008). Whether an algorithm has been disclosed is determined from the standpoint of one skilled in the art. *AllVoice Computing PLC v. Nuance Commc'ns Inc.*, 504 F.3d 1236, 1245 (Fed. Cir. 2007).

Here, one skilled in the art would appreciate that the patents disclose sufficient structure to meet the definiteness requirement. *See id.* at 1245. The parties stipulated that the "means for generating data indicative of the audio signal" in claims of the '691 patent corresponds to an analog to digital ("A to D") converter

and a microprocessor. The specialized microprocessor in the '691 patent is a DSP. JA-536; JA-538; JA-61 (Choma Decl., ¶¶ 22-23 & 28; '691 patent, col. 4 ll. 44-58). The A to D converter and microprocessor work together to transform the analog signal derived from sound received by a microphone into an encoded, amplitude-modulated signal. JA-538-39; JA-64; JA-61 (Choma Decl. ¶¶ 28-29; '691 patent, col. 10 ll. 1-4; col. 4 ll. 43-64). The A to D converter converts analog data representative of the audio signal into digital data that is then sent to the microprocessor for further processing. JA-538-39 (Choma Decl. ¶¶ 28-29). The input signal from the WP to the ICS is an encoded, amplitude modulated signal. JA-539 (¶ 29). Encoding a digital signal with amplitude data is function performed by a DSP. *Id.* Thus, one of ordinary skill in the art would understand that the microprocessor found in the '691 patent encodes the digital signal received from the A to D converter with amplitude data. *Id.* (¶ 30). Because one of skill in the art would appreciate that the microprocessor is performing the steps of encoding the digital data with amplitude information to generate an encoded, amplitude modulated signal, *id.*, the '691 patent has disclosed a sufficient algorithm to meet the definiteness requirement. *See SPX Corp. v. Bartec USA, LLC*, 557 F. Supp. 2d 810, 819 (E.D. Mich. 2008) ("providing modulation" was sufficient disclosure of an algorithm).

Additionally, the specification need not disclose a particular algorithm "if the selection of the algorithm or group of algorithms needed to perform the function in question would be readily apparent to a person of skill in the art." *Aristocrat*, 266 Fed. Appx. at 947. Here, on or before September 22, 1989 (the filing date of the earliest application to which the '691 patent claims priority), algorithms for generating pulsatile input data signals for cochlear implants were known in the art. JA-539-40; JA-2407 (Choma Decl. ¶¶ 31-34; COC-0120987). Thus, one skilled in the art would readily appreciate that this known algorithm could be used to generate

data indicative of the audio signal. *See AllVoice*, 504 F.3d at 1245; *SPX*, 557 F. Supp. 2d at 819.

Cochlear cites Dr. Choma's deposition testimony to assert that no algorithm is explicitly disclosed in the '691 patent. Yet, Cochlear ignores Dr. Choma's testimony clarifying that when he initially testified about "algorithms," he applied a narrow definition of "algorithm" to mean a program written in a particular computer language such as "C++, for example, or what ever language." JA-1246 (Choma Dep. at 151:10-12). Dr. Choma clarified that "an algorithm is merely a description of a path from input to output," and concluded that the '691 patent adequately disclosed an algorithm. JA 1245-48 *Id.* at 150:19-153:3. Dr. Choma's explanation of an algorithm is consistent with the definition of an algorithm found in the case law of the Federal Circuit. *See AllVoice*, 504 F.3d at 1246 (reversing summary judgment on issue of indefiniteness); *SPX*, 557 F. Supp. 2d at 819 (granting motion for reconsideration on issue of indefiniteness).

The '616 patent also discloses sufficient structure relating to the "external processor means" limitations of claims 1 and 12. The parties stipulated that the structures that perform these functions are either "an antenna, receiver, and microprocessor" (claim 1) or "a microprocessor" (claim 12). The result of each function is to "deriv[e] information" from "status-indicating signals" transmitted from the cochlear implant to a physician's tester. These signals include voltage and current. JA-41; JA-24 ('616 patent, col. 32 ll. 34-46 & Fig. 6 (disclosing controls for voltage, current, and impedance)). The process of deriving information from a status-indicating signal, for example, calculating impedance from voltage and current, is simple and would readily be understood by one skilled in the art. JA-541 (Choma Decl. ¶ 39). If the tester is set to display impedance, the microprocessor uses Ohm's law to calculate impedance as the ratio of the measured voltage to a pre-set current. JA-541-42 (*Id.*, ¶ 40). The microprocessor acts like a commercially available ohmmeter and calculates and displays impedance. JA-542 (¶ 41). One of

skill in the art would appreciate that the algorithm disclosed in the '616 patent is simply the application of Ohm's Law. *Id.* (¶ 42).[46]

Both the '616 and '691 patents disclose sufficient detail that one skilled in the art would appreciate as algorithms to perform the recited function. "This is all the definiteness requirement demands." *SPX*, 557 F. Supp. 2d at 819 (citing *AllVoice*, 504 F.3d at 1244-46). At the least, genuine issues of material fact remain; accordingly, the Court should deny Cochlear's motion for summary judgment on this issue.

II. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT RE INFRINGEMENT

A. AMF Cannot Prove Infringement Of Claim 10 Of The '616 Patent

Claim 10 of the '616 Patent recites a "method for testing an implantable tissue stimulating system." That method includes, among other steps, the step of:

> "displaying the processed status-indicating signals, whereby the status of the implanted stimulator, including the results of the measurements made within the implanted stimulator, may be made known"

AMF contends that "the results of the measurement made within the implanted stimulator" should be given its customary and ordinary meaning, and Cochlear contends that the claim term means: displaying "the voltage measured across two intra-cochlear electrodes at the time of stimulation."[47] Regardless of

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[46] Cochlear's effort to exclude Choma's declaration on this point should be rejected. Cochlear has the burden of proving invalidity by clear and convincing evidence. Cochlear did not rely on Stevenson and Loeb's expert reports in support of this motion, but instead tendered lengthy declarations from Stevenson and Loeb. AMF is entitled to respond to those declarations, and did so with Choma's declaration. There is no lack of disclosure. Also, Cochlear apparently does not disagree with Choma's analysis. Thus, there is no harm to Cochlear. Fed. R. Civ. P. 37(c)(1). Further, Loeb's report failed to disclose his lengthy opinions in his declaration that the McDermott Article and Thesis allegedly disclose monitoring a pair of electrodes. *Compare* JA-579 (Loeb Report) *with* JA-629-32; JA-644-49 (Loeb Decl. ¶¶ 36-39 & 62-68). If Cochlear contends that Choma's point should be excluded, then paragraphs 36-39 and 62-68 of Loeb's declaration should be excluded as well.

[47] Joint Appendix at **JA-105-125**

which party is correct, AMF lacks any evidence capable of proving that Cochlear's products perform the displaying step of claim 10.

1. Under Either Parties Claim Construction Voltage Measured At The Time Of Stimulation Must Be Displayed

If the Court were to adopt Cochlear's proposed claim construction, then claim 10 explicitly requires the display of voltage measured at the time of stimulation. But even considering the plain meaning advocated by AMF, the claim requires the display of voltage measured at the time of stimulation. Specifically, Claim 10 requires, *inter alia*:

> selectively monitoring the at least one pair of the multiplicity of electrodes *to measure a voltage associated therewith at the same time the stimulation signals are applied thereto*;
>
> generating stimulator status-indicating signals representative of *the measurements* made with the implanted stimulator; …
>
> receiving and processing the status-indicating signals to produce processed status-indicating signals which convey information regarding the status of the implanted stimulator, including *the measurements* made within the implanted stimulator; and
>
> *displaying* the processed status-indicating signals whereby the status of the implanted stimulator, including *the results of the measurements* made within the implanted stimulator, may be made known.

(Emphasis added). In other words, "the results of the measurements made within the implanted stimulator" must be displayed, and the measurements made are "voltage associated therewith at the same time the stimulation signals are applied thereto." Thus, the plain meaning of claim 10 requires the display of voltage measured at the time of stimulation.

This requirement for displaying voltage measured at the time of stimulation was the reason why the Patent Office allowed claim 10. Specifically, claim 10

(numbered claim 12 during prosecution) was initially rejected as indefinite for using the phrase "voltages/current" and as unpatentable over the prior art. AMF subsequently amended the claim language to change "measure voltages/currents associated with the stimulation signals" to read "measure a voltage associated therewith at the same time the stimulation signals are applied."[48] As a result of this amendment, the patent examiner allowed the claims, stating that the claim was "allowable over the prior art of record since the prior art does not show or suggest the measuring of the electrode voltage for external display."[49]

2. AMF Cannot Prove That Cochlear's Products Display Voltage Measured at the Time of Stimulation

AMF bears the burden of proving infringement. *Kegel Co., Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997). To carry its burden, AMF must come forward with evidence capable of proving that Cochlear's product perform each and every step of claim 10 of the '616 patent. *Id.* ("the claims as properly construed must be compared to the accused device or process.").

With regard to infringement, AMF again relies on Choma. In his report, Choma says he "found" that the accused devices and systems literally infringe the claims of patents-in-suit, including claim 10 of the '616 patent.[50] (Choma explicitly states that he has "not included any opinion as to infringement under the doctrine of equivalents."[51]) With respect to the step of "displaying the processed status-indicating signals, whereby the status of the implanted stimulator, including the results of the measurements made within the implanted stimulator, may be made known," the evidence cited by Choma is:

> The Custom Sound software will, based on measurement of voltage during voltage telemetry, *display electrode impedance*. Custom Sound

[48] Joint Appendix at **JA-1936-51**
[49] Joint Appendix at **JA-1952-55**
[50] Joint Appendix at **JA-138-453**
[51] Joint Appendix at **JA-146**

will also indicate compliance current level which is derived using voltage telemetry.[52]

Thus, AMF has evidence that Cochlear's products "display electrode impedance." Impedance "is a ratio of voltage across and current through a two-terminal element,"[53] not voltage itself. AMF cannot prove Cochlear's products display voltage measured at the time of stimulation, as claim 10 of the '616 patent requires.

Although AMF's opposition asserts that it has raised an issue of fact regarding the display of voltage, it does not actually do so. Indeed, AMF factually concedes that Cochlear's system displays impedance, not voltage. Because infringement under the doctrine of equivalence is not asserted, the relationship between voltage and impedance – much discussed in AMF's opposition – is irrelevant. Both under Cochlear's proposed construction and the plain meaning advocated by AMF, AMF lacks evidence capable of proving the required display of voltage. The last ditch attempt in AMF's opposition to recast the language "whereby … the results of the measurements … may be made known" as not limiting in any way should be rejected as an untimely attempt to change AMF's proposed claim construction. Partial summary judgment of no infringement of claim 10 of the '616 patent is appropriate.

B. Issues of Fact Preclude Summary Judgment on Cochlear's Non-Infringement Defense

The Court should deny Cochlear's motion for partial summary judgment that claim 10 of the'616 patent is not infringed. The sole step that Cochlear argues is missing is "displaying the processed status-indicating signals, whereby the status of the implanted stimulator, including the results of measurements made within the implanted stimulator, may be made known." JA-43 ('616 patent, col. 36 ll. 4-7).

[52] Joint Appendix at **JA-399,404**
[53] **JA-1169** (Choma Depo. 74:15-17)

Cochlear's argument is premised on a faulty legal assumption—that this claim element requires display of a "voltage" even though the claim requires only "displaying the processed status-indicating signals."

Cochlear admits that "AMF has evidence that Cochlear's products 'display electrode impedance'" and that "[i]mpedance 'is a ratio of voltage across and current through a two-terminal electrode." Cochlear also admitted that "[w]hat we measure is not impedance, it is voltage." JA-1405; JA-1397-98; JA-1704-06 (Nygard Dep. at 125:22-23; *see also* 108:1-109:24 & Ex. 4). The measured voltages are transmitted from the implant using a "voltage telemetry circuit." JA-1394-96 (Nygard Dep. at 87:15–89:8). Using Ohm's Law, the voltage measured is divided by the current applied, and the quotient is displayed as impedance. JA-1399-1406 (Nygard Dep. at 125:7–126:12; 115:18–119:24; 121:13).

Cochlear's argument that, because voltage is not displayed, the step of "displaying the processed status-indicating signals" is missing should be rejected. Cochlear improperly combines the "selectively monitoring . . . to measure a voltage" step with the "displaying the processed status-indicating signals" step. Yet by its express language and structure, the claim does not require the display of "voltage" but instead of "the processed status-indicating signal"—that is, a signal that has been transmitted by the ICS, received, and processed before it is displayed.[54] And the "processed status-indicating signals" need only "convey information regarding the status of the implant, including the measurements made within the implanted stimulator." Because impedance is the measured voltage divided by the preset current, impedance "convey[s] information" about both "the status of the implant"

[54] While vaguely suggesting that there may be an issue, Cochlear does not appear to be asserting that the "at the same time" clause should be read into the "displaying the processed status indicating signals." To the extent that defendants argue that position, it should be rejected. It is clear that the "displaying" step has to occur after "status indicating signals" are generated, transmitted, received, and processed. Thus, the claim language does not require or even permit display of "processed status-indicating signals" at the same time as the voltage is measured.

and "the measurements made within the implant." Nothing in the specification limits the "processed status-indicating signals" to voltage. In fact, the "processed status-indicating signals" include not only voltage, but also either current or impedance. JA-28; JA-41-42; JA-24 ('616 patent, col. 5 ll. 24-47; col. 31 ll. 28-61; col. 32 l. 34–col. 33 l. 55 (including Table 7); Fig. 6 (disclosing controls for voltage, current, and impedance)). The meaning of claim terms derived from the specification is usually dispositive. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). In Cochlear's devices, the "processed status-indicating signals" are impedance values that are calculated by dividing the measured voltages by the current applied. *See* JA-1398 (Nygard Dep. at 109:3-24). There is no question that the calculated impedances are displayed. JA-1405 (Nygard Dep. at 125:2-24).

Cochlear's argument is also flawed because the "whereby" clause is not a claim limitation. *See Texas Instruments v. United States ITC*, 988 F.2d 1165, 1171-72 (Fed. Cir. 1993). Additionally, the clause is permissive providing that such results—i.e., "the status of the implanted stimulator" and "the results of the measurement"—"***may*** be made known." *Cybergym Research LLC v. Icon Health & Fitness, Inc.*, 2007 U.S. Dist. LEXIS 97891, **59-60 (E.D. Tex. 2007). Thus, while the "processed status-indicating signals" are to be displayed, the data from which those "processed" signals is derived need not be displayed. Impedance calculated from the measured voltage is ***displayed*** and is thus explicitly "made known." JA-1405 (Nygard Dep. at 125:2-24). Because the measured voltage can be calculated by simply applying Ohm's Law to the displayed impedance and the preset current, the display of the calculated impedance also makes the voltage known, thereby meeting the "may be made known" whereby clause even if it were limiting. At the least, genuine issues of material fact preclude summary judgment.

Similarly, the prosecution history does not limit "processed status-indicating signals" to voltages. Even though the claim was amended from "measure voltages/currents" to "measure a voltage" and the claim was purportedly allowed

because "the prior art does not show or suggest the measuring of electrode voltage for external display," it does not follow that voltage must be displayed for at least the following reasons. The amendment was to the "selectively monitoring" step, not the "displaying the processed status-indicating signals" step. As discussed above, the latter step is not limited to "voltage." Additionally, in the response in which the "to measure" clause was amended, AMF also added the "displaying the processed status-indicating signals" step. That AMF said "processed status-indicating signals" in that step instead of "voltage" demonstrates that it intended that the two elements have different scope. In any event, the language of the claim should be given more weight than a statement made in the file history because the file history "often lacks the clarity of the specification." *See Phillips* at 1317. The lack of clarity is apparent here because while the examiner's statement referred to "voltage," the claim did not require displaying "voltage," but instead "displaying the processed status-indicating signals." *Compare* JA-1665 (Amendment (dated 3/18/96)) *with* JA-1679 (Office Action (dated 5/7/96)). The language of the claims as issued control. *See Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1054 (Fed. Cir. 1989) ("The claims themselves control."). In any event, the examiner's statement does not necessarily limit a claim. *See Sorenson v. ITC,* 427 F.3d 1375, 1379-81 (Fed. Cir. 2005). Here, given its ambiguity, the examiner's statement should not be given more significance than the claim language.

Infringement is a question of fact. *See Kegel Co. v. AMF Bowling*, 127 F.3d 1420, 1425 (Fed. Cir. 1997). Because genuine issues of material fact remain, Cochlear's summary judgment motion should be denied.

III. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT RE INVALIDITY OVER PRIOR ART

A. Claim 10 Of The '616 Patent Is Invalid In View Of The Prior Art

A patent claim is invalid under 35 U.S.C. § 102 as anticipated if a prior art reference discloses every limitation in the claim. *Richardson v. Suzuki Motor Co.*,

Ltd., 868 F.2d 1226, 1236 (Fed. Cir. 1989). A reference is prior art if, for example, it was "patented or described in a printed publication in this or a foreign country … more than one year prior to the date of the application for patent …." 35 U.S.C. § 102(b). In that regard, AMF's interrogatory responses admit that no claim of the '616 patent is entitled to an application date earlier than August 29, 1991. So, any publication prior to August 29, 1990 is prior art that can invalidate the '616 patent.

Even if it is not anticipated by a prior art reference, a patent claim may be invalid under 35 U.S.C. § 103 when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination of obviousness requires analysis of (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the art, and (4) any relevant secondary considerations, such as commercial success, long felt but unresolved needs, failure of others, etc. *KSR Int'l Co v. Teleflex Inc.*, 550 U.S. 398, 406, 127 S. Ct. 1727, 1734, 167 L. Ed. 2d 705 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

1. The Prior Art

More than a year before the earliest possible application date for the '616 patent, in July 1989, Hugh McDermott published an article entitled "An Advanced Multiple Channel Cochlear Implant" (the McDermott IEEE Article).[55] McDermott followed the article with the publication of his Ph.D. thesis "An Advanced Cochlear Implant Hearing Prosthesis for Profound to Total Deafness" (the "Thesis"), which was publicly available no later than January 1990.[56]

The McDermott IEEE Article and Thesis describe a cochlear implant system with telemetry that provides the capability of testing the cochlear implant after

[55] **JA-1827-35** (Exh. 1039)
[56] **JA-2199-2402** (Dott Decl.)

implantation. (The disclosures of the McDermott IEEE Article and Thesis are, in large part, the same.[57]) Figure 4 of the McDermott IEEE Article shows the basic system:

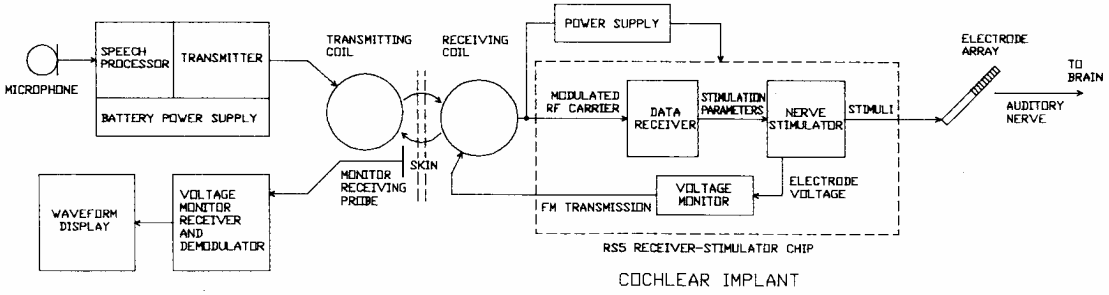

Fig. 4. Major functional blocks of the advanced cochlear implant hearing prosthesis.

The McDermott IEEE Article and Thesis explain that the stimulation parameters (stimulation amplitude and timing to be applied to selected electrodes) are controlled by digital data transmitted to the implant.[58] The digital data transmitted to the implant also controls the implant's monitoring system.[59] The implant receives and processes the data parameters to apply the selected stimulation signal to the selected electrodes to be stimulated.[60] To monitor an electrode voltage, the designated electrode selection parameter is transmitted to monitor the selected electrode, and a measurement of the electrode voltage is obtained from the

[57] *See* **JA-1196-98, 1206-08** (Choma Depo. 101:21-103:15; 111:6-113:22)

[58] *E.g.* **JA-1827-35** (Article p. 793 (sequence of 92 bits transmitted to implant "specify the active electrodes" and "control the amplitude, duration and onset time of each stimulus")); *see also* **JA-623-26, 637-41** (Loeb Decl. ¶¶ 26-29, 47-52)

[59] *E.g.* **JA-1827-35 (**Article p. 792 ("the monitor system can convey any electrode voltage waveform" based on control data transmitted to the implant); p. 793 ("electrode voltage monitor system is controlled by [a] ... 5-bit electrode selection parameter") and p. 795 (telemetry system can "monitor several critical nodes" in the implant "or the actual electrode voltage waveforms")); *see also* **JA-623-26, 637-41 (**Loeb Decl. ¶¶ 27, 48)

[60] *E.g.* **JA-1827-35** (Article pp. 794-795; Figures 3, 4 and 6)

monitored electrode.[61] The electrode voltage is converted to an FM signal (labeled "Mon_out" in Fig. 6, "FM transmission" in Fig. 4), which is transmitted externally.[62] The FM signal transmitted by the implant is received and processed by a monitor receiving probe and voltage monitor receiver and demodulator, and the measured electrode voltage is recovered and displayed on the display, as illustrated in Figure 4.

The McDermott IEEE Article and Thesis also describe initial results of the cochlear implant in a patient, including the selective variation of stimulation parameters during the programming or "mapping" of the speech processor, and the successful use of the telemetry system to monitor electrode voltages.[63] In so using the implant, the McDermott IEEE Article and Thesis practice the steps of claim 10 of the '616 patent.)

The McDermott IEEE Article and Thesis disclose each and every step of claim 10 of the '616 patent, as AMF would have the Court construe that claim, and thus anticipate and invalidate claim 10 under 35 U.S.C. § 102.[64] With regard to Cochlear's proposed construction, the minor feature that is not present in the McDermott IEEE Article and Thesis – *i.e.* the implant using two transmission coils – would have been obvious to a person skilled in the art.[65]

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[61] *E.g.* **JA-1827-35** (Article p. 795 (electrode voltage labeled V_MON in Fig. 6)); *see also* **JA-629, 644** (Loeb Decl. ¶¶ 36, 63)

[62] *E.g.* **JA-1827-35** (Article pp. 792, 795 (FM signal labeled "Mon_out" in Fig. 6, "FM transmission" in Fig. 4)); *see also* **JA-632-34, 649-51** (Loeb Decl. ¶¶ 40-41, 69-70; Loeb Report pp. 15-16)

[63] *E.g.* **JA-1827-35 (**Article p. 796 ("Threshold current levels varied from 180 to 330 [micro-amps] across electrodes, while sensations of maximum comfortable loudness were attained with current levels approximately three times the threshold levels. ... In addition, the telemetry system of the implant is being used successfully to monitor ... electrode voltage waveforms"); *see also* **JA-624-26, 629-32, 639-41, 644-49** (Loeb Decl. ¶¶ 28-29, 36-39, 50-52, 62-68)

[64] **JA-615-86** (Loeb Decl. ¶ 13 and attached Claim Chart)

[65] **JA-615-86** Loeb Decl. ¶ 13 and attached Claim Chart.

2. AMF Cannot Genuinely Dispute That the McDermott Article and Thesis Invalidate Claim 10 of the '616 Patent

AMF relies on Choma to rebut invalidity. In his expert report, Choma identifies one limitation of claim 10 of the '616 patent that he believes is not disclosed in the McDermott IEEE Article or Thesis: "selectively monitoring the at least one pair of the multiplicity of electrodes to measure a voltage associated therewith at the same time the stimulation signals are applied thereto."[66]

Despite Prof. Choma's opinion, there can be no genuine dispute that the McDermott IEEE Article discloses selectively monitoring the at least one pair of the multiplicity of electrodes to measure a voltage associated therewith at the same time the stimulation signals are applied thereto. Indeed, the undisputed facts show that the McDermott IEEE Article discloses that voltages associated with a selected pair of electrodes can be measured at the time of stimulation.

Specifically, it is undisputed the McDermott IEEE Article describes monitoring electrode impedances.[67] It is also undisputed that impedance is the ratio of a voltage measured across two terminals of an electrical circuit to the current that is flowing through those two terminals.[68] To monitor electrode impedances using the circuitry described in McDermott IEEE Article, a voltage difference between a pair of electrodes must be measured while a known stimulation current is flowing through the pair of electrodes.[69]

Thus, although Choma attempts to offer an ultimate opinion to the contrary, the *undisputed facts* demonstrate that the McDermott IEEE Article discloses

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[66] Joint Appendix at **JA-471-506** (¶¶ 10-11 and 17-18)
[67] Statement of Undisputed Facts at D16
[68] Statement of Undisputed Facts at D19; *see also* **JA-631-32, 648-49** (Loeb Dec., ¶¶ 38, 67); **JA-1169-70** (Choma Depo. 74:7-74:17; 75:6-75:17)
[69] **JA-631-34, 648-51 (**Loeb Dec., ¶¶ 38-39, 67-68); **JA-1169-72, 1179-80** (Choma Depo. 74:7-77:2; 184:24-185:14)

monitoring electrode impedances by measuring the voltages between (e.g., at each one of) a pair of intra-cochlea electrodes at the time stimulation signals are applied to the electrodes, as claim 10 of the '616 patent requires.

Even if AMF could create a genuine issue of act as to whether the McDermott IEEE Article and Thesis disclose monitoring electrode impedances by measuring the voltages between a pair of intra-cochlea electrodes at the time stimulation signals are applied to the electrodes, there can be no genuine dispute that such a step would have been obvious to a person of ordinary skill given the disclosure of the McDermott IEEE Article and Thesis. *See* **JA-1280-81** (Choma Depo. 185:8-186:4):

> Q. Looking at the 1989 article and assuming for the purposes of the next few questions that measuring across two electrodes -- the voltage across two electrodes is not disclosed, in your opinion would it have been obvious to one of ordinary skill in the art how to measure the voltage across two electrodes and transmit that voltage externally?
>
> …
>
> THE WITNESS: It would have been clear to one skilled in the art, yes.
>
> Q. And same question with respect to the thesis. Assuming for the purpose of this question that the thesis does not disclose measuring a voltage across a pair of electrodes during stimulation, would it have been obvious to one of ordinary skill in the art how to measure the voltage across two electrodes and transmit that voltage externally? …
>
> THE WITNESS: Yes.

AMF's assertion in its opposition – that Choma's testimony is essentially irrelevant because the patent claim requires monitoring (not measuring) of electrodes – ignores the plain language of the claim, in which the purpose of "monitoring" is "to measure a voltage associated therewith." Given the language of the claim, Choma conceded the underlying fact of obviousness. That Choma maintains his

ultimate opinion that the claim is not obvious is of no import given the undisputed facts. *Various Slot Machines*, 658 F.2d at 701 (absent specific facts showing genuine issues for trial, expert opinion is irrelevant).

For the first time in its opposition, AMF raises a second issue regarding anticipation and obviousness: that the limitation "transmitting the stimulator status indicating signals to an external receiver coupled to the external transmitter" is not disclosed by or obvious from the prior art. Choma's opinion regarding the "transmitting" limitation was not disclosed in his expert report,[70] and Cochlear never had an opportunity to take Choma's deposition on this opinion. Indeed, AMF undoubtedly adds this new issue because Choma essentially conceded obviousness of the "monitoring" limitation at his deposition. By failing to disclose Choma's opinion regarding the "transmitting" limitation, AMF has unfairly deprived Cochlear of discovery. Choma's declaration testimony regarding the "transmitting" limitation is thus subject to automatic preclusion and cannot generate a genuine issue of material fact. Fed.R.Civ.P. 37(c)(1) (automatic preclusion of information not disclosed under Rule 26(a)).

3. No Secondary Considerations Suggest That Claim 10 Would Not Have Been Obvious

Assuming that claim 10 of the '616 patent is merely obvious and not anticipated, it is necessary to consider secondary considerations regarding obviousness. In this regard, AMF has repeatedly pointed to the commercial success of Cochlear's product as evidence of non-obviousness. Yet to have any relevance to the obviousness inquiry, there must be a link between the commercial success and the invention. *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008).

The evidence uniformly shows that Cochlear's commercial success is not

[70] *Compare* **JA-579-80** (Loeb Report, pp. 16-18 (addressing "transmitting" limitation)) with **JA-471-506** (Choma Report (silent on "transmitting" limitation))

linked to the invention of claim 10. Cochlear's sales growth has been driven by performance and cosmetics.[71] The primary and secondary reasons for choosing a particular brand of implant are patient performance and reliability, respectively.[72] Potential recipients do not raise telemetry as a decision making issue.[73] Nor does Cochlear advertise impedance telemetry (the feature that AMF's accuses of infringing claim 10) in marketing materials.[74] In contrast, AMF's opposition merely points to facts that suggest that telemetry in general (not tied to the invention at issue here) could be of some benefit in selling implants.

Likewise, the "long felt need" identified by AMF in its opposition has nothing to do with the invention. Specifically, the asserted "delay" while Cochlear commercialized its Nucleus 24 implant is related to design and development effort and FDA approval of the implant as a whole. Even under AMF's understanding of its invention, that invention occurred no later than 1991 when it filed its patent application. There is no evidence of a long felt need prior to that time. Nothing about Cochlear's commercial success or the time it took Cochlear to commercialize its implant undercuts the otherwise undisputed fact that claim 10 of the '616 patent is at least obvious.

4. Claim 10 of the '616 Patent Is Either Anticipated or Obvious

There are no genuinely disputed material facts at issue with respect to the validity of claim 10 of the '616 patent. If AMF's proposed claim construction is applied, the prior art McDermott IEEE Article and Thesis disclose each and every step of that claim, and thus anticipate and invalidate claim 10 under 35 U.S.C. § 102.

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[71] **JA-1428-29** (Patrick Depo. 60:13-61:1)
[72] **JA-1337-38 (**Kelsall Depo. 26:20-27:19)
[73] **JA-1488** (Rinehart Depo. 63:5-9)
[74] **JA-1325-26 (**Graunke Depo., 55:13-56:11 (Cochlear's regional director of sales, who has been with the company for more than six years, cannot recall impedance telemetry used in marketing materials))

If Cochlear's proposed claim construction is applied, the minor difference between the McDermott IEEE Article and Thesis and claim 10 would have been obvious, thus invalidating claim 10 under 35 U.S.C. § 103. Either way claim 10 is invalid given what the McDermott IEEE Article and Thesis disclose.

B. Issues of Fact Preclude Summary Judgment on Cochlear's Anticipation and Obviousness Defenses

Cochlear's motion for partial summary judgment that claim 10 of the '616 patent is invalid as anticipated or obvious should be denied because genuine issues of material fact remain.

A patent is presumed to be valid, and Cochlear must prove invalidity by clear and convincing evidence. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1322 (Fed. Cir. 2008); 35 U.S.C. § 282. If the prior art was considered by the USPTO, there is a particularly heavy burden in establishing invalidity because of the deference owed to the USPTO. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984). Anticipation requires that each claim limitation of the challenged claim be found in a single prior art reference. *Voda*, 536 F.3d at 1322-23. Anticipation is a question of fact. *Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1335 (Fed. Cir. 2009).

Obviousness is based on underlying questions of fact. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1085-86 (Fed. Cir. 2008). For example, the scope and content of the prior art are questions of fact. *Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.*, 554 F.3d 1010, 1019 (Fed. Cir. 2009). What a reference teaches and whether it teaches away also raise questions of fact. *In re Bell*, 991 F.2d 781, 784 (Fed. Cir. 1993). Secondary considerations of non-obviousness such as commercial success also raise questions of fact. *Spectralytics, Inc. v. Cordis Corp.*, 576 F. Supp. 2d 1030, 1056-57 (D. Minn. 2008). Obviousness cannot be proven by conclusory statements. The analysis must be explicit and supported by articulated reasoning

with a rational underpinning. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

References that teach away from a patented combination can not create a prima facie case of obviousness. *Id.* at 416. A reference teaches away when a person of ordinary skill would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant. *Id*. If the combined references would produce a seemingly inoperative device, they teach away from the combination. *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). A seemingly inoperative device would be created if, for example, the combination of prior art would destroy or remove a feature that is required for the prior art to successfully operate. *In re Sponnoble*, 405 F.2d 578, 587 (C.C.P.A. 1969).

Defendants have failed to produce evidence establishing that the Thesis was publicly available on or before August 29, 1990. Ms. Dott speculates that if a "regular practice was adhered to," then the Thesis "would have been available" on or before "25 January 1990." JA-2201 (Dott Decl. ¶ 13). Dott was not employed at the University of Melbourne Library ("UM Library") in 1990, she has no knowledge of the UM Library's procedures in 1990, and she did not talk to anyone about procedures in 1990. She instead cites current practices. *See* JA-2201-2202 (*Id.* ¶¶ 5-6, 8-9. Dott provides no information about the current or past practices of "Libraries Australia" and thus provides no factual basis for her conclusion of when the Thesis was available. *See* JA-2201; JA-2399 (*Id.*, ¶ 10 & Ex. B). Her declaration and its Exhibit B are thus inadmissible hearsay. *See* Fed. R. Evid. 801(c). Because Dott failed to establish procedures in effect on "25 January 1990," the Thesis is inadmissible. *See* Fed. R. Evid. 902(12).

The Article and Thesis disclose the same cochlear implant system disclosed by McDermott in U.S. Pat. No. 4,947,844 ("the McDermott patent"), which was cited to the USPTO by AMF and considered by the examiner during prosecution of

the '616 patent. JA-543; JA-549-63 (Choma Decl. ¶ 44 & attached chart). U.S. Pat. No. 4,612,934 to Borkan ("the Borkan Patent") was also cited to and considered by the USPTO. JA-1969; JA-543 (Choma Decl. ¶ 45). Defendants thus have a particularly heavy burden in establishing invalidity by clear and convincing evidence. *Am. Hoist*, 725 F.2d at 1359-60.

Each and every element of claim 10 is not disclosed in either the Article or the Thesis, thereby precluding anticipation. As a general matter, the physician's tester in the '616 patent is integrated to the cochlear implant system to provide communication with the ICS for the purpose of monitoring, control and measurement of the ICS parameters. JA-543-44 (Choma Decl. ¶ 46). In contrast, the Article and Thesis disclose laboratory equipment (external receiver and probe) that passively detects a signal from the implant and displays it as a waveform. JA-544 (*Id.* ¶ 47). This equipment is not integrated and does not communicate with the ICS for the purpose of monitoring, control and measurement of the ICS parameters. JA-543-44 (*Id.* at ¶¶ 46-47).

Neither the Article, nor the Thesis disclose the step of "transmitting the stimulator status-indicating signals to an external receiver coupled to the external transmitter." The alleged "external transmitter" (speech processor) and the alleged "external receiver" (external receiver and probe) in the Article and Thesis are not physically coupled. JA-544-49; JA-1831; JA-2105 (Choma Decl. ¶ 49; Ex. 1039, Fig. 4; Ex. 1157, Fig. 6.4).

The external transmitter and the external receiver are not electrically coupled either. To avoid interference, the voltage monitor circuit in the implant is disconnected, and therefore data is not being transmitted to the external receiver when data is being received by the implant from the external transmitter of the speech processor. JA-545; JA-1833; JA-2075 (Choma Decl. ¶ 50; Ex. 1039; Ex. 1157). Thus, there is no electrical coupling of the external probe and receiver with the speech processor. JA-545 (Choma Decl., ¶ 50). Accordingly, claim 10 is not

anticipated because at least the "transmitting" step of claim 10 is not shown by the Article or Thesis. At the least, questions of fact remain.[75]

Cochlear has failed to present any non-conclusory analysis that Claim 10 is obvious over the Article and Thesis combined with the '934 Patent. Loeb's statement that it would be "obvious" to combine Borkan with the Article and Thesis is conclusory. JA-634-35; JA-545 (Loeb Decl. ¶ 42; Choma Decl. ¶ 51). Loeb does not provide details on how or why the McDermott and Borkan systems would be combined, or whether they could be combined successfully. Such conclusory statements are insufficient to meet Cochlear's burden of proving obviousness by clear and convincing evidence. *See Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1152 (Fed. Cir. 2004); *Myers v. Master Lock Co.*, 2008 U.S. Dist. LEXIS 41145 at **30-33 (D. Colo. 2008).

The references teach away from the proposed combination because the systems are incompatible at the transistor level and have different carrier frequencies that would make the transmitting and receiving coils, active circuitry, and filters incompatible. JA-545-46 (Choma Decl. ¶¶ 52-53). Accordingly, the proposed combination would require a significant redesign that would discourage a circuit designer from combining the two systems. *Id*. The references therefore teach away from the proposed combination. *Tec Air*, 192 F.3d at 1360. Combining incompatible systems is made more difficult because of the complexity of designing

[75] Cochlear's effort to exclude Choma's declaration on this point should be rejected. Choma's report opined that the references cited by Loeb did not anticipate the '616 patent or render it obvious, and further, that Loeb's report was conclusory and unsupported by specific evidence. JA-473, 482-83 (Choma Rebuttal ¶¶ 4-5). Cochlear has the burden of proving invalidity by clear and convincing evidence. Cochlear did not rely on Loeb's report in support of this motion, but a lengthy declaration from Loeb, which was likewise conclusory and unsupported on the "transmitting…" step. AMF is entitled to respond to Loeb's declaration, and did so with Choma's declaration. There is no lack of disclosure. Also, Cochlear apparently does not disagree with Choma's analysis. Thus, there is no harm to Cochlear. Fed. R. Civ. P. 37(c)(1). As discussed, *supra* at n. 46, if Cochlear seeks exclusion of Choma's point, then paragraphs 36-39 & 62-68 of Loeb's declaration should likewise be excluded.

a cochlear implant system. *See* JA-1367; JA-1348 (Loeb Dep. at 122:7-10 ("there is nothing about the design of . . . a cochlear implant that is a trivial exercise."); Loeb Dep. at 65:9-13). At the least, questions of fact preclude summary judgment.

Additionally, the Article and Thesis do not anticipate claim 10 because neither reference discloses "selectively monitoring the at least one pair of the multiplicity of electrodes to measure a voltage associated therewith at the same time stimulation signals are applied thereto." JA-546 (Choma Decl. ¶ 54). The Article discloses that only a single electrode, and not a pair of electrodes, is monitored with respect to ground to obtain the voltage of that electrode: JA-546-67; JA-1830 & 1833; JA-1211 & JA-1245; JA-1257-58; JA-543; JA-1967; JA-26 (Choma Decl. ¶ 54; Exh. 1039; Choma Dep. 116:17-25, 150:9-14, 162:3–163:10; Choma Decl. ¶ 44; '844 patent, col. 8, ll. 13-24; '616 patent, col. 2, ll. 48-61; Statement of Uncontroverted Facts, D17-D18 & D20-D22 (Opposing Evidence)). Likewise, the Thesis does not disclose monitoring a pair of tissue-stimulating electrodes as the stimulation signal is applied thereto, as required by claim 10 of the '616 patent, but only a single electrode with respect to ground. JA-546-47; JA-2072, 2075, 2096, 2100; JA-1242-44; JA-543; JA-1967; JA-26 (Choma Decl. ¶ 54; Exh. 1157; Choma Dep. 147:19 – 149:6; Choma Decl. ¶ 44; '844 patent, col. 8, lines 13-24; '616 patent, col. 2, lines 48-61; Statement of Uncontroverted Facts, D36-D38 & D40-D41 (Opposing Evidence)). The Thesis also teaches away from monitoring a pair of tissue-stimulating electrodes: "V_MON is measured relative to the receiver-stimulator ground potential by the monitor circuit." JA-546-47; JA-2090 (Choma Decl. ¶ 54; Exh. 1157). "It is essential that the monitor of each RS5 implant is accurately calibrated during final testing of the assembled device. This procedure, which involves placing a variable voltage source on ***a monitored electrode***, yields a graph showing monitor frequency for every possible input voltage value." JA-2091 (Exh. 1157) (emphasis added). A person of skill in the art would understand the Thesis

discloses monitoring of a single electrode and not a pair of electrodes. JA-546-47 (Choma Decl. ¶ 54).

Dr. Choma's deposition testimony that it would be clear to one of skill in the art to ***measure*** a voltage across two electrodes and transmit that signal externally does change not his opinion that claim 10 of the '616 patent is not obvious. JA-546-47 (Choma Decl. ¶ 54). The claim element requires ***monitoring*** of a pair of electrodes, and neither the McDermott Article, nor the McDermott Thesis disclose monitoring a selected pair of electrodes, but monitoring one selected electrode at a time. *Id.* Nor would it have been obvious to monitor a pair of electrodes separately or within the context of all of the other steps of the method claimed in claim 10 of the '616 patent. *Id.*

Summary judgment should also be denied because there is a question of fact regarding secondary considerations of non-obviousness concerning whether impedance telemetry contributes to Cochlear's commercial success in selling the implants. *See Spectralytics*, 576 F. Supp. 2d at 1056-57; *Medtronic Vascular, Inc. v. Advanced Cardiovascular Sys., Inc.*, 2009 U.S. Dist. LEXIS 8948 *43-*44 (N.D. Cal. 2009). Mr. van den Honert of Cochlear testified that telemetry was "a valuable feature." JA-1581 (van den Honert Dep. at 58:20-22). Cochlear's marketing literature refers to the telemetry feature, and Cochlear witnesses admitted that Cochlear's Custom Sound software, which contains the impedance telemetry feature, facilitates sales and contributes to sales growth of the implant systems. JA-1092-93; 1323; 1328 (Adkins Dep. at 29:1-20; 30:7-14; Graunke Dep. at 28:5-16 & 65:3-9). Dr. Kelsall, a surgeon who implants Cochlear's devices, testified that he would recommend a cochlear implant having telemetry feature over a cochlear implant that did not. JA-1338-39 (Kelsall Dep. at 27:20–28:1-2).

The record also contains evidence of other secondary considerations, including a long-felt, unsatisfied need. In technical memoranda, Cochlear identified the need for telemetry as early as 1990 and 1991, yet it was not until 1997 that

Cochlear was able to commercialize an ICS and WP including back telemetry. *See* JA-1422-26; JA-1774-75; JA-2409; JA-2416-17; JA-1777-1825; JA-1810; JA-1752-53 (Patrick Dep. at 46:21–50:5; COC-1009446-47; COC-1000001; COC-1000008-9; COC-1001287-1335, at p. COC-1001320; AMF004663-64). Indeed, Dr. Loeb acknowledged that design of such a system was not trivial. JA-1367 (Loeb Dep. at 122:7-10). This evidence creates an issue of fact concerning the long-felt need for the patented invention.

Experts in the field have also praised the invention. Cochlear's employees described the telemetry feature as "a leading innovation" and "a valuable feature." JA-1747-73; JA-1431-32; JA-1581-82 (AMF004658-84; Patrick Dep. at 80:1-81:1; van den Honert Dep. at 58:20-59:1). Dr. Kelsall testified that "clearly telemetry is a benefit." JA-1337-38 (Kelsall Dep. at 26:20-28:2).

Accordingly, there are questions of act on the issues underlying obviousness. Cochlear's motion should be denied.

Respectfully submitted,

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