** NOT FOR PRINTED PUBLICATION **

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

MARK BARRY, M.D.,	§	
	§	
Plaintiff,	§	CIVIL ACTION No. 1:14-cv-104
	§	
v.	§	JUDGE RON CLARK
	§	
MEDTRONIC, INC.,	§	PRD
	§	
Defendant.	§	

ORDER REGARDING DEFENDANT'S MOTIONS FOR JUDGMENT AS A MATTER OF LAW

Plaintiff Dr. Mark A. Barry brought suit, asserting that Defendant Medtronic, Inc. indirectly infringed two patents relating to a system and method of aligning spinal vertebrae to correct for common spinal deformities likes scoliosis. The jury returned a verdict that was adverse in all respects to Medtronic, which timely moved for judgment as a matter of law ("JMOL") on several grounds.[1] Dkt. 406; *see also* Tr. at 1605–1629 (oral motions after Dr. Barry rested); Tr. at 1920–1962 (oral motions at close of evidence) (collectively, "Oral JMOL Motion").[2]

[1] The court has not yet entered final judgment in this case. Therefore, motions under Rule 50(b) have not yet been made. The parties' oral motions and any briefing submitted prior to final judgment being entered are considered in support of a party's Rule 50(a) motion. Under the rules, however, a party moving for JMOL must first do so at the close of all evidence in order to renew such a motion after judgment has been rendered. *Taylor Pub. Co. v. Jostens, Inc.*, 216 F.3d 465, 471 (5th Cir. 2000); FED. R. CIV. P. 50(b). Therefore, any grounds for JMOL that were not asserted at the close of the evidence are deemed waived. *Taylor*, 216 F.3d at 471.

[2] The official trial transcript will be referenced in this Order as "Tr. at [line:page]" and appears on the docket at Dkts. 421–427.

Medtronic claims that it is entitled to JMOL on the issue of induced infringement, overseas infringement, willfulness, damages, and invalidity. Dkt. 406; Oral JMOL Motion. Medtronic also claims that the patents are unenforceable under the doctrine of inequitable conduct. Dr. Barry opposes Medtronic's Motions for JMOL and inequitable conduct claims. Dr. Barry claims that he is entitled to enhanced damages based on the jury finding of willfulness.

In this Order, the court addresses Medtronic's motions for JMOL.[3] The court grants Medtronic's motions for judgment as a matter of law solely with regard to overseas infringement under Section 271(f)(1) and the corresponding damages award, because there was insufficient evidence to support a jury verdict in Dr. Barry's favor on that issue or the corresponding jury award based on overseas infringement. All other motions for JMOL are denied.

I. PROCEDURAL HISTORY

On February 18, 2014, Dr. Barry sued Medtronic, alleging infringement of U.S. Patent No. 7,670,358 ("the '358 Patent") and U.S. Patent No. 8,361,121 ("the '121 Patent"),[4] two patents issued to and owned by Dr. Barry himself. The court conducted a Markman hearing on November 10, 2015 and issued an order construing disputed claim terms (Dkt. 122).

Issues of infringement, invalidity, and damages were tried to a jury between November 3, 2016, and November 11, 2016. The jury returned a verdict adverse to Medtronic in all respects. Dkt. 411. The jury found as follows:

a) Claims 4 and 5 of the '358 patent and claims 2, 3, and 4 of the '121 patent were directly infringed. Answer to Question No. 1, Dkt. 411 (Jury Verdict), at p. 2;

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[3] The court intends to address inequitable conduct, enhanced damages, and attorneys' fees in separate orders.

[4] On October 13, 2015, the court granted a joint motion to dismiss with prejudice all causes of action regarding the third previously-asserted patent, U.S. Patent No. 7,776,072. Dkt. 102.

b) Medtronic actively induced the direct infringement of claims 4 and 5 of the '358 patent and claims 2, 3, and 4 of the '121 patent. Answer to Question No. 2, Dkt. 411, at p. 3;

c) Medtronic supplied or caused to be supplied from the United States all or a substantial portion of the components of the systems claimed in claims 2, 3, and 4 of the '121 patent and actively induced others to combine those components outside of the United States in a way that would infringe if such combination occurred within the United States. Answer to Question No. 3, Dkt. 411, at p. 4;

d) Medtronic's infringement with respect to the '358 patent and the '121 patent was willful. Answer to Question No. 4, Dkt. 411, at p. 5;

e) The jury did not find that any of the asserted claims of the '358 patent or the '121 patent were invalid due to public use. Answer to Question No. 5, Dkt. 411, at p. 6;

f) The jury did not find that any of the asserted claims of the '358 patent were invalid due to prior sale. Answer to Question No. 6, Dkt. 411, at p. 7;

g) The jury did not find that any of the asserted claims of the '358 patent or the '121 patent were invalid due to prior invention. Answer to Question No. 7, at pp. 8–9 (parts (a) and (b) pertain to the '358 patent; parts (c) and (d) pertain to the '121 patent).

h) The jury awarded Dr. Barry damages in the following amounts (Answer to Question No. 9, Dkt. 411, at p. 10):

   i. For infringement of the '358 patent within the U.S.: $15,095,970.00;
   ii. For infringement of the '121 patent within the U.S.: $2,625,210.00;
   iii. For infringement of the '121 patent outside the U.S.: $2,625,210.00.

While the jury was deliberating, the parties tried the issues of inequitable conduct and laches to the bench. Prior to the return of the verdict, the court ruled on the issue of laches in favor of Dr. Barry, finding that there was insufficient evidence to support a finding that Dr. Barry unreasonably delayed in filing suit or that any alleged delay resulted in material prejudice to Medtronic. The court deferred ruling on inequitable conduct, an issue on which both parties submitted additional briefing leading up to trial and after trial. Dkts. 346 (Medtronic), 356 (Medtronic), 429 (Dr. Barry), 436 (Medtronic Opp.).

The court's order on inequitable conduct and enhanced damages will be entered separately.

II. PATENT BACKGROUND AND TECHNOLOGY

Both patents have a priority date of December 30, 2004, the day that the application which issued as the '358 Patent was filed. Each patent bears the same title, "System and Method for Aligning Vertebrae in the Ameliorating of Aberrant Spinal Column Deviation Conditions" and has the exact same specification. Dr. Barry asserted claims 4 and 5 of the '358 Patent and claims 2, 3 and 4 of the '121 patent.

Figure 1 of both patents displays the basic components of the invention as follows:

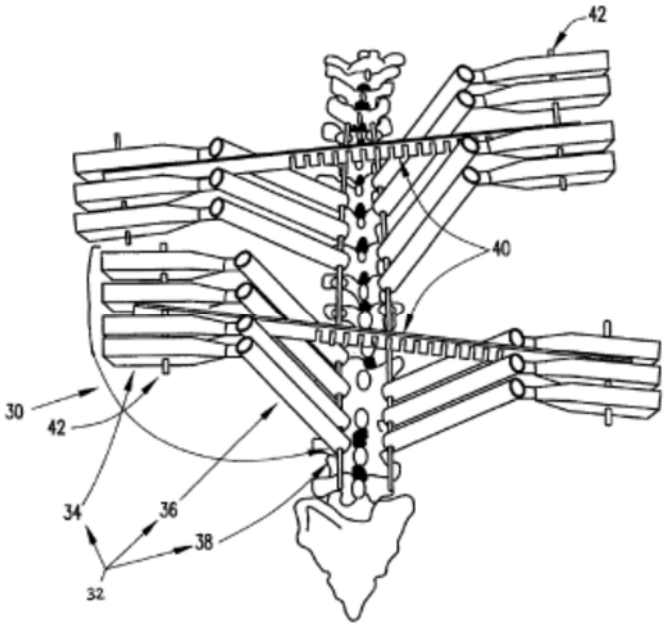

Fig. 1

The invention permits rotation of the spinal column as a whole by a single surgeon without applying significant force to individual vertebrae. *See* '358 Patent, 2:39–67. It involves inserting pedicle screws into to-be-rotated vertebrae and vertebrae that are not rotated. The vertebrae to be rotated are rotated with a pedicle screw cluster derotation tool **30** (*Id*. at 2:32) that engages the pedicle screws inserted into the vertebrae. The spine is set by fixing the pedicle screws to pre-contoured spinal rods. *See id*. at 3:34–4:4. The "pedicle screw cluster derotation tool" consists of

pedicle screw wrenches **32** that are made up of "a handle **34**, a shaft **36**, and a distal end which is configured to reversibly engage the head segment . . . of a pedicle screw." *Id*. at 5:12–14 (emphasis in original). The patents claim, variously, a first and second pedicle screw derotation tool.

The '358 patent claims are directed towards the method for performing the derotation, and the '121 patent claims are directed to the system, or apparatus, to be used. Additionally, the '121 patent contains a "cross-linking" limitation, which refers to a cross-linking member **40** across the spine that connects what is referred to as the first and second handle means in the inventions.

III. LEGAL STANDARD FOR JUDGMENT AS A MATTER OF LAW

JMOL is appropriate where "a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Rule 50(a)(1); *see also Reeves v. Sanderson Plumbing Prods, Inc*., 120 S. Ct. 2097, 2109 (2000). The Federal Circuit reviews an appeal from a grant or denial of a motion for JMOL under the law of the regional circuit in which the appeal from the district court would usually lie. *ACCO Brands, Inc. v. ABA Locks Mfr. Co. Ltd.*, 501 F.3d 1307, 1311 (Fed. Cir. 2007); *Apple, Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1040 (Fed. Cir. 2016) (en banc). A finding in a patent case by a jury in a federal district court in the Fifth Circuit is therefore reviewed under the "substantial evidence" rule. *Mettler-Toledo, Inc. v. B-Tek Scales, LLC*, 671 F.3d 1291, 1294 (Fed. Cir. 2012) (applying Fifth Circuit's substantial evidence standard and affirming denial of judgment as a matter of law because substantial evidence supported jury verdict of invalidity based on obviousness); *see also ACCO Brands*, 501 F.3d at 1311.

"Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1363 (Fed. Cir. 2004) (internal citation omitted). "Substantial evidence is

not a fixed quantum of evidence: What is or is not substantial may only be determined with respect to the burden of proof that the litigant bore in the trial court." *Id*. at 1363. Where the party with the burden of proof by clear and convincing evidence fails to obtain a favorable finding, more will be needed to overturn the verdict. *Eli Lilly*, 376 F.3d at 1363.[5] "Courts grant JMOL for the party bearing the burden of proof only in extreme cases, when the party bearing the burden of proof has established its case by evidence that the jury would not be at liberty to disbelieve and the only reasonable conclusion is in its favor." *Mentor H/S, Inc. v. Med. Device All., Inc.*, 244 F.3d 1365, 1375 (Fed. Cir. 2001).

In entertaining a motion for JMOL, the court must review all of the evidence in the record. *Reeves*, 120 S. Ct. at 2110. In doing so, "the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Id*. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Id*. Thus, although the court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury is not required to believe. *Id*. That is, the court should give credence to the evidence favoring the nonmovant as well as that "evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that evidence comes from disinterested witnesses." *Id*. Under Fifth Circuit law, a jury's verdict is given great weight and all reasonable inferences are drawn in

[5] A court must be careful to determine which party had the burden of proof, and what that burden is. If a party has the burden of proof and the jury fails to find in its favor, it is not precisely correct to say that there must be substantial evidence supporting the non-movant. If there is no evidence on an issue, the party with the burden of proof should lose. Even where the movant presented an interested witness on an issue, and the non-movant presented no witnesses, the jury might simply have decided that the movant's witness was not credible and/or was impeached on cross-examination.

the light most favorable to the verdict. *Thomas v. Texas Dep't of Criminal Justice*, 220 F.3d 389, 392 (5th Cir. 2000); *see also Krystek v. Univ. of S. Mississippi*, 164 F.3d 251, 258 (5th Cir. 1999) ("We accord great deference to a jury's finding of facts.").

IV. INDUCED INFRINGEMENT

Medtronic moves for JMOL as to induced infringement, asserting that no reasonable factfinder could conclude that (A) surgeons directly infringe the asserted claims of either the '358 patent or the '121 patent; (Dkt. 406 at p. 1) or that (B) Medtronic induced infringement of either patent, because Dr. Barry failed to identify any actions by Medtronic sufficient to constitute inducing acts. Dkt. 406 at p. 8. The jury found that Medtronic induced infringement of all of the asserted claims of both patents-in-suit in violation of 35 U.S.C. § 271(b).

To show induced infringement, a patentee must prove by a preponderance of the evidence that (1) there was underlying direct infringement; and (2) the accused infringer knowingly induced infringement and possessed specific intent to encourage another's infringement. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014).

Dr. Barry sought to prove that surgeons performing spinal correction surgeries with Medtronic's accused products, the CD Horizon Legacy and Solera systems with Vertebral Column Manipulation (VCM) kits,[6] directly infringed the patents and that Medtronic induced infringement.

[6] A dispute regarding the definition of the "accused products" in this case arose at trial. Prior to trial, in the parties' joint pre-trial order, the parties referred the accused products as "Medtronic CD Horizon Legacy Spinal System with Vertebral Colum Manipulation ("VCM") Instrument Set" and/or . . . Medtronic CD Horizon Solera Spinal System with VCM Instrument Set." Dkt. 386 at p.4 ¶ 1. Accordingly, the court's jury instructions adopted the same characterization when referring to the accused products. Neither side objected to this formulation in the instructions at the charge conference.

The jury was asked in the verdict form to make a finding regarding underlying direct infringement. The following analysis addresses underlying direct infringement and inducement in turn.

A. Substantial evidence supports the jury's finding of underlying direct infringement. – Jury Verdict (Dkt. 411), Question No. 1

There is substantial evidence that surgeons using Medtronic products directly infringe the patents-in-suit. Dr. Barry's technical expert, Dr. Walid Yassir, the Chief of Pediatric Orthopedics at the Children's Hospital of Michigan in Detroit,[7] testified extensively as to how the Medtronic products directly infringe each and every asserted claim of the patents. Tr. at 788–819; 854–866 (testimony on a claim-by-claim basis over two days). Dr. Yassir testified that his ultimate opinion was that there has been direct infringement of both patents. *See, e.g.*, Tr. at 777 (both patents), 785–86, 854. Dr. Barry also presented substantial evidence of infringement through a survey involving hundreds of surgeons, a number of whom admitted that they used Medtronic equipment in a way that, as supported by Dr. Yassir's opinions, infringe the patents-in-suit (the "Neal survey," PX 309[8]). Dr. Lawrence Lenke, a surgeon called by Medtronic, testified that he himself had performed infringing surgeries "continuing until after 2010." Tr. at 1708:3–25. Notwithstanding

[7] As one would expect, Medtronic's infringement expert Dr. Rex Marco disagrees with Dr. Yassir's testimony regarding infringement. Dr. Marco's credibility and qualifications were called into question during trial at several junctures. For instance, on cross-examination Dr. Marco admitted that he had never used a VCM kit yet Medtronic hired him as its infringement expert, something that "surprised" even him. Tr. at 1842. A jury could have reasonably concluded that Dr. Yassir was more qualified and more credible, especially since Dr. Yassir stated that he had used a Medtronic VCM kit. Tr. at 775. Having observed both witnesses, the court could not disagree. The reaction of the jury to Dr. Marco's statement that he himself was surprised to be called may not be apparent from a cold record but it was palpable to those in the courtroom, including the undersigned.

[8] Plaintiff's and Defendant's Trial Exhibits will be referenced in this Order, respectively, as "PX ____" and "DX ___."

this evidence, Medtronic objects to the Neal survey and several specifics related to this underlying direct infringement evidence. Each objection is addressed in turn below.

1. The Neal Survey

In addition to presenting evidence of the survey responses through Dr. Yassir, the individual that helped create and administer the survey, Dr. David Neal, also testified before the jury. Dr. Neal explained the results of the survey, specifically how the survey responses demonstrate what percentage of derotation surgeries performed with the Medtronic products at issue infringe the asserted claims. Tr. at 593–94.

The jury verdict demonstrates that the jury evidently found the Neal survey evidence and the accompanying expert testimony by Dr. Neal to be credible in demonstrating direct infringement. Medtronic, however, contends that the survey is unreliable as a matter of law, recycling many of the same arguments raised in its earlier *Daubert* motion, which the court has already concluded lack merit. Dkt. 430 at p. 9; *id*. at p. 11–12; Dkt. 293 (Order on Neal Survey). To the extent that Medtronic raises any new reliability arguments based on trial testimony, for instance based on testimony solicited during the cross examination of Dr. Neal regarding biases in the survey creation or alleged gaps in Dr. Neal's methodology and how the survey was administered (Dkt. 430 at 11), those factors go to the weight attributed to the survey evidence rather than whether the evidence was admissible. *See C.A. My Marine Supply Co. v. Brunswick Corp.*, 649 F.2d 1049, 1054 (5th Cir. 1981). For the same reasons previously articulated in the court's *Daubert* Order (Dkt. 293), the court overrules Medtronic's reliability objections.

Medtronic also objects to the wording of the survey questions. First, Medtronic asserts that the responses are not evidence of direct infringement because the questions do not mention "VCM kit" but only the Medtronic Legacy and Solera "systems" more generally. Dkt. 406 at p. 7; Tr. at 1944–45. Medtronic's argument turns on the mistaken premises that the *only* "accused product"

in this case is the VCM kit (*see* Tr. at 1944) and that the VCM kit can be properly characterized as the "accused VCM Kit." Dkt. 406 at p. 7. This misrepresentation does not comport with the joint pre-trial order, which characterizes the accused products as "Medtronic CD Horizon Legacy Spinal System *with* Vertebral Colum Manipulation ("VCM") Instrument Set" and/or . . . Medtronic CD Horizon Solera Spinal System *with* VCM Instrument Set." Dkt. 386 at p. 4 ¶ 1 (emphasis added). Direct infringement was never at any point in this case limited to use of the VCM kit alone. An attack on the survey questions based on this misunderstanding therefore falls flat.

Further, Dr. Barry testified that the survey need not use the exact words "VCM" in order to tell survey reviewers about infringement using the VCM. Tr. at 644:15–18. Those receiving the survey were 121 surgeons highly familiar with spinal correction procedures and with pedicle screw and spinal rod implant systems. *See* Tr. at 578–79 (Dr. Neal's testimony regarding screener questions); PX 309 (survey questionnaire). Dr. Yassir also provided rebuttal testimony, testifying that given the timeframe of the survey, surgeons were more likely than not also using the VCM kits. Tr. at 831:17–23; 858:9–23. Medtronic offers Dr. Marco's "unrebutted testimony" that survey participants could have used Medtronic's tube derotators rather than the VCM kit to perform the steps of the Neal survey (Dkt. 430 at p. 10)—but this ignores the reality that a jury could have chosen to find that Dr. Marco's testimony lacked credibility.[9]

[9] Further, the jury heard evidence about use of the Legacy and Solera kits only in relation with use of the VCM kit; the court even made the point during oral motions that, as the evidence had come in, there was a suggestion that the Legacy and Solera kits are sold as highly-specialized for use with the VCM kit. *See* Tr. at 1945. To the extent that Medtronic now belatedly argues that SmartLink products "could have" been used instead of the VCM kits and, because of this, the survey results are faulty (*see, e.g.*, Dkt. 430 at p. 11), the jury never heard about SmartLink or any other alternatives to the VCM kit. As Medtronic admits, Medtronic refused to proffer discovery on SmartLink products (*see* Dkts. 156 and 164) and previously stated that it would

Medtronic also complains that the Neal survey questions do not specifically mention all of the claim limitations and mischaracterize the claims. Dkt. 430 at p. 12. But requiring a survey to spell out every claim limitation in order to evidence direct infringement would, as Dr. Neal's testimony supports, be overreaching, especially given the practical need for an approachable—not incomprehensible—survey. Dr. Neal effectively discussed how the survey was created and Dr. Yassir explained to the jury how the survey results map to the asserted claims. The court rejects the invitation to proscribe an unduly rigid rule that survey questions must recite the claim terms exactly in order to reveal direct infringers. Medtronic also had ample opportunity on cross-examination to poke holes in the probative value of the survey evidence, an attempt which the jury obviously found non-compelling.

2. Evidence that Medtronic's own consultant, Dr. Lenke, directly infringed

Additional evidence of direct infringement was provided by Medtronic's own longtime consultant, Dr. Lawrence Lenke. He testified that he himself performed the claimed technique with the VCM kit after 2010 (Tr. at 1708), which could reasonably have been taken by the jury as evidence of direct infringement. Dr. Yassir's testimony buttressed this conclusion. Tr. at 908 ('121 patent); Tr. at 836 ('358 patent); Tr. at 836 (explaining photos of Lenke surgeries). Documents corroborating Dr. Lenke's admission include a 2012 presentation by Lenke (PX 202.005), a 2010 presentation (PX 142), and a 2008 Spine Journal article (PX 109).

Medtronic argues that these acts and the accompanying documents are undated or predate the patents and therefore cannot evidence direct infringement because direct infringement of a

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"not use SmartLink for any purpose in this trial, for damages or otherwise." (Mar. 22, 2016 hearing, Tr. at 79:23–24). Even closer to trial, Medtronic agreed that those products be excluded; the court therefore excluded SmartLink, without exception. Dkt. 378 (MIL Order) at p. 2; Dkt. 348 (Medtronic Brief on MIL #2) at 7–8. To rely on evidence at JMOL that was agreed upon to be excluded is improper.

patent can only take place after a patent's issuance. Dkt. 430 at pp. 12–13. While Medtronic correctly states the law, they ignore the fact that Dr. Lenke's testimony was not limited to acts that pre-date either of the patents. Dr. Lenke admitted to infringing surgeries "continuing until *after 2010*." Tr. at 1708:3–25.

3. Medtronic's challenges to direct infringement of both patents based on claim limitations are unavailing.

Medtronic challenges the jury's finding of underlying direct infringement on several technical grounds based on specific claim limitations. Each of these challenges is addressed below.

Medtronic first argues that Dr. Yassir's testimony that a single handle means could meet the limitations requiring a first and second handle means cannot support a finding of infringement. Dkt. 406 at p. 6 (citing Tr. at 821:13–16, 962:20–963:3, Tr. at 964:19–24, Tr. at 967:1–4; Tr. at 1026:14–1027:1). As an initial matter, the court is troubled that neither party during claim construction requested construction of "second handle means" or a determination that the use of "first" and "second" implied separate handles—even though both sides at JMOL briefing offer cases on this subject. Nevertheless, the court need not revisit claim construction because, notwithstanding Dr. Yassir's testimony, there does not appear to be a live claim construction issue under the standard in *02 Micro Inter'al, Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351 (Fed. Cir. 2008).

Dr. Yassir's testimony at one point appears to track the description of one embodiment in the specification of the '358 patent, which explicitly references a "single handle member" replacing the "linked, multiple wrenches." '358 Patent, col. 5, ll. 19–35. Regardless of how this testimony is interpreted, there is other significant evidence that Medtronic's products contain a first and second handle means that supports the jury's finding. For instance, the technical surgical

guide (PX 116, Fig. 10b) displays a product that has two separate handle means, one on each side of the spine. Tr. at 811:17–815:8 (Yassir testimony explaining the figure).

Medtronic also claimed at oral motions that there was insufficient evidence that the VCM kit contains "pedical screw engagement members which are ***mechanically linked*** with handle means," a limitation required by both patents. However, Dr. Yassir opined that the engagement members are mechanically linked, relying on Figure 5 of the Medtronic surgical technical guide, which appears at PX 116. Tr. at 808–09. This testimony was unrebutted at trial.[10]

Medtronic also argued at oral motions that there is no evidence that surgeons "select a second pedicle screw cluster derotation tool." But Dr. Yassir specifically connected the survey evidence, where surgeons admitted to performing certain actions with regards to the Medtronic VCM kits, to infringement of this particular limitation. Tr. at 821–822. Dr. Yassir also explained to the jury specifically how the VCM kit infringed, including describing the second derotation tool. Tr. at 825–826. The Surgical Technique Guides also show the VCM kit and include diagrams that Dr. Yassir used to describe how the various parts infringe Dr. Barry's patents. PX 116, Fig. 10b. This is sufficient to support the jury's finding.

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[10] At trial, the court excluded the opinion of Medtronic's non-infringement expert Dr. Marco that the pedicle screw and handle are not mechanically linked (Tr. at 1800; 1803), because it became clear to the court from observation of the Medtronic product that the engagement member and the handle means were screwed together, which the court had stated in its claim construction order could constitute a mechanical linkage. *See* Dkt. 122 (Claim Construction Order), at p. 11 ("Defendant acknowledged that there were 'other ways' to mechanically link the shaft and handle. Barry Tr. [Claim Construction Tr., Dkt. 119] at 106:14–20. For example, they could be screwed together."). Dr. Marco's opinion that this connection could not constitute a mechanical linkage was excluded because it would have conflicted with the court's construction. Given that Defendants previously acknowledged that screwing the shaft and the handle together would be a mechanical linkage (*see* Dkt. 119 (Claim Construction Transcript) at 106:14–20), this point on JMOL is a groundless attempt to backtrack on Defendant's prior argument.

4. Medtronic's challenges specific to direct infringement of the '121 patent are also unavailing.

Medtronic raises several non-infringement arguments on JMOL specific to the '121 patent. Medtronic argues that there was insufficient evidence that any VCM kit assembled after 2013 (issuance date of the '121 patent) contained (a) two pedicle screw derotation tools, "each of which has a group of ***three or more*** pedicle screw engagement members" that are mechanically linked, (b) three of more pedicle screw engagement members that are ***each*** linked to their own handle means, and (c) ***a linking member*** that links the handles across the spine. Dkt. 405 at pp. 5–6. The limitations that are bolded and italicized highlight the specific portion on which Medtronic bases its objections. On each ground, there is substantial evidence to support the verdict.

In regards to (a), Dr. Yassir specifically described why there are at least three engagement members in the tool. Tr. at 840. Moreover, Dr. Yassir, relying on Medtronic's statements in its surgical guide, opined that he understood that the VCM kit typically attaches to two or three vertebrae simultaneously, which is a construct that would infringe the '121 patent. Tr. at 844. He also connected this limitation to the Neal survey, which specifically asked about six or more derotators linked bilateral and transverse connections and moved simultaneously. Tr. at 844–45. This support's a determination that the Medtronic VCM kits contain a group of three or more pedicle screw engagement members.

Regarding (b) above, the Surgical Technique Guide (PX 116), specifically Figure 10b, and Dr. Yassir's testimony about that figure, support the jury's conclusion that Medtronic's products contain three engagement members that are each linked to their own handle means.

Finally, regarding (c) above, there is substantial evidence that Medtronic instruments have handles on each side of the spine that are linked together by a "cross-linking member." Dr. Yassir explained how the VCM kits infringe this limitation, this time relying in part on the survey and

statements about the VCM kits from the Medtronic-sponsored iScoliosis website (*see* PX 475 at p. 3). Dr. Yassir also stated that surgeons infringed this limitation based on Dr. Lenke's presentations (Tr. at 842–44), which showed Dr. Lenke performing surgeries where he utilized a cross-linking member from a Medtronic VCM kit. Dr. Yassir also testified that an exhibit showing the lid of a VCM kit (PX 99) combined with Dr. Lenke's instructions in how to use the kit constitutes evidence that use of the VCM kit infringes the cross-linking member limitation specific to the '121 patent.

5. Substantial evidence supports the jury's verdict on underlying direct infringement.

The jury was entitled to weigh the evidence and the credibility of the witnesses. There is substantial evidence to support the jury's verdict on underlying direct infringement. Medtronic's motions for JMOL on underlying direct infringement are denied.

B. <u>Substantial evidence supports the jury's finding of active inducement by Medtronic. – Jury Verdict (Dkt. 411), Question No. 2</u>

There is substantial evidence that Medtronic actively induced infringement of Dr. Barry's patents. To satisfy this element of induced infringement, Dr. Barry was required to prove by a preponderance of the evidence that Medtronic knowingly induced infringement and possessed specific intent to encourage another's infringement. *Limelight*, 134 S. Ct. at 2117. Circumstantial evidence of inducement is sufficient for inducement. *See Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016).

Medtronic's main argument on this point is mistakenly grounded in the presumption that, in order to prove inducement, Dr. Barry was required to present direct evidence of inducement. Under Medtronic's theory of induced infringement, Dr. Barry must have solicited testimony stating "Medtronic encouraged me to do X," and direct evidence that every one of the alleged

direct infringers were induced by Medtronic. On both accounts, circumstantial evidence is sufficient. *Id.*

Dr. Yassir, relying on Medtronic documents, Medtronic's instructions to surgeons through their sales force, and Dr. Lenke's instructions[11] (Tr. at 908), opined that Medtronic induces infringement. Tr. at 874. Dr. Yassir testified extensively about the technical training that Medtronic provides to its surgeons through its salesforce and the technical guides. Tr. at 885–86.

The Medtronic surgical guides (PX 116, PX 115) themselves are evidence of inducement in that they provide instructions for techniques using Medtronic systems with VCM kits in an infringing manner. Tr. at 782–83 (Yassir testimony on this point). Medtronic complains that these materials pre-date issuance of the patents and thus cannot evidence inducement since the patents were issued (Dkt. 430 at p. 15). But Dr. Yassir testified, and the jury was entitled to find credible, that Medtronic puts out guides like these "all the time." Tr. at 782:23. Dr. Yassir also detailed typical industry practices for issuing technical guides that support a finding that Medtronic regularly distributes these guides and instructs surgeons on how to use the equipment supplied, regardless of when the patents in this case issued. Tr. at 783. Therefore, the mere fact that PX 115 and PX 116 may not post-date 2010 or 2013, when the respective patents were issued, does not necessarily undercut this evidence.[12]

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[11] The parties stipulate in the joint pre-trial order that Dr. Lenke has been a paid consultant for Medtronic since at least 2001. Dkt. 386 at p. 13.

[12] Medtronic also contends that the survey evidence, in particular Question 19, cannot evidence inducement because the question was not limited to actions after 2010, when the '358 patent issued, or after 2013, when the '121 patent issued. Dkt. 430 at p. 14. To Medtronic, the question was too broad-sweeping. But, on cross-examination, Dr. Neal explained that the question properly captured inducement. A jury is entitled to accept Dr. Yassir's rebuttal testimony. The survey responses are also not the only evidence of inducing acts.

Other evidence abounds on the record. The jury saw a presentation (PX 125) wherein Medtronic educates the sales force about using the VCM kit in the same infringing manner described through the surgical technique guides. Medtronic witnesses testified that they were present in the operating room for surgeries, Tr. at 1355:14–15, suggesting that they may encourage surgeons to infringe in the operating room itself. The inside of the lid of the VCM kit (PX 99) has instructions from Medtronic on how to use the kit in an infringing manner, as Dr. Yassir testified. Tr. at 845, 846.

The jury also heard evidence that Dr. Lenke encouraged infringement through at least two lectures and various articles. Tr. at 888–89; PX 141 (2010 Lecture); PX 475 (iScoliosis website); PX 202 (2012 Lecture); PX 109 (Spine Article). Medtronic claims that Dr. Lenke's instructions regarding the VCM kit cannot be attributable to Medtronic. Dkt. 430 at p. 15. However, Dr. Lenke, according to party stipulation, has been a paid consultant of Medtronic since at least 2001. Dkt. 386 at p. 13. He is the named author of the Medtronic technical surgical guides. *See* PX 115, PX 116 (front covers). He has traveled the world on behalf of Medtronic participating in surgeon training sessions. DX 498 at pp. 183, 184, 185; *see also* PX 203. It would be completely reasonable to attribute Dr. Lenke's instructions and actions with regard to the VCM kits to Medtronic.

Medtronic claims that there is no evidence that anyone that Dr. Lenke taught to infringe actually infringed, citing *Crystal Semiconductor*, 246 F.3d 1336, 1351 (Fed. Cir. 2001) for the proposition that this is required. Tr. at 1943 (Medtronic oral motion). Medtronic's reliance on *Crystal Semiconductor* is misplaced. *Crystal Semiconductor* did not hold that inducement requires a patentee to prove that those who were induced were the same persons that directly infringed the patent. There, the court upheld a jury verdict on inducement despite defendant's objection that the

instructions and verdict form improperly required that the jury make a finding as to "literal infringement," even for the indirect infringer. In concluding that there was no legal error, the court recognized that because the acts of the indirect infringer in that case were a proximate cause of the direct infringement (and thus it was proper to refer to both as "literal infringement"), there was no error. But it never set forth a requirement that, in all inducement cases, there must be direct proof of that proximate causation, i.e. that those that are induced are those that actually directly infringed. The one line from the decision identified by Medtronic in supplemental briefing (*see* Dkt. 430 at p. 15) is taken out of context.

Even if there was such a requirement, there is certainly no "absence of evidence" on this point. Dr. Lenke himself testified that he used the VCM kit (Tr. at 1708) at a time in which when he was consulting for Medtronic. Also, responses to the Neal survey evidence overlap between those that admitted to receiving training materials and those that admitted to using the products in an infringing manner. Asking questions that boil down to "did you receive training materials" and "did you commit this act that would infringe" in a single survey, as was done through the Neal survey, creates a causal link, if such a link is required. Medtronic's objection on this ground is therefore unfounded.

Medtronic further contends that there was a lack of evidence on specific intent. Dkt. 430 at 15. Demonstrating specific intent to induce requires proof that a defendant have knowledge of the patent and proof that the defendant knew the induced acts were infringing. *Warsaw*, 825 F.3d at 1347. Willful blindness can satisfy the knowledge requirement for inducement, and the knowledge of infringement can be inferred from circumstantial evidence. *Warsaw*, 825 F.3d 1344, 1347 (Fed. Cir. 2016) (listing cases). As the Federal Circuit stated in *Warsaw*, a recent opinion relying on *Commil* and *Global-Tech*, "[t]o show the intent to induce infringement, it is sufficient

that the plaintiff establish that a defendant's asserted belief in non-infringement was unreasonable." *Id*. at 1351 n.2. In *Warsaw*, "there was substantial evidence that [defendant's] infringement position was objectively unreasonable" and the court concluded "that the jury, based on this evidence, could reasonably have concluded that [the defendant] had knowledge (or was willfully blind to the fact) that it was infringing." *Id*. at 1348.

Here, there is substantial evidence that Medtronic had knowledge of the '358 Patent at least as early as March 2010 (PX 619 or PX 619-A, MicroPatent Alert) or May 2010 (PX 618, discussing Dr. Barry's sale of "VCM-like IP" to Biomet)[13] and, despite this knowledge, continued manufacturing VCM kits. Tr. at 756–67 (testimony from Medtronic's corporate representative Mr. Ballard). Regarding Medtronic's knowledge of infringement, it would have been reasonable for a jury to ignore Medtronic's position that Medtronic may have known about the patents but was not aware that the VCM kit infringed those patents. Particularly telling was the revelation that Dr. Lenke, Medtronic's part-time consultant, claimed in his *curriculum vitae* to be the inventor of the patents-in-suit. Tr. at 1584–85.

Alternatively, the Neal survey evidence, the Medtronic surgical guides, the lid to the VCM kit, and Dr. Lenke's presentations and instruction, for instance, collectively present strong infringement evidence based on, in some cases, Medtronic's own materials. A jury could have attributed great credence to this rebuttal evidence and concluded that Medtronic knew about the patents but was willfully blind to its infringement. This is all that Dr. Barry was required to prove.

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[13] Even though Mr. Ballard attempted to testify that February 2013 was the date of Medtronic's first awareness of a Barry patent (Tr. at 766), there was substantial contradictory evidence to support a March 2010 date. There was even some evidence that Medtronic had knowledge of Dr. Barry's intellectual property ventures as early as April 2007 (PX 613, suggesting Medtronic employees discussing a potential file on Dr. Barry's IP).

Medtronic's objection entirely ignores a willful blindness theory and assumes that Dr. Barry's alleged failure to present direct evidence of Medtronic's knowledge of its infringement was fatal.

V. INFRINGEMENT OUTSIDE OF THE UNITED STATES

Medtronic moved for JMOL on induced overseas infringement, arguing that no reasonable jury could find that Medtronic actively induced infringement overseas in violation of 35 U.S.C. § 271(f)(1). As a matter of law, the court agrees. Substantial evidence does not support the jury's finding with regards to overseas infringement. *See* Dkt. 411 (Jury Verdict), Question No. 3.

There was evidence of several facts related to Section 271(f)(1), but Dr. Barry still failed to meet his burden. There was evidence, presented through the testimony of Dr. Yassir and Dr. Barry's damages expert, Ms. Kimberly Schenk, that Medtronic shipped rods used in conjunction with infringing surgeries overseas. Tr. at 1154–55; PX 324 (Schedule to Schenk Report demonstrating overseas sales); Tr. at 1224–25. There was also evidence that direct infringement using Medtronic products occurred, at least in 2009, overseas, and a jury could have concluded that this infringement was ongoing. PX 622 (international surgeons discussing using the VCM); Tr. at 869–872; Tr. at 1042 (Dr. Yassir's testimony regarding circumstantial evidence of overseas infringing procedures after issuance of '121 patent). There was also evidence that Dr. Lenke, as a paid Medtronic consultant, presented slides overseas that perhaps induced infringing activity overseas. PX 203.71; Tr. at 1716. The Neal Survey, however, was limited to domestic respondents. Tr. at 578:8–14 (Schenk testimony).

However, there is a lack of evidence on other important elements that Dr. Barry was required to prove. There was no evidence that Medtronic, rather than any other Medtronic subsidiary or third party, was supplying the rods or causing the rods to be supplied. Neither of Dr.

Barry's experts could support the jury's finding. Dr. Yassir admitted that he had "no evidence that Medtronic is shipping the VCM kit overseas." Tr. at 1040:13–18; *see also* Tr. at 1040:4–7 (admitting he had not seen any documents to this effect). Dr. Schenk likewise conceded that she did not have evidence that Medtronic shipped VCM kits overseas. Tr. at 1292:2-5. Medtronic also has locations overseas, as Dr. Yassir admitted (Tr. at 1038–39), which undercuts Dr. Barry's premise that Medtronic is actually the party supplying the alleged patented component.

What is most critically missing is evidence that the single component that Medtronic did ship overseas, the rods, constituted a "main" or "major" component of what was combined overseas, which is still required under foreign inducement law regardless of what happens at the Supreme Court in *Life Technologies v. Promega*. [14] Without this critical evidence, there is

[14] There is some uncertainty in the current state of Section 271(f)(1) law that may affect this case. In *Promega Corp. v. Life Tech. Corp.*, the Federal Circuit rejected the proposition that infringement under 271(f)(1) required at least two components to be supplied from the United States. 773 F.3d 1338, 1353 (Fed. Cir. 2014), *cert granted in part* 136 S. Ct. 2505 (June 27, 2016) (Mem.). It held that "there are circumstances in which a party may be liable under 271(f)(1) for supplying or causing to be supplied a single component for combination outside the United States." *Id*. at 1353. The record at trial demonstrated there that Taq polymerase, the single component that was supplied overseas to the Defendant's United Kingdom facility, was one of the "main" or "major" components of the accused genetic testing kits; the court noted that without "Taq polymerase, the genetic testing kit recited in the Tautz patent would be inoperable." 773 F.3d at 1356. Based on this, it upheld the jury verdict finding a violation of Section 271(f)(1).

At the time of the writing of this Order, the Supreme Court has heard oral arguments but not yet opined on the issue of whether Section 271(f)(1), which explicitly requires that "all or a substantial portion of the components of a patented invention" to be supplied or caused to be supplied overseas, could be violated by supplying or causing to be supplied a single component of a patented invention. This court acknowledges that the outcome in that case, *Life Tech. Corp. v. Promega Corp.*, Case No. 14-1538, 136 S.Ct. 2505 (June 27, 2016), could very well alter the proper analysis in this case.

In the event that the Supreme Court overrules the Federal Circuit and requires that more than one component be supplied overseas in order to infringe under Section 271(f)(1), there was no evidence that other components of the patented invention other than the rods were supplied or caused to be supplied overseas. Dr. Schenk's damages model for overseas sales was even based

insufficient evidence to support a finding that Medtronic supplied all or a substantial portion of components of the patented invention overseas.[15] None of Dr. Barry's contentions suggest otherwise.

VI. WILLFULNESS[16]

Medtronic moved for JMOL on the issue of willfulness. *See* Dkt. 411 (Jury Verdict), Question No. 4. Medtronic bases its motion in part on its claims that there was no proof of direct infringement, no proof of inducement, and that the patents are invalid. The court has already dealt with the first two points. Medtronic failed to meet its burden of proof on invalidity, as will be dealt with in the section on its motions for JMOL on that point.

Medtronic also asserts that if Medtronic did induce infringement of a valid patent claim, "Dr. Barry has failed to establish that Medtronic did so in a subjectively willful

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entirely on shipments of the rods. In the event that the Supreme Court reverses the Federal Circuit on this point, Dr. Barry's proof still fails on this requirement.

[15] The court here need not reach the final inquiry of whether there was sufficient evidence of Medtronic's specific intent with regards to foreign infringement. However, the court notes that the Federal Circuit has cited favorably the holding that a patentee is required to prove that a Defendant intended that all components be combined abroad under the *mens rea* requirement of Section 271(f)(1). *See WesternGeco L.L.C. v. ION Geophysical Corp*, 781 F.3d 1350, 1349 (Fed. Cir. 2015), *vacated on other grounds by WesternGeco L.L.C. v. ION Gephysical Corp.*, 136 S.Ct. 2486, 2486 (June 20, 2016), *reinstated by WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358 (Fed. Cir. Sep. 21, 2016). The intent requirement under Section 271(f)(2), a corollary statute, similarly requires knowledge that the exported components would be combined "in a manner that would infringe the patent if such combination occurred within the United States." *Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 136–69 (Fed. Cir. 2001) (stating that Section 271(f)(2) requires an intent by the infringer that the exported components will be assembled into the patented product, but not actual assembly). Given the dearth of evidence regarding Medtronic's supply of infringing components, it is unlikely that the jury's implicit finding as to Medtronic's knowledge that its components would be combined overseas is supportable either.

[16] The court will issue a separate order regarding whether there the evidence supports enhanced damages under 35 U.S.C. § 284 based on the facts of this case.

manner." Dkt. 406 at p. 11. There is substantial evidence to support the jury's finding that Medtronic's infringement was willful. Willfulness required that Dr. Barry prove by a preponderance of the evidence that Medtronic knew, or it was so obvious that Medtronic should have known, that its actions constituted infringement of a valid and enforceable patent. *Halo* 136 S. Ct. 1923, 1934 (2016); see also *WesternGeco*, 837 F.3d 1358, 1362. "Recklessness" is defined as "knowing or having reason to know of facts which would lead a reasonable man to realize his actions are unreasonably risky." *Halo*, 136 S. Ct. at 1933 (internal citations omitted). What the jury was required to do was to make a finding as to willfulness, and this court is charged with deciding whether or not enhanced damages are merited based on a "the particular circumstances" of this case.

Underlying the jury's finding is a determination, which is supported by substantial evidence, that Medtronic was aware of Dr. Barry's patents at the time of infringement. The evidence supporting the conclusion that Medronic was aware of Dr. Barry's patents as early as March 2010 is set out *supra* Section IV and need not be repeated here.

Medtronic contests that, even if infringement was proven, infringement was not done in a subjectively willful manner. Dkt. 406 at p. 11 (citing *WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358, 1362–63 (Fed. Cir. 2016)). It claims that it had "strong reasons" to believe that the patents-in-suit were invalid. While it is true that objective reasonableness can still be relevant to the inquiry of whether enhanced damages are appropriate (*see WesternGeco*, 837 F.3d at 1363), an after-the-fact robust defense of invalidity cannot defeat a willfulness finding by a jury. *See WBIP, LLC v. Kohler, Co.*, No. 14-1038, 820 F.3d 1317, 1341 (Fed. Cir. July 19, 2016) ("Proof of an objectively reasonable litigation-inspired defense to infringement is no longer a defense to

willful infringement."). *Halo* reminds us that "culpability is generally measured against the knowledge of the actor at the time of the challenged conduct." 136 S. Ct. at 1933.

Through the proper legal lens, there was no evidence presented that Medtronic had a belief that the patents-in-suit were invalid at the time it became aware of the patents. There was no evidence that Medtronic, for instance, took any efforts to investigate the patents at the time it became aware of them in March 2010. On the other hand, the credibility of several of Medtronic's witnesses took a hit by their repeated attempts to explain why Medtronic received, and then ignored, detailed patent alerts containing information about Dr. Barry's patents. The juxtaposition of inaction with evidence that Medtronic employees may have been keeping files on Dr. Barry's IP throughout the relevant time period darkens the shadow on Medtronic's position. If there was a file kept, and that file contained information that suggests that Medtronic had a good-faith belief that Dr. Barry's patents were invalid, this might have been probative evidence to support Medtronic's collateral attack on the jury verdict. However, that evidence—if it exists—was not presented to the jury, which evidently was troubled by Medtronic's explanations for acts and omissions that reasonable minds could conclude constituted willful misconduct.

Again, the revelation that Dr. Lenke was claiming that he was the inventor of the patents-in-suit on his CV cannot be overlooked. Tr. at 1584–85. The timeline of events revealed to the jury also calls into question much of his testimony. Dr. Lenke, in part in his role as a paid consultant for Medtronic, had been trying to develop an appropriate method for spine derotation. Tr. at 1596–97 (testifying to start of work on apical derotator project in 2000 or early 2001); Tr. at 1685–86. Then, Dr. Lenke, who was the chairman of the IMAST meeting (Tr. at 1595), helped review abstracts and group them together for the June 2004 meeting. Tr. at 1703–04. Dr. Barry had submitted an abstract for that particular meeting outlining his method, and Dr. Lenke admitted

that he and Dr. Barry spoke about "a scoloiosis presentation" at the meeting itself. Tr. at 1595. Within days, Dr. Lenke notified Medtronic internally to prepare to file a patent application. DX 186 (Invention Disclosure dated July 1, 2004, signed by Dr. Lenke on September 8, 2004). For some reason, Dr. Lenke delayed and his application was filed after Dr. Barry's application. *See* '008 patent (DX 4); Tr. at 1698 (noting filing date of February 9, 2006). Then, at trial, the jury learned that Dr. Lenke had listed Dr. Barry's patents on his own CV. In almost the same breath, Dr. Lenke testifies that he was not "personally aware" of Dr. Barry's patents prior to Dr. Barry filing suit. Tr. at 1596. This court does not judge credibility, which is squarely within the province of the jury. But this court would not criticize any inferences that jurors may have drawn regarding Medtronic's willfulness based on their assessment of Dr. Lenke's credibility.

VII. DAMAGES

Medtronic moves for JMOL on damages, asserting that "evidence of damages was insufficient on several grounds." Dkt. 406 at p. 11. Prior to the jury's deliberation, the court denied Medtronic's motion for JMOL on damages, which through oral motions largely focused on the Rule 702 reliability of the damages model employed by Dr. Barry's damages expert, Ms. Kimberly Schenk. Tr. at 1955–58. The court's rulings with regards to Medtronic's Rule 702 objections stand.

Medtronic's attack consists largely of recycled *Daubert* attacks. For instance, Medtronic attacks the evidence on which Ms. Schenk relied (Dkt. 406 at pp. 11–12), her alleged disregard for certain evidence (*id.*), and her model's reliance on an "implausible royalty of $1200 per procedure." (Dkt. 406 at p. 12). According to Medtronic, her model consisted of "an estimate times an estimate times seven." Dkt. 430 at p. 29. Rather than reiterating its analysis as to why Ms. Schenk's model is not unreliable under *Daubert*, the court directs the parties to its prior Order

(Dkt. 293). To the extent that the court previously concluded that Medtronic's objections go to the weight of Ms. Schenk's testimony, Medtronic had ample opportunity to cross-examine Ms. Schenk (a total of approximately 2.5 hours, in fact), who withstood vigorous cross-examination and was evidently deemed credible by the jury.

To the extent that Medtronic raised grounds other than its Rule 702 objections (Dkt. 406 at pp. 405–06), substantial evidence supports the jury's damages award for induced infringement in the United States. Medtronic claims that the start date chosen by Ms. Schenk for damages calculations, which is the date on which the '358 patent issued, was wrong because Dr. Barry did not establish inducing acts, knowledge of the patent, and knowledge of infringement until much later. Dkt. 406 at p. 12. This is incorrect. As discussed above, there is substantial evidence of Medtronic's induced infringement starting from March 2010, and Ms. Schenk's damages model began from the date on which the '358 patent issued, March 2, 2010.

Medtronic also claims that Schenk's damages model is legally insufficient because, in relying on the Neal Survey, it captures compensation for use of the CD Horizon Solera or Legacy systems without use of the VCM kit—which is the same argument made to attack the reliability of the survey too. Dkt. 406 at p. 11. However, for the same reasons articulated above with regards to the Medtronic's objections to the Neal Survey, its attacks based on the characterization of the accused products in this case ring hollow.

In a last lunge, Medtronic attacks Ms. Schenk's model for alleging a royalty of $1200 per procedure based on her reliance and comparison to a non-exclusive license and posits that there is "no reasonable basis for" the revenue-per-surgery or price of pedicle screws in her analysis. Dkt. 406 at p. 12. Medtronic amply cross-examined Ms. Schenk on these issues of factual issues of weight, and there is no basis to overturn the jury's conclusion on this point.

Regarding overseas infringement, because this Order overturns the jury's verdict on overseas infringement, there is no longer a need to address Medtronic's contentions about the jury award on overseas infringement; likewise, there is no remaining basis to award Dr. Barry for damages based on overseas infringement. Because the jury delineated its award for overseas infringement in the verdict form (Dkt. 411 at p. 11), that amount ($2,625,210) will simply be subtracted from the base damages award in the Final Judgment entered in this case.

VIII. INVALIDITY[17]

A. Clear and convincing evidence is required to prove invalidity.

Clear and convincing evidence has been described as "evidence that places in the ultimate factfinder an abiding conviction that the truth of its factual contentions are highly probable." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 n.5 (Fed. Cir. 2007) (citing *Colorado v. New Mexico*, 104 S. Ct. 2433 (1984)). While it is true that once a defendant has presented a prima facie case of invalidity, a patentee bears the burden of going forward with rebuttal evidence,

> all that means is that even though a patentee never must submit evidence to support a conclusion by a judge or jury that a patent remains valid, once a challenger introduces evidence that might lead to a conclusion of invalidity – what we call a prima facie case – the patentee would be well advised to introduce evidence sufficient to rebut that of the challenger.

Pfizer, 480 F.3d at 1360 (internal quotation omitted). This requirement does not shift the burden of persuasion to a patentee, because the presumption of patent invalidity "remains intact and the ultimate burden of proving invalidity remains with the challenger throughout the litigation." *Id*. On a motion for JMOL, the court must therefore consider "the totality of the evidence, including any rebuttal evidence presented by the patentee." *Id*.

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[17] Medtronic withdrew its obviousness claims at trial, leaving anticipation (albeit on several separate grounds) as the only invalidity issue for the jury. Tr. at 1921.

B. Analysis Regarding the Priority Date for the '121 Patent

For the first time at JMOL, Medtronic argued that the '121 patent is not entitled to the December 30, 2004, priority date. Tr. at 1948–1952. Based on testimony from Dr. Barry that linking derotator handles with a cross-linking member, a limitation specific to the '121 patent, was not possible until certain "slots" were reduced to practice, Medtronic claims that the earliest priority date for the '121 patent is August 10, 2005, rather than the priority date supplied based on the filing of its parent ('358 patent) application, December 30, 2004.

First, Medtronic's claim to a later priority date is too little too late. Neither side proposed adding a question to the verdict form regarding this priority date dispute, nor did either side present this as a contested issue of fact or law in the joint pretrial order (Dkt. 386).[18]

Second, even if the issue were properly preserved and presented to the jury, the '121 patent is entitled to claim priority of the '358 patent application because the '358 patent application reasonably supports what is claimed in the '121 patent. Notably, the specifications are identical. But Medtronic claims that, because Dr. Barry testified that what he described as "slots" were important to coming up with cross-linking in the '121 patent, the '358 patent does not support what is *claimed* in the '121 patent. Dkt. 430 at p 24. But the '121 patent does not anywhere claim "slots," making it difficult to demonstrate that these so-called "slots" should have been disclosed in the parent application in order for the written description of the parent to support the '121 patent claims. For that matter, "slots" are not claimed in the '358 patent. Dr. Barry's testimony that "slots" enabled him to link the derotator handles—the testimony on which Medtronic's belated argument relies—thus cannot establish that Dr. Barry failed to possess the subject matter of the

[18] Medtronic did attempt to insert this dispute into the verdict form through question 5b, a question on invalidity. Tr. at 1948-1952.

'121 patent when the earlier parent application was filed. Medtronic fails to provide and the court has not located any authority for the proposition that the way an inventor describes a device to a jury somehow inserts new claim language or a new limitation into the patent. Such verbal description does not create a brand new triable issue of fact as to priority between a parent and child application that share an identical specification, especially when neither side properly preserved the issue as a factual dispute.

The court concludes that the '121 patent is entitled to the priority date of its parent '358 patent application under 35 U.S.C. § 120. "To obtain the benefit of the filing date of a parent application, the claims of the later-filed application must be supported by the written description in the parent in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Anascape, Ltd. v. Nintendo of America, Inc.*, 601 F.3d 1333, 1335 (Fed. Cir. 2010); *see also Ralston Purina Co v. Far-Mar-Co, Inc.*, 772 F2d. 1570, 1575 (Fed. Cir. 1985) ("[a] patent is entitled to the priority date of a parent if the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."). Section 120 cites 35 U.S.C. § 112 and requires that the specification of the earlier-filed application provide an adequate written description of the invention claimed in the later-filed application. *Cordance Corp. v. Amazon.com, Inc.*, 658 F.3d 1330, 1334-35 (Fed. Cir. 2011) ("written description support of the asserted claims must be found in the [parent] patent").

For the purposes of the court's analysis, the priority date of the '121 patent is the filing date of its parent application, December 30, 2004, and the critical date for the purposes of invalidity under 102(a) will be December 30, 2003.

C. Invalidity Under 35 U.S.C. § 102(b) – Public Use and On-Sale Bar

Medtronic claimed the patents-in-suit are invalid under the public use and on-sale statutory bars set forth in 35 U.S.C. § 102(b). Under Section 102(b), Medtronic had to show by clear and convincing evidence that the inventions embodied by the claims of the patent were in public use or offered for sale or sold in this country more than one year prior to December 30, 2004, the priority date for both of the patents-in-suit (*see supra* Section B). The court addresses each in turn below.

1. Law on Public Use

"An anticipatory public use under [Section] 102(b) must exhibit all of the claim limitations." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co*., 655 F.3d 1364, 1377 (Fed. Cir. 2011). Past this, the "proper test for the public use prong of the section 102(b) statutory bar is whether the purported use was accessible to the public or was commercially exploited." *Delano Farms Co. v. Cal. Table Grape Comm'n*, 778 F.3d 1243, 1247 (Fed. Cir. 2015) (quoting *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1380 (Fed. Cir. 2005)). The touchstone question for determining if something was accessible to the public is "whether the actions taken by the inventor . . . create a reasonable belief as to the invention's public availability." *Id*. at 1247.

"[I]n determining whether an invention was in public use, a court must consider how the totality of the circumstances comports with the policies underlying the on sale and public use bars." *Invitrogen*, 424 F.3d at 1380 (internal citations and quotations omitted). The "totality of the circumstances" can include the following: "the nature of the activity that occurred in public; the public access to and knowledge of the public use; [and] whether there was any confidentiality obligation imposed on persons who observed the use." *Delano Farms*, 778 F.3d at 1247 (internal citations and quotations omitted).

"[S]omething that would otherwise be a public use may not be invalidating if it qualifies as an experimental use." *Clock Spring, L.P. v. Wrapmaster, Inc*., 560 F.3d 1317, 1326 (Fed. Cir. 2009). "Experimental use" is not a separate doctrine. Rather, "[a] use may be experimental only if it is designed to (1) test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose—itself a requirement of patentability." *Id*. at 1327. In assessing whether a prior use is experimental, a court may consider the following factors: (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers. *Id*.

In addressing whether a prior public use is experimental, "the inquiry is not: (1) was there a public use, and, if so, (2) was the public use for a bona fide experimental purpose and thus excused. Rather, there is only one inquiry—was there a public use within the meaning of section 102(b)." *Tone Bros*., 28 F.3d at 1198. This does not mean that the defendant "has the burden of proving that the use is not experimental" or that the plaintiff "is relieved of explanation." *Id*. at 1199 (quoting *TP Labs., Inc. v. Prof'l Positioners, Inc*., 724 F.2d 965, 971 (Fed. Cir. 1984)). Rather, "[i]t means that if a prima facie case is made of public use, the patent owner must be able to point to or must come forward with convincing evidence to counter that showing." *Tone Bros.*, 28 F.3d at 1199 (quoting *TP Labs.*, 724 F.2d at 971); *see also Lisle Corp. v. A.J. Mfg. Co.*, 398 F.3d 1306, 1316 (Fed. Cir. 2005); *Netscape*, 295 F.3d at 1320–21. In doing so, the court must

consider "all of the evidence put forth by both parties" and decide "whether the entirety of the evidence [leads] to the conclusion that there [has] been 'public use.'" *Tone Bros.*, 28 F.3d at 1198–99 (quoting *TP Labs.*, 724 F.2d at 971).

The question of whether a public use has occurred is a mixed question of law and fact. *Netscape Commc'ns Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002). In analyzing judgment as a matter of law on a mixed question of law and fact given to a jury without a special verdict form delineating the questions of fact, the jury's conclusion must be upheld "unless the jury was not presented with substantial evidence to support any set of implicit findings sufficient under the law to arrive at its conclusion." *Eli Lilly*, 376 F.3d at 1362–63 (internal citations omitted).

2. Substantial evidence supported the jury's failure to find the patents-in-suit invalid based on public use. – Jury Verdict (Dkt. 411), Question No. 5

Medtronic claims that Dr. Barry publically disclosed his inventions more than one year before the priority date by performing surgeries at Sunrise Hospital between 2002 and 2003 that practiced the asserted claims of the patents.[19]

The jury was instructed on the elements of Medtronic's public use claim, including experimental use. Dkt. 414 at pp. 22–25. Medtronic objected to the court's instruction explaining the difference between "experimental use in the context of patent law and the way the word 'experiment' is used in the context of medicine" (Tr. at 1975–1976), but that objection does not relate to their grounds for JMOL.

[19] To the extent that Medtronic alleged that Dr. Barry's discussions with medical device companies between 2002 and 2003 constituted a public use rather than an invalidating offer for sale, the court incorporates its discussion of those facts and its conclusions as to why there was insufficient evidence regarding those meetings to support overturning the jury's determination that the patents were not invalid (*see infra* Section VIII.C.3).

Medtronic's position is that these surgeries were "accessible to the public" in part because Dr. Barry did not produce non-disclosure agreements.[20] The court ruled at trial prior to charging the jury that there was a question of material fact on the issue of prior public use based on testimony from both sides. Tr. at 1929–30. The jury found that Medtronic had not proven by clear and convincing evidence that either patent was invalid due to prior public use. There is substantial evidence to support the jury's finding.

Weighing heavily in favor of upholding the verdict in favor of Dr. Barry is the substantial evidence from which a jury could reasonably conclude that confidentiality obligations were

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[20] Medtronic sought to question several witnesses, including Dr. Barry, Dr. Davidson (through deposition), and Dr. Barry's nurse, Mr. Janice Munro, as to whether they disclosed to the patients that the surgeries Dr. Barry was conducting were "experimental." The court excluded this line of questioning on several grounds. First, "experimental" surgeries on children and whether patients were told that these surgeries were "experimental," have a different meaning in the patent context than such topics would have to a layman. The court found that the probative value was substantially outweighed by the danger of unfair prejudice and confusing the jury. Tr. at 1057–1063. Second, there is limited case law suggesting that, in the context of a medical procedure, the probative value of whether patients were aware of the experimental nature of the surgery or procedure is minimal. *See McGuire v. Acufex Microsurgical*, 868 F. Supp. 388, 395–98 (D. Mass. 1994). Medtronic relied on one case, *Paragon Podiatry v. KLM*, 984 F.2d 1182, 1186 (Fed. Cir. 1993), for the proposition that whether customers were aware of the experimentation is highly probative (Dkt. 395) (Medtronic Bench Memorandum). That case does not concern the evidentiary issue or present a potential for undue prejudice, because it deals with orthotics rather than spinal deformity correction on children. In dicta, *Paragon Podiatry* does state that proving up "experimental *sales*" (in the context of the on-sale bar) "requires that customers be made aware of the experimentation," which appears on first blush to be a helpful statement to Medtronic. However, there was no dispute there that 300 units sold were commercially *sold* (unlike this case), the court found that the invention was "actually placed outside of the inventor's control" (the opposite of what the jury found here), and the court found that "the inventor's averment that his sales were for experimental purposes amounts to no more than a conclusory legal opinion." *Paragon Podiatry*, 868 F. Supp. at 1188. These distinctions are critical to the Rule 403 balancing that this court performed. Excluding this line of questioning did not at all preclude Medtronic from attempting to discredit Dr. Barry's experimental use theory. Medtronic certainly probed the lack of non-disclosure agreements and explored with several witnesses whether there was an expectation of confidentiality and privacy surrounding the surgeries—topics that have stronger probative value as to the ultimate question and avoided the risk of unfair prejudice by discussing "experimentation" on children.

imposed on those persons allowed in the operating room who would have observed the use through these surgeries, rendering the use experimental. *See Clock Spring*, 560 F.3d at 1327. Dr. Barry testified as much and explained in detail the protocols around those surgeries, including the fact that he was in control of the method and systems used in the surgeries. Tr. at 303–305. Anesthesiologists, for example, were largely unable to see the operating field or view the use of his method because there was a gauze screen, or a drape, separating the sterile field. Tr. at 308 (Dr. Barry testimony), Tr. at 724:19–23 (testimony from Dr. Stephanie Davidson, Dr. Barry's anesthesiologist during the surgeries). Even though there was testimony that medical device representatives were allowed in the operating room, Dr. Barry also testified that representatives such as Mr. Bob Pfefferkorn of DePuy were required to stand back from the operating field. Tr. at 310–11. Mr. Pfefferkorn himself confirmed this and that he is not aware of any sales representative that takes notes on the steps or the instruments that are used during a surgery. Tr. at 183:11–17, 184:9–15.

And several of these witnesses testified extensively about how assistants and those in the operating field are bound by an implicit professional and ethical confidentiality rule in this field. Tr. at 310-11 (Dr. Barry testimony); Tr. at 478–79 (testimony of Ms. Janice Munro, Dr. Barry's former nurse); Tr. at 729 (Davidson testimony). Medtronic's own witnesses buttressed this conclusion: for instance, Mr. Robert Mellinger stated that, in the context of working with surgeons, "with or without an NDA [non-disclosure agreement], we did not publicly disclose things we were working on or talking to surgeons about." Tr. at 515:14-16. Not one witness testified that they witnessed Dr. Barry using the patented inventions and that he or she thereafter publicly disclosed details about the system or technique.

There is evidence that might have supported a contrary finding. *See, e.g.*, Tr. at 692:14–25. For instance, Mr. Pfefferkorn stated that the kits of instrument parts Dr. Barry used would have been seen in the sterilization room; but he did not say whether the instruments were still assembled as they would be for surgery or if they were merely an unenlightening collection of parts. *Id.* This appears to be a hard-fought battle of disputed material fact and credibility of the witnesses; Dr. Barry ultimately prevailed.

3. Substantial evidence supports the jury's failure to find the '358 patent invalid based on the on-sale bar. – Jury Verdict (Dkt. 411), Question No. 6

In order to prove an invalidating prior sale under the on-sale bar of Section 102(b), Medtronic had to prove by clear and convincing evidence that (1) the product was the subject of a commercial offer for sale, and (2) that the invention was ready for patenting at the time of the offer for sale. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 67–68 (1998). Prior sale, like public use, is a mixed question of law and fact. The jury was properly instructed on this issue. Dkt. 414 at pp. 25–26. The jury's conclusion must be upheld "unless the jury was not presented with substantial evidence to support any set of implicit findings sufficient under the law to arrive at its conclusion." *Eli Lilly*, 376 F.3d at 1362–63 (internal citations omitted).

Medtronic's prior sale theory concerns only the '358 patent[21] and is two-fold: Medtronic argues that (1) Dr. Barry and other members of Dr. Barry's surgical team were compensated for the 2002 and 2003 surgeries, and as a result, these constituted invalidating prior sales; and, alternatively, (2) Dr. Barry's discussions with various medical device companies such as DePuy

[21] At trial, Medtronic agreed not to send the question regarding invalidity due to prior sale as to the '121 patent, effectively abandoning its prior sale theory as to the '121 patent. Tr. at 2066. Medtronic also did not object at the charge conference to the fact that the prior sale instruction discussed only the '358 patent. Nor did Medtronic's expert opine regarding a prior sale theory as to the '121 patent.

Spine and SpineVision constituted invalidating "offers for sale" under Section 102(b). At the close of evidence, the court denied JMOL on the issue of prior sale, ruling that there was an issue of fact for the jury. Tr. at 1934–35. The jury returned a verdict on prior sale in favor of Dr. Barry, which there is substantial evidence under either theory to support.

With regard to theory (1), there is substantial evidence to support the jury's implicit finding that there was no commercial offer for sale during the surgeries. The jury was instructed that the essential question is whether there was an attempt on Dr. Barry's part to "obtain a commercial benefit from the invention *beyond incidental benefit derived* from" the potentially infringing activity. Dkt. 414 (Jury Instructions) at pp. 25–26 (emphasis added). This instruction comports with controlling precedent. *See EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347, 1357 (Fed. Cir. 2002) ("[T]he question is whether the transaction constituting the sale was not incidental to the primary purpose of experimentation."). Medtronic did not object to this portion of the instruction at the charge conference. Tr. at 1988:5–11, 1989:8–10.

On the issue of payment, Dr. Barry testified that he was paid. Tr. at 430:11–19. However, several witnesses stated that this was "money for the hospital," not money compensated for the inventive concept of the surgery. Tr. at 491:8–19. Ms. Janice Munro, one of Dr. Barry's nurses for instance, stated that she was paid her typically hourly rate for those surgeries. Tr. at 491:4–7. The record is void of evidence that any party to the surgery received more than a typical paycheck or other incidental benefit, which supports the jury's finding. Given Medtronic's burden of clear and convincing evidence, this is certainly no basis to reverse the jury verdict.

Regarding theory (2), there was evidence that Dr. Barry had discussions with other medical device companies in the timeframe alleged; however, there was a dearth of detail surrounding these alleged "offers to sell" his inventions. For instance, Dr. Barry admitted that he conducted a meeting

in July 2003 with Mr. Pfefferkorn, a DePuy marketing manager, and two other DePuy representatives. Tr. at 434–38, 671:10-14, 674-675, 677. In fact, he went into great detail about these types of meetings in describing conception and development of his idea. While Dr. Barry admitted that he described his concept of linking handles at that 2003 meeting, he never testified that that he was offering to *sell* his patented invention:

> Q: So, by July you told DePuy that this patent was enabled, ready to go; and you are talking to marketing people, correct?
> A: It says that marketing people were there, yes.
> Q: Because you were trying to sell it or pitch it to them to sell it, true?
> A: There were a variety of people at that meeting.
> Q: Dr. Barry, were you trying to sell it to them?
> A:What is normally done at those meeting is that several people from various different divisions of a company show up and – to hear what the surgeon has to offer.
> Q: Sure. To offer for sale, correct?
> A: What I offered was principally – and I mentioned this before – to see if DePuy was going to get behind my work.
> …
> Q: So, sir, I'm just taking your answer under oath. You went to offer for sale to DePuy in July, 2013 [*sic*], your invention in the '358 patent, true?
> A: I was – I don't think I was ready to sell it. Like I said, it was a preliminary meeting to talk about my system that was in evolution and to see if they would get behind it; and, ultimately, yes, if they got behind it, then potentially market it and sell it.
> …
> Q: You were offering to make a business deal with them.
> A: Not at that time. Like I said, this was very preliminary.

Tr. at 434–38. Likewise, Mr. Pfefferkorn testified about the 2003 meeting, but he never testified that there was an offer for sale. He only admitted to vague statements that Dr. Barry was reaching out to DePuy to "try to set up a meeting about interest in licensing his products and his technique." *See, e.g.*, Tr. at 677:5-9. Mr. Pfefferkorn outright stated that he did not remember specific details about the meeting, like when it started or who was present. Tr. at 677:16-25.

Dr. Barry also testified that there was an industry expectation that conversations about custom instruments with spinal medical device companies, for example those conversations he had with Interpore Cross International ("Interpore") in developing his custom instruments, would

"absolutely" be kept confidential. Tr. at 168. Mr. Pfefferkorn corroborated this, testifying that it was his understanding that there was a non-disclosure agreement signed by Dr. Barry and DePuy (with regards to the 2003 meeting) because "that was just the nature of the companies with their surgeons." Tr. at 679:19-25. A reasonable juror could have deemed credible the testimony that these meetings were confidential or, alternatively, found insufficient evidence to support a finding that these conversations constituted "offers for sell" because there was not enough testimony about details of those conversations. Either ways, there is insufficient evidence to overturn the jury's verdict on the Section 102(b) on-sale bar.

The jury also could have reasonably concluded that the on-sale bar did not apply because the inventions were not ready for patenting at the time of alleged offers for sale. *See Pfaff*, 525 U.S. at 67–68. "Ready for patenting" can be satisfied in at least two ways: (1) proof of reduction to practice before the critical date, or (2) proof that the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. *Id*. at 67–68. Reduction to practice can be constructive, marked by the filing of a patent application, or actual. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). "In order to establish [actual] reduction to practice, the prior inventor must have (1) constructed an embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose." *Teva Pharm. Indus. v. AstraZeneca Pharm. LP*, 661 F.3d 1378, 1383 (Fed. Cir. 2011); *see also Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002) (citing *Cooper*, 154 F.3d at 1327). This may require testing and "there must be recognition and appreciation [by the inventor] that the tests were successful." *Cooper*, 154 F.3d at 1327–28 (citing *Estee Lauder Inc. v. L'Oreal S.A.*, 129 F.3d 588, 594–95 (Fed. Cir. 1997)).

Dr. Barry testified—and the jury could reasonably have accepted— that his method and system were not recognized to work for their intended purpose until January 2004. Dr. Yassir supported this, stating that "there was no method to sell before January 2004" because "you can't sell a way of doing something until you've got that way of doing it." Tr. at 1898:14–15. Dr. Barry also testified that he was not aware whether his invention worked until follow-up with his patents, which occurred at least three months after the surgery itself. Tr. at 196. Dr. Yassir, also corroborating this point, testified that one cannot confirm the safety of these procedures until a follow-up after completion of a surgery. Tr. at 1899:23–1901:2. While this testimony was rebutted by Dr. Rex Marco, Medtronic's infringement expert (*see* Tr. at 1759:9–23), Dr. Marco's credibility and qualifications were otherwise called into question.

Because the jury did not hear evidence that Dr. Barry had prepared descriptions of the invention prior to the critical date of December 30, 2003, the other prong of the test for "ready for patenting," Medtronic had to establish by clear and convincing evidence that Dr. Barry reduced to practice prior to the critical date of December 30, 2003. Based on the record, it would have been reasonable for the jury to conclude that Dr. Barry's reduction to practice occurred in January 2004, past the critical date. This would have rendered irrelevant any evidence related to the potentially invalidating surgeries that occurred in August and October 2003 (Tr. at 190:3–6; 195:12–16; 203:19–205:4).

D. <u>Invalidity Under 35 U.S.C. § 102(g)(2) – Prior Invention</u>

Medtronic further alleged that the patents are invalid under 35 U.S.C. § 102(g)(2) due to alleged prior invention by Dr. Lawrence Lenke.

1. Law on Prior Invention

Under Section 102(g)(2), a patent may be invalidated if 'the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.'" *Fox Grp., Inc.*

v. Cree, Inc., 700 F.3d 1300, 1304 (Fed. Cir. 2012) (quoting Section 102(g)). "[A] challenger . . . has two ways to prove that it was the prior inventor: (1) it reduced its invention to practice first . . . or (2) it was the first party to conceive of the invention and then exercised reasonable diligence in reducing that invention to practice." *Fox*, 700 F.3d at 1304 (citing *Mycogen Plant Sci., Inc. v. Monsanto Co*., 243 F.3d 1316, 1332 (Fed. Cir. 2001)). This Order defines "reduction to practice" in the prior section. Conception occurs "when the inventor has a specific, settled idea, a particular solution to the problem at hand." *Teva*, 661 F.3d at 1383. Diligence requires evidence "that the alleged earlier inventor was diligent throughout the entire critical period," but does not require "evidence of activity on every single day if a satisfactory explanation is evidenced." *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1369 (Fed. Cir. 2001) (citations omitted).

"[A] party claiming his own prior inventorship must proffer evidence corroborating his testimony." *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001). In assessing corroboration, the Federal Circuit applies a case-specific "rule of reason" analysis to determine whether the "inventor's story is credible" and "the evidence as a whole is persuasive." *Id*. (internal citations and quotations omitted). "[C]orroboration is properly viewed as a subsidiary factual finding . . . [and] is fundamentally about credibility." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1171 (Fed.Cir. 2006) (citations omitted).

"Priority, conception, and reduction to practice are questions of law which are based on subsidiary factual findings." *Teva*, 661 F.3d at 1381; *Eaton v. Evans*, 204 F.3d 1094, 1097 (Fed. Cir. 2000). Therefore, a court should not disturb "the jury's conclusion unless the jury was not presented with substantial evidence to support any set of implicit findings sufficient under the law to arrive at its conclusion." *Eli Lilly*, 376 F.3d at 1362–63 (internal citations omitted).

Again, the jury was properly instructed on this theory. Dkt. 414, at pp. 26–30. Medtronic did not object.

2. Substantial evidence supports the jury's failure to find the patents-in-suit invalid based on prior invention. – Jury Verdict (Dkt. 411), Question No. 7

There is substantial evidence to support various sets of implicit findings that would be sufficient under the law to arrive at the conclusion, as the jury did, that the patents are not invalid due to prior invention by Dr. Lenke.

Medtronic's evidence regarding prior invention by Dr. Lenke consisted of Dr. Lenke's own testimony, testimony from past and current Medtronic employees, such as Mr. Matthew Meyer and Mr. Lex Armstrong, and documents regarding the "apical derotator project." Medtronic's overall theory was that Dr. Lenke conceived and reduced to practice the outcome of the "apical derotator project" prior to Dr. Barry. Dr. Lenke allegedly worked on this project with the various employees that testified on Medtronic's behalf.

But there were serious flaws in Medtronic's evidence. Both Mr. Meyer and Mr. Armstrong conceded critical points of material fact. Mr. Meyer testified that the apical derotator project (as shown in DX 207, a Medtronic schematic drawing), was not a "final design" prior to December 30, 2003. Tr. at 1494–96. This would support a conclusion that Dr. Lenke had not reduced to practice prior to Dr. Barry's alleged reduction to practice date of January 2004.

Mr. Armstrong conceded that he had, on a prior occasion, testified that the apical derotator project did *not* lead to the VCM kit. Tr. at 1449:19–1450:23. This contradicts Medtronic's theory and Dr. Lenke's testimony that the apical derotator project is what led to Medtronic's VCM products (*see, e.g.*, Tr. at 1574, 1597 (Dr. Lenke testifying that "apical derotator" was the "precursor of the VCM")). These concessions would be enough to diminish the credibility of much of Medtronic's prior invention evidence, including the numerous "Lenke Status Reports"

(*see, e.g.*, DX 197, discussed further below) that Medtronic proffered in an attempt to corroborate Dr. Lenke's alleged conception and reduction to practice. [22]

Assuming all of Medtronic's evidence was deemed credible, the earliest reduction to practice by Dr. Lenke for the linked derotators would be 2002 (*see supra* note 22, discussing the lack of a concrete date), and April 2004 for the cross-linking member invention.[23]

Even with regard to Dr. Lenke's conception, Medtronic's evidence did not come in clearly. No one, including Dr. Lenke himself, was able to provide a concrete date for conception. *See supra* note 22. The testimony from Dr. Lenke could reasonably have been discounted as being less credible for various reasons, not the least of these was the veritable "gut punch" he took when he had to admit that he had claimed Dr. Barry's patents on his own CV. [24] *See* Tr. at 1584–85; *see also supra* Sections III.B. & IV. In a prior invention scenario where the credibility of the dueling inventors is paramount, a credibility issue like this may have been fatal to Medtronic's theory.

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[22] Medtronic witnesses were, for the most part, inconsistent in providing or unable to provide precise dates for Dr. Lenke's conception or reduction to practice, supporting the reasonableness of a jury's determination that Medtronic's evidence was less credible. The general 2002 date may be supported by Mr. Amstrong's testimony that Dr. Lenke would have presented the concept of linking derotators to the apical derotator project team between the publication of two dated Lenke Status Reports. Tr. at 1423. Mr. Meyer also testified that Dr. Lenke was practicing the concept in "fairly early 2002." Tr. at 1460–61. Mr. Meyer also testified that he personally observed in 2002 Dr. Lenke using a set of linked derotators. Tr. at 1462. But, contrastingly, Mr. Armstrong testified that he observed one surgery in 2002 and, in that one surgery, Dr. Lenke was using four derotators on either side of the spine and Dr. Lenke and his assistants would simultaneously grab the handles and derotate the spine, i.e. the derotators were not linked. Tr. at 1398–99. Mr. Armstrong did not testify to any personal observation of the use of linked derotators in 2002.

[23] Dr. Barry's counsel admitted at a side bar conference that the testimony that has come in from Dr. Lenke is that conception also occurred in 2002. Tr. at 1772.

[24] Despite Dr. Lenke explaining that the patents-in-suit must have been "inadvertently added" to his CV and he only realized that the patents were on his CV half an hour before testifying, the skunk was in the box for the remainder of Dr. Lenke's testimony.

While the court makes no credibility determination of its own in ruling on a motion for JMOL, it could not argue with a juror's determination that Dr. Lenke's demeanor was less than convincing.

The jury reasonably could have concluded that Dr. Lenke was an interested witness. He testified that he earned $200,000.00 to $300,000.00 from Medtronic for development of the VCM technology (Tr. at 1590) and that he has been paid by Medtronic somewhere between $4 to $4.5 million per year in the form of royalties. *Id*. Further, the Lenke Status Reports, which may have provided key dates, were covered in handwritten notes, which were not separately dated in any way. *See, e.g.*, Tr. at 1410 (discussion about handwritten notes on DX 367). The jury could have also reasonably doubted the source of that handwriting (*see e.g.*, Tr. at 1419–20). Overall, Medtronic's evidence could reasonably have been accorded less weight than Dr. Barry's.

Assuming that the jury discounted the evidence regarding Dr. Lenke's alleged prior conception, the only way Dr. Lenke could qualify as a prior inventor would be if Medtronic were able to prove by clear and convincing evidence that Dr. Lenke reduced to practice prior to Dr. Barry's conception—a conclusion not at all supported by the remaining evidence—or that Dr. Barry was not diligent between conception and reduction to practice and Dr. Lenke reduced to practice prior to Dr. Barry. Regarding diligence, Dr. Barry offered nearly two hours of testimony regarding his diligence between conception and reduction to practice. The court details Dr. Barry's conception timeline below.

Assuming the jury deemed the evidence regarding the apical derotator project as unworthy of credence, the earliest reduction to practice date supported by the evidence would be the date on which Dr. Lenke filed his own patent, the '008 patent (DX 4), which is February 9, 2006. This date does not predate Dr. Barry's latest reduction to practice for both patents-in-suit (January 2004) or conception.

On the other hand, there is substantial evidence to support the jury's verdict in favor of Dr. Barry on the prior conception, diligence, and reduction to practice.

With regards to the asserted claims of the '358 patent,[25] there is substantial evidence that Dr. Barry conceived of the inventions in 2002, prior to Dr. Lenke, and diligently reduced to practice by January 2004. The table below illustrates the relevant dates of conception and reduction to practice and cites to the relevant testimony or evidence at trial:

Date	**Activity**	**Evidentiary Support**
Dec. 10, 2002	Dr. Barry uses derotation technique on multiple vertebrae as compared to traditional derotation technique. Practiced using Interpore Cross International ("Interpore") levers.	Tr. at 164–65. PX 746 – Record of 12/10/02 surgery
"Not long after" Dec. 10, 2002	Dr. Barry conceives of linking derotators	Tr. at 170 ("Well it wasn't long after that that I realized that if I could link these derotators . . . .")
Early 2003	Dr. Barry makes attempts to link derotators	Tr. at 171.
April 7, 2003	Dr. Barry performs first surgery with modified torque wrenches from DePuy (still no slots)	Tr. at 184–85 PX 601 (modified torque wrenches)
Spring 2003	Dr. Barry practices five surgeries between 12/10/02 surgery and comes to the realization that linking derotators was another possible improvement	Tr. at 176.
After July 2003	Dr. Barry comes up with another modification, slots, that would allow better linking.	Tr. at 188; PX 602, 603, 604 slots (admitted at Tr. at 189)

[25] For this analysis, the court discusses the '358 claims and the '121 claims separately, because the '121 claims require a cross-linking member, a limitation that is specific to the '121 patent and addressed separately by Dr. Barry and others in discussing the development of Dr. Barry's inventive concept.

Date	Activity	Evidentiary Support
Spring 2003	Dr. Barry is paid for and receives from Mr. Pfefferkorn (DePuy) derotation levers with slots. Dates of payment below: March 10, 2003 and March 17, 2003 (PX 67) April 3, 2003 and April 4, 2003 (PX 68) July 30-31, 2003 (PX 69) (mentions slots)	Tr. at 205–209 (testimony on receipts) PX 67, PX 68, PX 69 (photocopies of invoices from Gilbert's Precision Machine, Inc.)
August 4, 2003	Dr. Barry practices derotation levers with slots in the handles in surgery at Sunrise Hospital. But he was not entirely satisfied (Tr. at 191).	Tr. at 189–90.
Spring and Summer 2003	Dr. Barry was diligent in developing prototypes to carry out his method	Receipts
January 2004	Dr. Barry decided that two sets of linked derotation levers worked for the purpose he had set out to achieve (work for intended purpose)	Tr. at 196.

With regards to the cross-linking limitation of the '121 patent, there is also substantial evidence that Dr. Barry conceived of cross-linking limitation prior to Dr. Lenke and was diligent before reducing to practice in Fall 2004, months prior to applying for the '358 patent. According to Dr. Barry, after he was satisfied that the linked handles worked for their intended purpose in January 2004, Dr. Barry realized he was not done. Tr. at 209–10. The timeline below summarizes his conception and reduction to practice of the cross-linking member limitation:

Date	Activity	Evidentiary Support
Jan. 2004	At the time of preparing the IMAST Abstract, Dr. Barry realizes he's not done and that there was "another piece to go."	Tr. at 209–10.

Date	Activity	Evidentiary Support
February 20, 2004	Dr. Barry meets with Interpore, discusses the concept of cross-connector (potentially not corroborated)	Tr. at 221
June 24, 2004	Dr. Barry receives notice about prototypes from Interpore, and shortly thereafter, receives the prototypes themselves. It was not a priority for Interpore to work on cross-connectors, so these did not have them.	Tr.at 218 – 221 PX 505
July 2004	International Spine Conference (IMAST)	PX 21 abstract, noting 21 surgeries between December 2002 and March 2004
October 11, 2004	Dr. Barry corroborated conception of cross-connector. Corroborated by PX 563.	Tr. at 221 - 23 PX 563 (drawing of cross-connector, faxed to Interpore)
"Soon after" October 11, 2004	Interpore fabricated the cross-connection device for Dr. Barry	Tr. at 223–24
November 2004	Dr. Barry used all the prototypes, including cross-connector prototypes, in surgery	Tr. at 221, 224
Fall 2004	Dr. Barry for the first time "put it all together" – first surgery where Dr. Barry used two sets of linked derotators that were also linked together themselves across the spine	Tr. at 224 PX 72 – list of Barry's surgeries

Overall, with regards to all the asserted claims of both patents, Dr. Barry's testimony, which is corroborated by documents and certain witness testimony, constitutes substantial evidence to support a finding that Dr. Barry either reduced to practice before Dr. Lenke or conceived of prior to Dr. Lenke and diligently reduced to practice so as not to render Dr. Lenke's activities invalidating.

IX. LACHES

The court previously ruled that Medtronic had presented insufficient evidence of delay or material prejudice to support a finding of laches. Tr. at 2282–87. The court set out its reasons, including the law on which it relied, on the record in its ruling from the bench.

X. STANDING

Medtronic raised the issue of standing for the first time in the joint pre-trial order. Dkt. 386 at p. 7. While one might expect a "drop dead" dispositive issue like standing based on a contractual provision to have been raised as soon as the contract was obtained, "[s]tanding . . . is jurisdictional and not subject to waiver." *Lewis v. Casey*, 518 U.S. 343, 349 n.1 (1996); *see also Nat'l Org. of Women, Inc. v. Scheidler*, 510 U.S. 249, 255 (issue of standing raised for first time on appeal); *FWIPBS, Inc. v. City of Dallas*, 493 U.S. 215, 230 (standing raised sua sponte on appeal to the Supreme Court).

Medtronic asserts that Dr. Barry contracted away his standing by granting an exclusive license to a company called EBI, which later was acquired by Biomet. The license in question (PX 261; also appearing as DX 18) was frequently referred to in discussions by counsel as the "Biomet Agreement" although the named licensee is EBI. The EBI/Barry Agreement was an exclusive license of the "Technology," which was defined as the "present and future knowledge and intellectual property rights of Licensor [Dr. Barry] regarding the formulation, fabrication . . . inventions . . . relating to the Products and spinal orthopedic apparatus and methods of Dr. Barry for the surgical treatment of spinal deformity that is related to the use of the Products (the "Barry Technique.")." Section 1.4 at p. 2. "Products" is defined as "any device apparatus, or system that falls within the scope of the following claim language," interpreted in the view of the disclosure set forth in [the U.S. Patent Application that issued as the '072 patent, one of Dr. Barry's related

patents with a nearly identical specification to the patents-in-suit]." Section 1.3, DX 16 at p. 1. The license therefore covered the technology of the patents-in-suit. Dr. Barry did not appear to contest this at the pre-trial conference.

The relevant provision regarding standing under the EBI/Barry Agreement is Section 7.11, which provides:

Section 7.11 Third Party Infringers

(a) EBI shall have the right, but not the obligation, to pursue third party infringers of the intellectual property rights that are licensed by Licensor to EBI hereunder. If such enforcement right is executed by EBI,

(i) EBI shall bear all expenses related thereto, including paying for all necessary and proper expenses of Licensor relating to any required participation by Licensor in EBI's enforcement actions.

(ii) In the event that EBI obtains any kind of monetary recovery from enforcement of the intellectual property rights, after subtracting all of EBI's expenses related thereto, EBI shall then pay Licensor five percent (5%) from the remaining amount of monetary recovery.

(b) In the event EBI elects not to pursue a suspected infringer, then Licensor shall have the right, but not the obligation to do so. If such enforcement right is executed by Licensor,

i. Licensor shall bear all expenses related thereto, including paying for all necessary and proper expenses of EBI relating to any required participation by EBI in Licensor's enforcement actions.

ii. In the event that Licensor obtains any kind of monetary recovery from enforcement of the intellectual property rights, after subtracting all of Licensor's expenses related thereto, Licensor shall then pay EBI five percent (5%) from the remaining amount of monetary recovery.

DX 18, PX 261 (EBI/Barry Agreement) at p. 8.

A similar provision was considered by the Federal Circuit in 2010. *See Alfred E. Mann Foundation For Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1357–58 (Fed. Cir. 2010). In that case, "AMF" granted exclusive rights to "AB" to commercially exploit two patents, the "first right to sue to enforce the patents," the right to "settle any AB-controlled litigation and the right

to grant sub-licenses. *Id*. at 1357–58. However, AMF retained the right to sue to enforce the patents when AB declined to do so. *Id*. at 1357–58.

In *Mann*, the Federal Circuit set out a two-step approach for analyzing whether a patentee who owns a patent for which he has granted an exclusive license has standing.

Under that test, the first question is whether the license is exclusive. *Id*. at 1360. Here, the license to Biomet is an exclusive license by its own terms. Section 2.1 states that "[l]icensor hereby grants to EBI for the term of this Agreement an exclusive license to the Technology." EBI/Barry Agreement at p. 2. Almost identical language was interpreted in *Mann* as sufficient to confer a grant of an exclusive license. 604 F.3d at 1360. Dr. Barry, though he is the patentee, no longer holds "*all* the exclusionary rights" to the patents-in-suit.

The second question of the *Mann* test requires that the court look at the scope of the license grant, in this case the EBI/Barry Agreement, in order to decide which party was the legal "owner" of the patents. 604 F.3d at 1360. This is a fact-intensive analysis focused on the agreement. The "nature and scope of the licensor's retained right to sue accused infringers is the most important factor in determining whether an exclusive license transfers sufficient rights to render the licensee the owner of the patent." *Id*. at 1361. Here, the court finds that, though the agreement is exclusive, it does not transfer sufficient rights to render EBI the outright "owner of the patent."

Section 7.11 of the license provides for rights to sue third party infringers to both Dr. Barry and EBI/Biomet. EBI/Biomet Agreement at p. 8. Part (a) of that section states that "EBI shall have the right, but not the obligation, to pursue third party infringers. *Id*. Part (b) provides that Dr. Barry retains the right "in the event EBI [or Biomet] elects not to pursue a suspected infringer." *Id*.

This clause is very similar to the clause in *Mann.* The only real difference in wording is that in the *Mann* license, licensor AMF had the secondary right to sue to enforce the patents "when AB decline[d] to exercise its right to sue." 604 F.3d at 1358. In the present license, Dr. Barry retains the right to sue if "EBI elects not to pursue a suspected infringer." EBI/Biomet Agreement, § 7.11(b)(ii) at p.8. There is no provision in the Biomet Agreement that requires that Dr. Barry seek waiver or otherwise obtain permission from Biomet *before* his right to sue vests.

Reading Section 7.11 in context of other clauses does not show a demonstrative party intent to requiring the licensor (Dr. Barry) to obtain waiver or written consent. For instance, other provisions, like Section 7.7 (*see* EBI/Barry Agreement, at p. 7), require "prior written consent of the other party" before another party acts, in that case before a party assigns its rights or obligations to another. Section 7.2, entitled "Notices," provides that "all notices required . . . shall be in writing," but then Section 7.11, the Third-Party Infringers section is entirely devoid of a notice requirement. The four corners of the agreement, therefore, do not imply the parties intended to require Dr. Barry provide written notice to Biomet of his intent to sue.

EBI's right to sublicense under Section 3.1 does not render Dr. Barry's secondary right to enforce illusory. EBI agreed that if it sublicensed the patent rights, it would compensate Dr. Barry to the same extent as it would if it sold or distributed the products itself. *See* EBI/Biomet Agreement, § 3.1(a) at p. 3. This was a factor in the analysis in *Mann*. 604 F.3d at 1362.

Finally, as to the absence of a time limit for Dr. Barry to exercise his right, the *Mann* decision also provides guidance. No time limit was provided in the contract in that case and the Court held that a reasonable time limit would be implied under the law of the state controlling that contract, California. 604 F.3d at 1363. In the EBI/Barry Agreement, Section 7.3 provides that the law of New Jersey controls. Under New Jersey law, "where no time is fixed for the

performance of a contract, by implication a reasonable time was intended." *See Black Horse Lane Assoc., L.P. v. Dow Chem. Corp.*, 228 F.3d 275, 284–85 (3rd Cir. 2000) (collecting cases).

Dr. Barry testified that, through his attorney Mr. David Henry, he provided notice to Biomet in 2011 after he learned of suspected infringement. Tr. at 287. Dr. Barry filed this lawsuit in 2014. Dr. Barry could not say if Biomet responded "one way or another to [Dr. Barry's] request that they [Biomet] decide whether to enforce" the patents against third-party infringers between 2011 and 2014. Tr. at 293. There was no evidence that, between 2011 and 2014—the time that Dr. Barry claims that he waited—Biomet at any point expressed any intent to "elect to sue" the third-party infringers. The term of the agreement was for 10 years from November 6, 2006. EBI/Barry Agreement at p. 5. The court finds the time that Dr. Barry waited to hear from Biomet, and the time elapsed between Dr. Barry's learning of third-party infringement and filing suit against Medtronic, roughly three years, to be reasonable. This is especially true looking at the general "course of dealing" between the parties and in light of post-filing notification that Biomet provided to Dr. Barry. *See Voda v. Medtronic, Inc.*, No. CIV-09-05-L, 2009 WL 1457530, at *3 (W.D. Okl., May 21, 2009).

Based on the plain language of the agreement itself, Dr. Barry's right to sue vests as long as "EBI elects not to pursue a suspected infringer" (EBI/Barry Agreement, § 7.11(b) at p. 8), regardless of when EBI declines to sue or whether Dr. Barry approaches Biomet to seek waiver. Therefore, Dr. Barry's right to sue vested at the time that Dr. Barry elected to sue in February 2014.[26] The course of dealing between EBI/Biomet and Dr. Barry, and the post-suit

[26] Given that Dr. Barry had standing at the time of filing the lawsuit, the court here does not reach the question of whether lack of standing at the time that the lawsuit was filed could have been cured by post-suit waiver or permission from Biomet.

correspondence also suggest that Dr. Barry's right vested when his "enforcement right" (a term found in Section 7.11(b)) was "executed," i.e. when suit was filed.

XI. INEQUITABLE CONDUCT

Medtronic pled inequitable conduct as an affirmative defense. The issue was tried separately to the bench following the jury trial. Tr. at 2167–2278. Following the bench trial, Dr. Barry moved for a ruling that Medtronic had failed to prove inequitable conduct. Dkt. 429. Medtronic responded. Dkt. 436. The court will address the issue of inequitable conduct in a separate order.

XII. CONCLUSION

For the foregoing reasons, Medtronic's Motions for Judgment as a Matter of Law are GRANTED IN PART, DENIED IN PART. The court grants Medtronic's motion as to infringement under 35 U.S.C. § 271(f)(1). The court grants Medtronic's motion as to damages only as it applies to the jury's award based on overseas induced infringement under 35 U.S.C. § 271(f)(1), as will be reflected in the Final Judgment. The court denies Medtronic's motions for judgment as a matter of law with regards to all other issues. Orders regarding inequitable conduct, enhanced damages, and attorney's fees will issue separately.

So **ORDERED** and **SIGNED** this **25** day of **January, 2017.**

Ron Clark, United States District Judge