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.	§	

FINDINGS AND CONCLUSIONS
REGARDING INEQUITABLE CONDUCT

Plaintiff Dr. Mark A. Barry brought suit, asserting that Defendant Medtronic, Inc. indirectly infringed two patents,[1] U.S. Patent No. 7,670,358 ("the '358 Patent") and U.S. Patent No. 8,361,121 ("the '121 Patent"), which relate to a system and method of aligning spinal vertebrae to correct common spinal deformities like scoliosis. The issues of infringement, invalidity, willfulness, and damages were tried to a jury. The jury found that Medtronic indirectly infringed each of the asserted claims of the patents-in-suit, did not find any of the asserted claims to be invalid, and awarded damages. Dkt. 411 (Jury Verdict).

Following the jury trial, the court held a bench trial on Medtronic's claims of inequitable conduct,[2] which fall into two categories: (A) Dr. Barry made and failed to correct false statements

[1] 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.

[2] Medtronic pled inequitable conduct as an affirmative defense and also asserted an inequitable conduct counterclaim. Prior to trial, both parties filed Proposed Findings of Fact and Conclusions of Law on the issue. Dkts. 353, 355. Medtronic moved for a separate bench trial *preceding* the jury trial and/or a finding of an intent to deceive (Dkt. 346), which the court denied. Dkt. 357. Following trial, Dr. Barry submitted supplemental briefing in support of its

and withheld material information regarding Figure 6 (a photograph of a set of x-rays) in the patents' specification; and (B) Dr. Barry failed to disclose to the PTO several categories of material prior art. There are four categories of prior art that were allegedly withheld: (a) Dr. Barry's own surgeries that took place prior to the critical date of December 30, 2004 ("pre-critical date surgeries"), (b) an abstract authored by Dr. Barry for an industry conference known as the IMAST conference ("the IMAST Abstract") (Dkt. 353-1 at 31), (c) Dr. Barry's pre-critical date interactions with medical device companies (Dkt. 353-1 at 34, 38), and (d) Dr. Lawrence Lenke's alleged prior invention (Dkt. 353-1 at 42).[3]

With regards to Figure 6, Medtronic also alleges that Dr. Barry's misconduct continued after issuance of the patents-in-suit, giving rise to a "continuing pattern of deceit," which is relevant to a finding of specific intent. Dkt. 353-1 at 42–49 (citing *Intellect Wireless Inc. v. HTC Corp.*, 732 F.3d 1339, 1344–45 (Fed. Cir. 2013)). According to Medtronic, Dr. Barry's attempts to correct the specification, his more recent filing of continuation application No. 13/645,589 (an application related to the patents-in-suit), and his representations to the PTO during *inter partes* review of the '358 Patent demonstrate a continuing pattern of deceit. Dkt. 353-1 at 42–49.

Pursuant to Federal Rule of Civil Procedure 52(a)(1), the court now makes these findings and conclusions with respect to Medtronic's inequitable conduct allegations. In summary, Medtronic did not meet its burden of proving by clear and convincing evidence that the patents are

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contention that Medtronic had failed to prove inequitable conduct (Dkt. 429) and Medtronic responded. Dkt. 436.

[3] Medtronic included its theory that Dr. Barry failed to disclose this alleged prior invention in its Proposed Findings of Fact and post-trial briefing but seemingly abandoned it during the bench trial after the court asked a few pointed questions about the lack of evidence that Dr. Barry was aware of Dr. Lenke's surgeries or alleged prior inventions. *See* Tr. at 2243:1–2244:11. The court addresses it in this Order for the sake of completion.

unenforceable due to inequitable conduct under any of its theories. The court finds Medtronic did not show that Dr. Barry or his attorneys, with a specific intent to deceive the PTO made, or failed to correct, representations they knew at the time to be false or that they knowingly failed to disclose material prior art to the PTO.

Specifically, the court finds that Medtronic completely failed to sustain its burden of proof on specific intent. It is therefore not surprising that the court finds that Medtronic did not prove affirmative egregious misconduct, which would establish an exception to the requirement that materiality be separately proven. The court also finds that Medtronic did not establish materiality. The materiality prong of inequitable conduct analysis involves consideration of the evidence under the PTO's preponderance of the evidence standard, so that determination may be a closer call than the finding of no specific intent. Regardless, because there was no specific intent, Medtronic's inequitable conduct allegations must fail.

I. FACTUAL BACKGROUND [4]

Medtronic presents a smorgasbord of acts and omissions, each of which are claimed to constitute inequitable conduct. The first of these supposedly occurred during the drafting of the initial application in 2004; the most recent were allegedly committed during the 2015-2016 *inter partes* review proceedings. The following timeline is helpful in understanding this litany of complaints.

[4] A detailed account of the patents-in-suit and the technology background is found in several prior orders, including the court's most recent order on Medtronic's Motions for Judgment as a Matter of Law (Dkt. 442). The factual background in this Order covers only those facts related to inequitable conduct.

Relevant Prosecution History

December 30, 2004: Dr. Barry and Mr. Henry filed the application that issued as the '358 Patent, application No. 11/027, 026. PX 1.

The involvement of patent attorney Mr. David Henry

- Dr. Barry's patent attorney at the time of prosecution was Dr. David Henry, an attorney at the law firm of Gray, Reed & McGraw.[5]

- Mr. Henry was first contacted by Dr. Barry regarding filing a patent in December 2004. Tr. at 2176:19–21.

- Mr. Henry assisted Dr. Barry in preparing and submitting that application to the PTO. (PX 4, File History). Mr. Henry signed the application and prepared Dr. Barry's patent. PX 004.005; *see also* Tr. at 270:8–271:5.

- Mr. Henry provided Dr. Barry with a questionnaire that was intended to "ferret" out issues of when something was invented, whether it was put into commercial or public use, described in printed publication, etc. Tr. at 2183:20–2184:15.

- A memo produced by Dr. Barry states, in part, that he has a duty to disclose prior art. As disclosed in the memo, that duty covers information regarding "sales, uses, or public disclosures of the invention or products similar to the invention." DX 105; Tr. at 2210 (Mr. Henry's testimony regarding DX 105); Tr. at 2237:23–2238:3 (Dr. Barry's testimony regarding DX 105).

January 23, 2008: the PTO examiner issued a non-Final Office Action rejecting claims 1 through 10 on the basis that a number of figures, including Figure 6 (then labeled Figure 7),[6] were "unclear" and did not "distinctly show features which are pertinent to the understanding of the disclosed device." The examiner required new "drawings." PX 004.075–PX 004.077 (Figure 7 and new Figure 6 are *photos* of three x-rays).

September 11, 2008: in response to the non-final Office Action, Dr. Barry replaced the photos of the x-rays with a clearer image. PX 004.151. Between the notice and Dr. Barry's response, the application was considered abandoned and revived under 37 C.F.R. 1.137(b). PX 004.160 (letter dated December 17, 2008).

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[5] On August 14, 2015, this court disqualified Mr. Henry as Dr. Barry's trial counsel in this case because it was clear he would be a witness on Medtronic's claims regarding Figure 6 and perhaps other claims. Dkt. 73. That Order permitted other members of Mr. Henry's law firm, Gray Reed & McGraw, to serve as general counsel at trial, but the firm eventually withdrew from the case entirely.

[6] The current Figure 6 was previously marked Figure 7 during the course of prosecution. That changed in the file history in Dr. Barry's response to the rejection. *See* PX 004.120.

February 11, 2009: the PTO issued a Final Office Action in which it rejected certain claims and once again objected to Figure 6, again stating that it "is unclear and does not distinctly show features which are pertinent to the understanding of the disclosed device." PX 004.163–PX 004.164.

July 13, 2009: In response to the February 11th rejection, Dr. Barry amended Figure 6 (PX 004.181; PX 004.194) through a "Reply to Office Action," replacing the x-ray image, stating that the replacement was a "clearer image" and "no new matter has been introduced by the replacement drawing." PX 004.182.

October 1, 2009: the PTO sent Dr. Barry a notice of allowance. PX 004.197.

March 2, 2010: the '358 Patent issued. PX 1.

August 16, 2010: the application that later issued as the '121 Patent, application No. 12/857,320, was filed as a continuation of application No. 11/202,409, which was filed on January 29, 2013, as a continuation in part of application No. 11/027, 026, which was the application that issued as the '358 Patent. PX 2.

January 29, 2013: the '121 Patent issued. PX 2.

- The '358 and '121 Patents bear the same title, "System and Method for Aligning Vertebrae in the Ameliorating of Aberrant Spinal Column Deviation Conditions" and share an almost identical specification.[7]

- Both patents have a priority date of December 30, 2004, the day that the application which issued as the '358 Patent was filed. *See* JMOL Order (Dkt. 442), at 28–29.

***Inter Partes* Review of the '358 Patent**[8]

September 9, 2015: the PTAB instituted review of claims 1-5 of the '358 Patent. *Medtronic, Inc. v. Mark A. Barry*, No. IPR2015-00780 (P.T.A.B. Sept. 9, 2015) (Paper 7, Institution Decision).

September 7, 2016: the PTAB in a Final Written Decision (Paper 51, Termination Decision Document) found that Medtronic had not demonstrated by a preponderance of the evidence that the challenged claims of the '358 Patent are unpatentable.

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[7] The court previously articulated the minor differences. Dkt. 66 at 2–3.

[8] The PTAB twice denied institution of IPR of the '121 Patent. *Medtronic, Inc. v. Mark A. Barry*, No. IPR2014-01211 (P.T.A.B. Feb. 10, 2015) (Paper 8, Decision Denying Institution of IPR); *Medtronic, Inc. v. Mark A. Barry*, No. IPR2015-00782 (P.T.A.B. Sept. 9, 2015) (Paper 6, Decision Denying Institution of IPR).

Figure 6 of the specification

- The patents' common specification contains a Figure 6, which is a photograph of a series of x-rays.

- At the time Dr. Barry filed his application for both patents-in-suit and when the claims were allowed, the specification described Figure 6 as:

> a three frame x-ray showing 'before and after' views of a scoliosis patient who was treated in an investigational procedure *using the system and method of the present invention.*

'358 Patent (PX 1) at 4:38–41; '121 Patent (PX 2) at 4:44–47

- The original specifications also state the following: "[a]s shown in FIG. 6, investigative practice of the present method achieves efficacy never before seen in the orthopedic field." '358 Patent (PX 1) at 5:60–62, '121 Patent (PX 2) at 6:10–13.

- In March 2015, during this litigation, Dr. Barry's law firm represented to Medtronic that "the x-rays depicted in Figure 6 were taken on or about July 10, 2003, and the surgery was performed June 10, 2003." DX 129; *see also* DX 122 (other emails). Dr. Barry's counsel also stated that "[t]hough Fig. 6 is mistakenly described in the patents, the figure represents the end result that would be achieved through the use of the invention claimed in the patents." DX 129.

- There is a series of internal communications between members of the Gray, Reed & McGraw law firm regarding Figure 6 from the March 2015 timeframe. *See, e.g.*, DX113 (3/8/15 Reed to Ellis, copying Henry), DX 114 (3/23/15 email from Henry to Ellis, copying Reed), DX 118, DX 122, DX 129.

Attempts to Correct and the Correction of the Description of Figure 6

- The description of Figure 6 found in the '121 Patent specification has been corrected. In March 2016, Dr. Barry requested a Certificate of Correction to correct the description of Figure 6 found in the '121 Patent, the PTO approved that request in a form response, and in August 2016, the PTO issued the Certificate of Correction. *See* USPTO website, Patent Application Information Retrieval (*available at* http://portal.uspto.gov/pair/PublicPair). [9]

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[9] The certified copy of the file history of the '121 Patent that was marked and admitted (PX 005), does not contain the correspondence between Dr. Barry and the PTO concerning his efforts to correct the '121 Patent specification, which occurred in 2015 and 2016. However, the complete file history publically available on the PTO website contains the full correspondence that demonstrates that the PTO corrected the '121 Patent specification, including the Certificate of Correction that issued in August 2016. Similarly, the version of the '121 Patent available on the

- Dr. Barry also applied to the PTAB to correct the description of Figure 6 found in the '358 Patent during IPR proceedings. DX 490. In moving for a Certificate of Correction, Dr. Barry stated that the proposed change to the description of Figure 6 was "minor in nature and should be made to ensure that the patent is accurate." Tr. at 2263:10–2264:15 (discussing DX 490).

- The PTAB denied Dr. Barry's motion for a Certificate of Correction regarding the description of Figure 6 in the '358 Patent. *Medtronic, Inc. v. Mark A. Barry*, No. IPR2015-00780 (P.T.A.B. Sept. 7, 2016) (Paper 50, Denial of Patent Owner's Motion for Certificate of Correction) (appearing at DX 492).[10] The PTAB found that the correction did not "appear to be of a minor character, reexamination of the patent with the proposed changes is appropriate, and Patent Owner [Dr. Barry] had not made a sufficient showing that the mistake occurred in good faith." *Id*. at 8.

- The PTO allowed Dr. Barry to correct the very same error in the description of Figure 6 found in the specification of a patent application related to the patents-in-suit, patent application No. 13/645,589, ("the '589 Application"). The PTO allowed Dr. Barry to correct the description through an Amendment after Allowance. DX 145. The '589 Application issued as U.S. Patent No. 9,339,301 ("the '301 Patent") on May 17, 2016.[11] The '301 Patent is a continuation of the applications that issued as the patents-in-suit.

PTO website (but not the version of the '121 Patent that was marked and admitted at trial (PX 002)) contains the Certificate of Correction. For purposes of this Order, the court assumes that the publically available patent and file history is true, correct, and complete, and the parties' failure to admit the current, publically-available versions was an unintentional omission. *See* 35 U.S.C. § 255.

[10] Dr. Barry was asked to testify at the bench trial in some detail about an exhibit labeled DX 492, described as the PTAB's final determination with regards to Dr. Barry's request to correct the '358 Patent, but DX 492 was never admitted. Tr. at 2264:16–2267:15. For this reason, this Order will refer to the publically-available version of DX 492, which is found on the PTO website. Dr. Barry's underlying motion to correct (DX 490), however, was admitted and is in the record.

[11] The '301 Patent was not admitted during the bench or jury trial in this case but can be accessed publicly on the PTO website.

II. ELEMENTS OF INEQUITABLE CONDUCT

A finding of inequitable conduct may result if a patent applicant breaches the duty to prosecute a patent application in good faith and with candor. *See* C.F.R. Section 1.56; *see also Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). A finding of inequitable conduct renders an entire patent unenforceable, making it the "atomic bomb" of patent law. *Id*. at 1288

In order to prevail on inequitable conduct, a defendant must prove by clear and convincing evidence that (1) a patentee misrepresented or omitted material information from the PTO ("materiality") (2) with the specific intent to deceive the PTO ("specific intent"). *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1334 (Fed. Cir. 2011) (citing *Therasense*, 649 F.3d at 1287). Inequitable conduct may involve actions by both "the patentee and the attorney who prosecuted the application that resulted in the patent-in-suit, because the knowledge and actions of applicant's attorney are chargeable to [the] applicant." *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 n.8 (Fed. Cir. 1987).

Specific intent and materiality each have their own legal underpinnings. After *Therasense*, they are to be treated as separate requirements and not on a sliding scale. *Therasense*, 649 F.3d at 1290. Because the consequences of an inequitable conduct finding are so grave, even if a court finds both elements are met, it "must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable." *Id*. at 1287.

A. Specific Intent

Establishing specific intent requires establishing that a patentee had knowledge of falsity. *See Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996) (concluding that a "holding of unenforceability based on the filing of a false oath requires that the oath was false, and made with

knowledge of the falsity . . . [which] is predicate to intent to deceive."). A specific intent to deceive must be the "single most reasonable inference" to be drawn from the evidence to meet the clear and convincing standard. *Am. Calcar*, 651 F.3d at 1334. "[W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Therasense*, 649 F.3d at 1290–91. "A finding that the misrepresentation or omission amounts to gross negligence or negligence under a 'should-have known' standard does not satisfy" the specific intent requirement. *Id*. at 1290 (citing *Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)). Proof that an inventor attempted to withhold material prior art, without more, is also not enough. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003); *see also Astrazeneca Pharm. LP v. Teva Pharm. USA, Inc.*, 583 F.3d 766, 777 (Fed. Cir. 2009).

B. <u>But-For Materiality</u>

"[A]s a general matter, the materiality required . . . is but-for materiality and the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference." *Therasense*, 649 F. 3d at 1291. In *Therasense*, the court articulated that an "accused infringer must prove both elements—intent and materiality—by clear and convincing evidence." *Id*. at 1287. However, the court also announced that "in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference [and in] making this patentability determination, the court should apply the *preponderance of the evidence standard* and give claims their broadest reasonable construction." *Id.* at 1291–92 (emphasis added). The court recognized that "even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards." *Id*. at 1291; *see also Am. Calcar*, 651 F.3d at 1334 (vacating the district court's findings on

materiality in part because the court failed to analyze but-for materiality under the preponderance standard).

In *Ohio Willow Wood Co. v. Alps South, LLC*, the Federal Circuit reiterated that "[b]ecause the analysis of this but-for materiality requirement is from the perspective of the PTO, we apply the preponderance of the evidence standard in assessing whether the withheld or misrepresented information would have blocked patentability." 735 F.3d 1333, 1345 (Fed. Cir. 2013); *but see Network Signatures, Inc. v. State Farm Mut. Auto. Ins. Co.*, 731 F.3d 1239, 1242 (Fed. Cir. 2013) (stating that the "*facts* of materiality and intent must be established by clear and convincing evidence.") In *Network Signatures*, an opinion from a dissenting judge stated that "the materiality component of inequitable conduct need be shown only by a preponderance of the evidence when the information relates to patentability" and that "[t]here is some dispute in our post-*Therasense* case law over the correct standard of proof on materiality." *See* 731 F.3d at 1244 n.1 (Fed. Cir. 2013) (dissent). The majority opinion stated that the *Therasense* court generally "establish[ed] a consistent standard." *Id*. at 1243, n.2 (majority).

When a defendant alleges that prior art was withheld, other District courts have found that a jury finding of no invalidity based on that prior art is at the very least relevant to and, in some cases, determinative of the materiality inquiry. *See, e.g., Activevideo Networks, Inc. v. Verizon Commc'ns., Inc.*, Civ. Action. No. 2:10-cv-248, 2011 WL 13113818, at *3–4 (E.D. Va. Aug. 17, 2011) (relying on the evidence summarized in the court's invalidating analysis at JMOL to find that, even under the preponderance of the evidence standard of *Therasense*, various references were not but-for material); *Triangle Software, LLC v. Garmin Int'l., Inc.*, Civ. Action No. 1:10-cv-1457, 2012 WL 527223, at *4 (E.D. Va. Feb. 14, 2012) (denying inequitable conduct claims because, in part, "the jury found all of the patents in-suit valid as not anticipated by the prior art.

A finding of inequitable conduct would, therefore, be inconsistent with the jury's verdict and evidence assessments on the issue of invalidity."); *Linear Tech. Corp. v. Monolithic Power Sys., Inc.*, No. CA 06-476-GMS, 2011 WL 4014467, at *7 (D. Del. Sept. 9, 2011) (recognizing the "interplay between materiality and a jury's verdict on anticipation and obviousness" and concluding that, in that court's view, "a jury verdict of non-obviousness creates a *strong presumption against but-for materiality*, particularly where . . . the accused infringer used the allegedly withheld information for a similar purpose during the invalidity portion of the trial.") (emphasis added).

Perhaps less clear is how, and to which aspect of the issue, the different standards of proof are to be applied when a Defendant alleges that there was a material misrepresentation. In *Ohio Willow*, there was an allegation of material misrepresentation and the Federal Circuit cited the preponderance standard. *See* 735 F.3d at 1345, 1349–50. However, this court must admit to some uncertainty as to exactly which aspects of the inquiry the preponderance of evidence standard is to be applied.

Accordingly, the court will apply the preponderance of the evidence standard when considering but-for materiality, specifically the ultimate question of patentability, with regard to each of Medtronic's theories, including its theory that Dr. Barry materially misrepresented Figure 6. However, the court will still require clear and convincing evidence of the *facts* underlying materiality. This approach comports with the approach taken towards allegedly withheld prior art in *American Calcar* and the Federal Circuit's announcements in cases like *Ohio Willow* and *Network Signatures*. Moreover, this approach is conservative. If Medtronic failed to prove even by a preponderance that misrepresented information or the withheld reference would defeat patentability of certain claims, it certainly cannot prevail under a clear and convincing standard.

With these requirements in mind, the court turns first to Medtronic's inequitable conduct allegations regarding Figure 6 of the specification (Section A) and then will address its allegations concerning failures to disclose prior art (Section B).

III. ANALYSIS

A. Medtronic's Inequitable Conduct Claims Regarding Figure 6

1. Background of the Dispute over Figure 6

Figure 6 is a group of three somewhat blurry "before and after" x-ray images. Medtronic claims that, at the time of application and leading up to allowance, the specification described Figure 6 as one thing, but Dr. Barry's statements in this litigation—and his statements to the PTO in an attempt to correct the specification—represent Figure 6 as something else.

Dr. Barry described Figure 6 at the time of application as the following:

> FIG. 6 is a three frame x-ray view showing ***'before and after' views*** of a scoliosis patient who was treated in an investigational procedure ***using the system and method of the present invention***.

See, e.g., '358 Patent at 4:38–41. While there was some back and forth between the patent examiner and Dr. Barry regarding the clarity of the image in Figure 6 (which originally appeared as Figure 7 in the '358 Patent application) (*see supra* Factual Background at 4, n.6), the file history does not demonstrate that Dr. Barry relied on Figure 6 to demonstrate patentability in the face of a rejection or that the patent examiner relied on any statements about Figure 6. For instance, Dr. Barry did not present a sworn statement separately in an affidavit in order to gain allowance over prior art.

During the week of March 10, 2015, in preparing for a mediation in this case, Dr. Barry and his counsel realized that the description of Figure 6 was not accurate. This is supported by

internal emails from March 2015 between Mr. Henry and other attorneys at his law firm. DX 114, DX 119, DX 120. In one email Mr. Henry told his co-counsel the following:

> Because I understood the invention to have only been made in the prior few months, there certainly was no digging into what these 'really were.' That was not even a known issue until this month.

DX 114. If Mr. Henry had knowledge of the misrepresentation before March 2015, certainly an internal email between him and others at his firm might have included mention of this prior knowledge. Mr. Henry's representations in that March 2015 email are consistent with his testimony during the bench trial.

In a March 12, 2015 email to Medtronic's counsel, Dr. Barry's counsel alerted Medtronic to the mistake and stated the following:

> Fig. 6 is mistakenly described and the x-rays depicted were taken on or about July 10, 2003, and the surgery was performed on June 10, 2003. The photos of Fig. 6 were mistakenly provided to the patent office instead of photos from a later surgery using the invention. The photos depict results that, though never achieved before the particular surgery, and not practicably before late 2004, are not, as an end product, different from that achieved through practice of the claimed invention.

DX 129 at Bates Dr. Barry023627. Dr. Barry amended his interrogatories explaining the same. PX 427 (March 2016 Interrogatory Responses, which incorporates by reference a prior response served on March 2015 at PX 423.005–06).[12] Dr. Barry's amended interrogatories also reflect that those pre-critical date surgeries were developmental. *Id.*

Between March and April of 2016, Dr. Barry and his counsel approached the PTO to correct the specifications. DX 490. With regards to the '121 Patent, the PTO approved Dr. Barry's

[12] Dr. Barry's March 2016 interrogatory responses (PX 427) were admitted during trial, but the earlier March 2015 responses (PX 423) that are incorporated by reference in PX 427 were not admitted.

request for Certificate of Correction and issued the Certificate of Correction on August 2, 2016. *See supra* Attempts to Correct and the Correction of the Description of Figure 6 at 6.[13] The correction, which the PTO freely accepted, means that the '121 specification no longer contains an erroneous description of Figure 6. And with regard to the '589 Application, a continuation application from the applications that issued as the patents-in-suit, the PTO also allowed Dr. Barry to correct the very same error after allowance. *Id*.; *see also* DX 490. As a result of Dr. Barry's efforts to correct the specifications, the '121 Patent and the patent that issued from the '589 application currently read as follows:

> FIG. 6 is a three frame x-ray view showing 'before and after' views of a scoliosis patient who was treated in an investigational procedure *in the development of the systems and methods of the present disclosure*.

'301 Patent at 4:47–52 (emphasis added); '121 Patent Certificate of Correction *available at* http://portal.uspto.gov/pair/PublicPair. The italicized text was amended from "*using* the systems and method of the present *invention*," which is the description appearing in the '358 Patent.

With regards to the '358 Patent, which was undergoing IPR, the PTAB denied Dr. Barry's motion to correct the specification in the very same way. *Medtronic, Inc. v. Mark A. Barry*, No.

[13] As explained above, the version of the '121 Patent admitted at trial (PX 002) does not contain the Certificate of Correction, but the version of the patent publically available on the PTO website does. The same applies to the file history marked and admitted at trial (PX 005). *See supra* note 10. Because Certificates of Correction take effect once issued and the court is to assume that the '121 Patent "originally issued in such corrected form" (*see* 35 U.S.C § 255; *see also* MPEP (9th ed. Rev. 07.2015, Nov. 2015) § 1481), the court considers the '121 Patent *with* the Certificate of Correction regarding Figure 6 to be the complete certified copy of the '121 Patent. The court assumes that marking and entering into evidence the '121 Patent *without* the Certificate (PX 002) was an unintentional error.

IPR2015-00780 (P.T.A.B. Sept. 7, 2016) (Paper 50, Denial of Patent Owner's Motion for Certificate of Correction) (appearing at DX 492) (*see supra* note 9).[14]

Medtronic claims that this course of conduct demonstrates that Dr. Barry made false statements to the PTO regarding Figure 6, failed to correct those false statements, and withheld information regarding Figure 6. However, Medtronic failed to prove that Dr. Barry or Mr. Henry had a specific intent to deceive the PTO with regards to Figure 6 either at the time of prosecution or through their post-issuance conduct.

2. No specific intent to deceive regarding Figure 6 during prosecution

It makes little sense to conclude that either Dr. Barry or Mr. Henry had a specific intent to deceive the PTO regarding Figure 6 at the time of prosecuting the '358 Patent. Logically, had Dr. Barry sought to provide an x-ray from a surgery where the inventive method and system were actually used, he could have. He testified to having conducted surgeries in the Fall of 2004 as he refined his methods and systems, fully reducing them to practice between the critical date and filing his application on December 30, 2004. Tr. at 221, 224. Unless all of those 2004 surgeries were failures, and there was no evidence they were, he could have prepared Figure 6 from a set of three x-rays from one of those 2004 surgeries. If Dr. Barry did not have earlier x-rays that were as clear as those in Figure 6, he needed only to correct the description in the specification, as he did with regards to the '589 Application.

Dr. Barry and Mr. Henry had no reason to lie about Figure 6 during prosecution. There is no claim, much less any shred of evidence, that either of them plotted to "gratuitously deceive"

[14] At first, Dr. Barry and his counsel requested an entry for Certificate of Correction (DX 496), just as he did with the '121 Patent, but then later formally moved to correct the '358 Patent, which was at the time going through IPR. DX 490. The MPEP makes clear that there are different procedures for correcting a patent based on applicant mistake for a patent that is undergoing IPR.

the PTO for the joy of "getting away with something" by submitting deceptive slides or giving a false description when they did not have to. If that had been the case, would they not have taken the opportunity to make the correction when the PTO first asked for clearer images? There is no evidence that Dr. Barry or Mr. Henry ever changed the x-rays in the figure. Based on the demeanor and testimony of Dr. Barry and Mr. Henry, the court finds that neither witness was so stupid or devious as to attempt to deceive the PTO on a subject for which there was no need to deceive.

A number of different reasonable inferences regarding both Mr. Henry's and Dr. Barry's conduct surrounding Figure 6 can be drawn, meaning an intent to deceive cannot be found. On the part of Mr. Henry, the court finds credible Mr. Henry's testimony that he did not have knowledge of the error regarding the description of Figure 6, or of the actual date of that surgery, at the time of application; Mr. Henry also credibly testified that he only became aware of the error during this litigation. Medtronic did not provide clear and convincing evidence to the contrary. *See* Findings ## 11, 12. Without knowledge of the falsity, Mr. Henry's conduct regarding Figure 6 cannot constitute inequitable conduct. *See Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004) (holding no deceptive intent where patentee's counsel believed the statements to be true at the time of submission to the PTO).

With regards to Dr. Barry, there are several plausible explanations supported by the evidence. Perhaps the most plausible inference to be drawn is that Dr. Barry approached Mr. Henry in December 2004, and Mr. Henry was trying to file the application before the end of the year. According to Dr. Barry, he discussed the surgeries and handed over the photographs to Mr. Henry, who assembled the x-rays and wrote the descriptions as he was told about them. Tr. at 2179–2180, 2185, 2183. Dr. Barry could have made a mistake in identifying the surgery that led to the x-ray images in Figure 6 or in describing what occurred during that surgery. A layman in

Dr. Barry's position might easily describe an x-ray in which he was developing methods and surgeries as one in which he "used" those inventions.

Mr. Henry, believing that Dr. Barry had reduced his invention to practice recently, did not press Dr. Barry as to the exact date of the surgery. *See* Finding # 4. Dr. Barry, who performs hundreds of surgeries each year did not catch the error in the description; this is not so unusual when the three x-rays were reduced to fit on a single 8½ x 11 piece of paper. Even a physician and a lawyer could make a mistake in characterizing x-rays that resulted from many surgeries, and matching up which x-rays are from which surgeries. This possibility may give rise to negligence under a "should have known" standard, but is not clear and convincing evidence of a specific intent to deceive. *See Therasense*, 649 F.3d. at 1290.[15]

With regards to either witness, there was no evidence of scheming or elaborate plans to deceive the PTO. Having listened to the testimony and observed the demeanor of both Dr. Barry and Mr. Henry, the court finds their testimony rebutting this assertion to be credible and supportive of various reasonable inferences other than either of them having a specific intent to deceive.

Medtronic claims that the "only possible conclusions are that *either* Dr. Barry misrepresented Figure 6 at the time of his application and allowed the misrepresentation to fester for more than a decade or that he is currently misrepresenting Figure 6 in an effort to aid his litigation position." Dkt. 436 at 9. This is an *ipse dixit* argument unsupported by evidence. At the bench trial, Medtronic did not ask Dr. Barry about his initial work with the x-rays and the photographs of these x-rays now labeled as Figure 6. No question was posed as to what efforts

[15] On the part of Mr. Henry, he explained that he was made aware of the accurate facts behind Figure 6 in 2015 during this litigation, not during the prosecution of the patents-in-suit; therefore he could not have withheld the correct information. *See* Finding # 5.

Dr. Barry took to identify from where the photographs came or to determine to which surgeries they related. Medtronic never questioned Dr. Barry about the efforts, or lack of effort, he made to investigate the source of the x-ray. In failing to ask, Medtronic failed to carry its burden.[16]

The court's failure to find specific intent does not imply that errors in a specification or lack of attention to detail are unimportant. The lack of attention to detail concerning Figure 6 in the preparation of the application resulted in the court disqualifying Mr. Henry as trial counsel because of the potential importance of his testimony concerning Figure 6. *See* Dkt. 73 (Order Granting in Part Motion to Disqualify the Gray Reed Law Firm). Likewise, while the PTO accepted Dr. Barry's proposed correction of the description of Figure 6 in the '121 Patent and the related patent application, the '589 Application, Dr. Barry must undertake the expense and effort of reexamination to correct the description in the '358 Patent. This is adequate to deter the applicant and his attorney from such negligence in the future and to deter patent practitioners from such conduct. Adherence to the duties of diligence and candor in the preparation of patent applications has been promoted. Accordingly, the totality of the circumstances demonstrate that this situation is not one that calls for the "atom bomb" of total patent invalidation.

Findings

1. The description of Figure 6 appearing in the specification of the '358 Patent and '121 Patent is erroneous. This is based on Dr. Barry and his counsel's attempts to correct the specification, and their email to Medtronic in which it stated that the patents mistakenly described the x-rays. DX 129 at Bates Dr. Barry023627.

2. Mr. Henry understood that both he and Dr. Barry had, and have, a duty of candor to the PTO. Tr. at 2201:2–7.

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[16] Medtronic also claims that "Dr. Barry has never offered an explanation for how this misrepresentation occurred, let alone a plausible explanation of inadvertent misrepresentation." Dkt. 436 at 9. But Dr. Barry does not carry that burden. It was incumbent upon Medtronic to solicit testimony on this point, which it did not.

3. Dr. Barry understood that he had, and continues to have, a duty of candor to the PTO. Dr. Barry was also aware that he had a duty to make certain disclosures to the PTO when filing a patent. Tr. at 2237:23–2238:3.

4. Mr. Henry conducted adequate due diligence into potential prior art during initial meetings with Dr. Barry and leading up to the filing of the application that led to the '358 Patent. Tr. at 2183:20–2184:15.

5. When he filed the applications that issued as the '358 and '121 Patents, Mr. Henry had not learned that Figure 6 reflected a June 23, 2003 surgery. *See* Tr. at 2189:2–6; Tr. at 2239:13–16.

6. The earliest that Dr. Barry became aware of the erroneous description of Figure 6 in his patents for the first time was March 2015, during this litigation. *See* DX113 (3/8/15 Reed to Ellis, copying Henry), DX 114 (3/23/15 email from Henry to Ellis, copying Reed), DX 118, DX 122, DX 129.

7. Upon realizing that the description of Figure 6 in the application and in the specification was incorrect, which occurred in March 2015 during this litigation (*see* Finding # 6), Dr. Barry and Mr. Henry diligently made Medtronic aware of the error.

8. Dr. Barry and his counsel made efforts to correct the erroneous description of Figure 6 in both the '121 Patent and the '358 Patent at the PTO.

9. The PTO issued a Certificate of Correction with regards to the '121 Patent, allowing Dr. Barry to correct the description of Figure 6 in that specification to reflect that the surgery that led to the x-ray images photographed in Figure 6 was an investigational procedure.

10. The PTO allowed Dr. Barry to correct the same mistake after allowance in the case of the '589 Application. DX 145.

11. Medtronic did not establish by clear and convincing evidence that Dr. Barry or Mr. Henry were aware that the description of Figure 6 was erroneous prior to March 2015. (Based on all of the evidence and the court's evaluation of the demeanor and credibility of the witnesses at trial and at the hearing, the court would reach the same conclusion under a preponderance of the evidence standard.)

12. Clear and convincing does not establish that, during preparation and filing of the applications and the prosecution of the patents, either Dr. Barry or Mr. Henry had a specific intent to deceive the PTO with regards to the erroneous description of Figure 6. (Based on all of the evidence and the court's evaluation of the demeanor and credibility of the witnesses at trial and at the hearing, the court would reach the same conclusion under a preponderance of the evidence standard.)

3. No "continuing pattern of deceit" to support a finding of specific intent to deceive

According to Medtronic, Dr. Barry's attempts to correct the statements about Figure 6 in the specification, his more recent filing of the related '589 Application with the same error, and his representations to the PTO during *inter partes* review of the '358 Patent, demonstrate a continuing pattern of deceit. *See* Dkt. 353-1 at 42–49. Where "[s]ubmission of an affidavit containing fabricated examples of actual reduction to practice in order to overcome a prior art reference raises a strong inference of intent to deceive," a pattern of deceit makes the inference of intent to deceive stronger. *Intellect Wireless*, 732 F.3d at 1344–45. While *Intellect Wireless* makes clear that post-issuance activity may be relevant, the conduct identified by Medtronic does not amount to a continuing pattern of deceit.

Dr. Barry's most recent attempts to correct his errors, in fact, actually undercut such a finding.[17] The PTO willingly accepted Dr. Barry's earnest efforts to correct the '121 Patent. Medtronic relies on the PTAB's latest rejection of Dr. Barry's attempt to correct the '358 Patent, where the PTAB stated that Dr. Barry had not proven that the correction was brought in good faith. But a failure to find good faith is not equivalent to a finding of bad faith, let alone a finding establishing the high bar of conscious wrongdoing required by specific intent to deceive. The PTAB did not assess credibility or intent. On the other hand, after seven days of jury and bench trials, this court had an opportunity to assess the credibility of those who testified about Figure 6.

[17] Medtronic complains that Dr. Barry improperly attempted to file a certificate of correction at the PTO while the '358 Patent was being reviewed by the PTAB through *inter partes* review, and did so "without informing the PTAB, Medtronic, or its attorneys at the PTAB or in this litigation." Dkt. 436 at 10–11. While it would have been prudent for Dr. Barry to advise opposing counsel regarding actions he takes towards the patents-in-suit in this litigation, notice is not required, especially when PTO filings are public. Further, Dr. Barry ultimately filed for a Certificate of Correction in the pending IPR (DX 490), about which Medtronic obviously learned.

The PTAB has not determined that Dr. Barry lied or that the PTAB would not have allowed the patents to issue but-for the incorrect statements about Figure 6.

The fact that the PTO has allowed Dr. Barry to correct the description of Figure 6 at issue in the '121 Patent and the '589 related patent application indicates quite the opposite. *See* Finding # 8, 9, 10; *see also* supra Factual Background, Attempts to Correct and the Correction of the Description of Figure 6 at 6; *see also* DX 145; *see also* Tr. at 2270:22–24. Even though the PTAB rejected Dr. Barry's efforts to correct the '358 Patent, the PTAB also never *required* a reissue, a fact that Medtronic acknowledges. Tr. at 2172:5–6. These facts differ from *Intellect Wireless*, where the patentee never "openly advise[d] the PTO of [his] misrepresentations." 732 F.3d at 1343. These attempts to correct the error, which in some cases where willingly accepted by the PTO, undercut Medtronic's continuing pattern of deceit theory.

Finding

13. Clear and convincing evidence does not establish that Dr. Barry or Mr. Henry engaged in a continuing pattern of deceit towards the PTO through their post-issuance conduct. (Based on all of the evidence and the court's evaluation of the demeanor and credibility of the witnesses at trial and at the hearing, the court would reach the same conclusion under a preponderance of the evidence standard.)

4. The statements regarding Figure 6 are not but-for material and this is not a case of affirmative egregious misconduct.

a. But-for materiality.

Medtronic also had the burden of showing that the erroneous description of Figure 6 was but-for material. Even though *Therasense* more squarely addressed "failure to disclose" inequitable conduct theories, misrepresentations must also be shown to be but-for material, meaning it must be shown that the PTO would have acted differently without the statement. *Therasense*, 649 F.3d at 1292; *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1235 (Fed. Cir.

2011) (applying *Therasense* materiality standard to false statement theory). As discussed above (Section II.B), the court applies a preponderance standard to the patentability inquiry and requires that all factual underpinnings to materiality be established by clear and convincing evidence.

It is undisputed that the description of Figure 6 at the time of application was incorrect. *See* Finding # 1, *see also supra* "Background of the Dispute over Figure 6" at 12. Either Dr. Barry identified the x-ray as linked to the incorrect surgery or mischaracterized the nature of the surgery that was linked to the x-ray. It is also uncontested that the error in description was the type of error that should have been corrected. *See* Finding # 8. Dr. Barry admits as much by his efforts to correct the statement. But merely because the error was important enough to correct does not imply it was per se but-for material to patentability.

Medtronic's principal but-for materiality argument is: "Dr. Barry's description of Figure 6 was a lie, therefore Figure 6 and its description were but-for material." This is merely an attempt to apply the affirmative egregious misconduct exception to the requirement for proving but-for materiality as a discrete element. But, as discussed below, at Section 4(b), this is not a case of affirmative egregious misconduct.

Medtronic did not prove that had Dr. Barry never submitted Figure 6 and its description, or some version thereof, the PTO would not have allowed the claims at issue. Medtronic tried to establish that the PTO relied on Dr. Barry's original representation about Figure 6 in analyzing non-obviousness, so Figure 6 must be material. Of course, whether the PTO relied on information during prosecution in granting or denying allowance is relevant to whether a statement, false or otherwise, is material. *See, e.g.*, *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1341–42 (Fed. Cir. 2003) (finding no material misrepresentation in part because a PTO examiner's reasons for allowance did not reflect that the PTO relied on the allegedly false applicant statements).

But Medtronic's evidence does not support a finding that the PTO relied on Figure 6. Medtronic identifies the following statement from the specification in support:

> As shown in FIG. 6, investigative practice of the present method achieves efficacy never before seen in the orthopaedic [*sic*] field

Dkt. 353-1 at 28–29 (*citing* '358 Patent 5:60–62; '121 Patent 6:10–12). But this statement is just one of several about the present invention found in the specification. Though one might be able to conclude that the PTO relied on this statement if it had appeared in an affidavit from Dr. Barry that was responsive to an obviousness rejection, for instance, the statement alone does not suggest clear and convincing evidence that the PTO relied on it.

The second statement that Medtronic identifies, again from the specification, is:

> In investigative procedures, the presently proposed system and method has achieved a measure of correction of scoliotic curvature never before seen in orthopaedic [*sic*] practice.

'358 Patent at 4:7–10. This statement does not mention Figure 6, even in the surrounding language. It too is simply one of several statements describing the invention, not one that demonstrates that the PTO relied on Figure 6 in analyzing non-obviousness.

The back-and-forth in the prosecution history regarding the clarity of the image (which was not discussed by any witness at trial) does not change this analysis. *See* PX 004.077, PX 004.151, PX 004.182. The PTO did state that the images "do not distinctly show features which are pertinent to the understanding of the disclosed device." PX 004.077. But the PTO was willing to accept, in fact invited, a replacement of the x-rays. In overcoming the PTO's rejection, Dr. Barry substituted a clearer image for Figure 6. Medtronic claims that this portion of the prosecution history demonstrates that Dr. Barry put "special emphasis on the alleged superior results, the alleged solution of a long-felt need, and the accuracy of Figure 6." Dkt. 353-1 at 27. However, Dr. Barry's response was merely a response to the PTO's request for a clearer image. Dr. Barry

did not change the description of the image, did not provide a date for the image, nor did he make any additional substantive statements about the image with regards to non-obviousness on which the PTO could have relied. After seeking and receiving a clearer image, the PTO did not again mention Figure 6.

The PTO's willingness to allow Dr. Barry to correct the '121 Patent and provide an Amendment after Allowance for the '589 Application for the very same 'mistake' (*see* Findings ## 8, 9, 10, DX 145) underscores that the '358 Patent, more likely than not, would have issued anyway had the correction been made prior to issuance. *See Therasense*, 649 F.3d at 1292. While the PTO's recent rejection of Dr. Barry's attempts to correct the '358 Patent indicates that the requested correction, some six years after issuance, is not "minor," the PTO merely stated that "reexamination of the patent with the proposed changes is *appropriate*." *Medtronic, Inc. v. Mark A. Barry*, No. IPR2015-00780 (P.T.A.B. Sept. 7, 2016) (Paper 50, Denial of Patent Owner's Motion for Certificate of Correction, at 8) (appearing at DX 492) (*see supra* note 9). The PTAB's decision establishes merely that a certificate of correction, which is intended to address corrections of *minor* character, was not the proper vehicle for the type of change sought by Dr. Barry, with regards to the '358 Patent specifically. *See* 35 US.C. § 255; *see also* 37 C.F.R. 1.323 (stating that if the PTAB rejects a Certificate of Correction, "reissue must be employed as the vehicle to correct the patent"). It does not prove that the issue underlying Dr. Barry's proposed change is but-for material to patentability of the claims.

Findings

14. Medtronic did not prove, under a preponderance of the evidence standard, that the PTO would not have allowed the claims of the '358 Patent or the '121 Patent that are at issue in this case without Figure 6 and its mistaken description, i.e. if Figure 6 and the mistaken description had never been submitted.

15. Medtronic did not prove, under a preponderance of the evidence standard, that the PTO would not have allowed correction of Figure 6 or its description during the application process for the '358 Patent or the '121 Patent had such a request been made during the application process, or that, after allowing such correction, that the PTO would not have allowed the claims at issue in this case.

16. Medtronic did not prove under a preponderance of the evidence standard that Figure 6 and its description were but-for material.

b. The "affirmative egregious misconduct" exception does not apply.

An exception to proving but-for materiality arises if an applicant engaged in "affirmative egregious misconduct." *Therasense*, 649 F.3d at 1292. This type of egregious misconduct involves "deliberately planned and carefully executed schemes to defraud the PTO and the courts." *Id*. (citing *Hazel-Atlas Glass Co v. Hartford-Empire Co.*, 322 U.S. 238, 245 (1944)). The exception arises because, as the Federal Circuit reasoned, "a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes the falsehood will affect issuance of the patent." *Therasense*, 649 F.3d at 1292. Examples of such conduct include filing an unmistakably false affidavit, perjury, bribery, or deliberate manufacturing of false documentation. *See id*. at 1292–93 (citing *Hazel-Atlas*, 322 U.S. at 245 (manufacturing evidence by drafting fake scholarly article in order to trick and defraud the PTO); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 809–10 (1945) (purposely false preliminary statement in PTO proceedings, followed by perjurious testimony); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 243, 246–47 (1933) (patentee bribed prior user to sign false affidavit, which patentee then filed with PTO)).

Courts have found affirmative egregious misconduct in only rare cases. *Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1362 (Fed. Cir. 2014) (acknowledging that the inventor's efforts to hire an expert that would submit to the PTO false statements that were "instrumental to issuance of the

patent" would "come close to the type of affirmative conduct that in *Therasense* [the court] held could justify finding inequitable conduct without showing but-for materiality."); *see Smith & Nephew, Inc. v. Interlace Med., Inc.*, Civ. Action No. 10-10951-RWZ, 2013 WL 3289085, at *2–3 (D. Mass. June 27, 2013) (finding that a patentee's "ambiguous misrepresentations" in the specification were "certainly somewhat misleading" but did not "present the extraordinary circumstances of affirmative egregious misconduct" because there was no "explicitly false statements, manufactured evidence, or other blatant deceit.") (internal citations omitted).

The court has already found that Medtronic did not prove a specific intent to deceive, so it is difficult to see how the court could find affirmative egregious misconduct. While it is only one factor in the court's analysis, the jury rejected Medtronic's claim that Dr. Barry's pre-critical date surgeries, which included the June 2003 surgery that led to the x-ray images in Figure 6, were invalidating prior art. The jury was instructed to use the clear and convincing standard for this determination, but even so, it is highly unlikely that jurors would have found someone they thought was a liar was entitled to a verdict that included approximately $20 million in damages.

Unlike cases in which affirmative egregious misconduct has been found, this case is not one involving fabricated evidence or bribery. The incorrect statements about Figure 6 were not made in a sworn affidavit or declaration submitted by Dr. Barry in order to overcome a prior art rejection. And upon learning about the misrepresentation, Dr. Barry and his counsel took action to correct the written descriptions.

Medtronic claims that the original description was "per se material" under the affirmative egregious conduct exception because Dr. Barry's conduct "goes far beyond submitting a false affidavit." Dkt. 436 at 8. But just because a statement appears in a published patent does not elevate it to the type of misrepresentation that constitutes affirmative egregious conduct. The

reason that false statements are more likely material when embodied in declarations or affidavits (*see, e.g., eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 480 F.3d 1129, 1136 (Fed. Cir. 2007)) is because such an affidavit often contains statements made to overcome prior art on which the PTO is more inclined to rely. This reasoning does not apply with equal force when it comes to statements like those regarding Figure 6, which appear within the specification.

Finding

17. Dr. Barry and Mr. Henry did not commit affirmative egregious misconduct.[18]

B. Medtronic's Claims of Failure to Disclose Material Prior Art

Medtronic alleges that Dr. Barry and Mr. Henry failed to disclose four categories of alleged prior art: (1) Dr. Barry's own pre-critical date surgeries, (2) the IMAST abstract (Dkt. 353-1 at 31), (3) Dr. Barry's disclosures and alleged offers for sale to medical device companies (Dkt. 353-1 at 34; Dkt. 353-1 at 38), and (4) the alleged prior invention by Dr. Lawrence Lenke, a Medtronic consultant (Dkt. 353-1 at 42). The court will address each category in turn below.

The court sets out its findings specific to a particular theory immediately before the court's discussion of that theory.

[18] To the extent Medtronic alleges that Dr. Barry or Mr. Henry withheld material information or failed to correct false statements regarding Figure 6, the court's failure to find materiality or specific intent applies equally to those theories. Specifically, the court found that Dr. Barry and Mr. Henry were not aware of the erroneous description at the time of prosecuting the patent. *See* Findings ## 5, 6, 7, 11, 12. The evidence also shows that Dr. Barry and Mr. Henry did, in fact, attempt to correct the erroneous statements. *See* Findings ## 8, 9, 10. Because Medtronic failed to demonstrate that statements regarding Figure 6 were material or any specific intent on the part of Dr. Barry or Mr. Henry, the court does not find that Medtronic proved inequitable conduct based on either of those sub-theories.

1. Dr. Barry's pre-critical date surgeries

Medtronic asserts that several surgeries Dr. Barry performed at Sunrise Hospital in Las Vegas, Nevada, at least one year before the application date of December 30, 2004 ("the pre-critical date surgeries" or "the surgeries"), were but-for material and intentionally withheld from the PTO, with an intent to deceive. Medtronic claims that the surgeries employed the inventions claimed in the patents and were but-for material for two separate reasons: (1) because they were open public uses of the patented method and system, they qualify as invalidating prior public uses under Section 102(b) and (2) because Dr. Barry was paid for the surgeries, they were invalidating prior sales under the on-sale bar of Section 102(b). In response to both of these theories, Dr. Barry asserts, as he did at trial, that the surgeries were experimental and constituted his legitimate efforts to test the claimed features of the inventions to determine if the method and system would work for their intended purpose. *See, e.g.*, Dkt. 429 at 11–12. Dr. Barry also testified that he did not actually reduce to practice during these surgeries.

At trial, these issues were hotly contested. Medtronic relied on Dr. Barry's pre-critical date surgeries as prior art, specifically alleging that the surgeries were invalidating pursuant to 35 U.S.C. § 102(b), as prior public uses and under the on-sale bar. The jury received a detailed instruction on public use and the on-sale bar, including instructions on experimental use and how that was one factor to be considered with regards to both theories. Dkt. 414 at 22–25. The jury found for Dr. Barry on both issues. Dkt. 411 (Answer to Question Nos. 5a and 5b); Dkt. 411 at 7. In its Order on Medtronic's motions for JMOL, the court found that there was substantial evidence to support the jury's findings. Dkt. 442 at 32–35. The court agrees with the jury's implicit finding that Dr. Barry and his witnesses were credible, and takes that into account in analyzing the evidence.

In sections (a), (b). and (c) below, the court explains its findings that these surgeries were experimental and the impact of this evidence of experimental use on the but-for materiality inquiry. This is relevant to both Medtronic's prior public use and on-sale bar theories. In section (d) below, the court discusses additional reasons for finding that these surgeries were not but-for material under the on-sale bar. Finally, in section (e) the court explains its finding that neither Dr. Barry nor Mr. Henry had a specific intent to deceive the PTO by not disclosing the surgeries.

The following findings relate to the pre-critical date surgeries and apply to sections (a) through (e) below.

Findings

18. Mr. Henry was unaware of the pre-critical date surgeries, which have been defined above as Dr. Barry's surgeries occurring between December 2002 and November 2004. Tr. at 2230:16–21 (Mr. Henry's testimony, which the court finds credible, that he was unaware of surgeries "that were used to investigate whether the invention worked for its intended purpose" taking place before the critical date), Tr. at 2212:22–24 (Mr. Henry's testimony stating "[a]gain, I was working on the premise that this was invented in, what, mid- to late-2004.")

19. The pre-critical date surgeries, i.e. Dr. Barry's surgeries between December 2002 and November 2004, were experimental attempts to perfect the claimed systems and methods and ensure that they performed as intended, which occurred between Dr. Barry's conception date and his actual reduction to practice at some time after the critical date of December 30, 2003.

20. None of the pre-critical date surgeries constituted an invalidating public use or sale. Dkt. 411 (Jury Verdict) at Questions ## 5 & 6.

21. Neither Dr. Barry nor Mr. Henry had a specific intent to deceive the PTO with regards to the pre-critical date surgeries.

22. Medtronic did not prove, under the PTO's preponderance of the evidence standard, that the PTO would have found any of the '358 Patent claims unpatentable had the PTO been aware of the pre-critical date surgeries.

23. Medtronic did not prove, under the PTO's preponderance of the evidence standard, that the pre-critical date surgeries were but-for material.

24. Medtronic did not prove by clear and convincing evidence that the pre-critical date surgeries were publically used or that, in those surgeries, Dr. Barry practiced

all the claim limitations. This removes any factual basis to find that the PTO, more likely than not, would have rejected the asserted claims had it been aware of the surgeries, i.e. that the surgeries were but-for material.

a. Dr. Barry's pre-critical date surgeries qualify as experimental uses

Given the weight of evidence suggesting that the surgeries were experimental, Medtronic did not establish even by a preponderance of the evidence that the surgeries were but-for material. The substantial evidence establishing that the pre-critical date surgeries were experimental included oral testimony from Dr. Barry and several witnesses who attended the surgeries: Dr. Stephanie Davidson, an anesthesiologist, Ms. Janice Munro, a scrub nurse, and Mr. Robert Pfefferkorn, a DePuy sales representative. The overview of their testimony, contained in the Order on the motions for JMOL, will not be repeated here. Dkt. 442. In brief, not one witness testified that he or she witnessed Dr. Barry using the patented inventions and then disclosed details about the system or technique to others. All agreed that there was some sort of expectation that the procedures were confidential, and in the case of the testimony of Mr. Pfefferkorn and Dr. Davidson, that persons inside the room are not privy to a view of the sterile operating field where the use of Dr. Barry's instruments could possibly have been viewed.[19] In response to Medtronic's contention that the instruments were left at the hospital for cleaning in between surgeries and therefore outside of Dr. Barry's control, Medtronic never solicited testimony that any witness saw even the system as assembled for use or actual use of the assembled system, which debunks

[19] Mr. Pfefferkorn also testified that sales reps rarely document anything about the surgeries and maintain a distance from the sterile field. Tr. at 684, 683:11–17, 683:17–23. He also stated that the kit of Dr. Barry's tools was left overnight in between surgeries in the sterile cleaning room, but there was no evidence that the various parts of the instruments were put together as it would be if the system were assembled or method used. The testimony suggested that the parts were kept separate and cleaned by others in a heavy duty washing machine. Tr. at 690:6–693:23. Medtronic never established that the kit was manipulated by others besides Dr. Barry. Mr. Pfefferkorn actually credibly testified that Dr. Barry was the only one that actually used the Monarch instruments as designed or ever showed those tools to anyone. Tr. at 693:20–694:2.

Medtronic's theory. The court finds the testimony of Dr. Barry and his witnesses to be credible on this point. *See* Finding # 19. The court finds that these pre-critical date surgeries were experimental surgeries conducted prior to Dr. Barry becoming aware that the inventions worked for their intended purpose.

b. <u>The relevance of experimental use to but-for materiality</u>

Whether experimental use is material to patentability under the *Therasense* standard appears to be a somewhat novel issue. Under the more lenient materiality standard prior to *Therasense*, there were cases that held that there is a duty to disclose pre-critical date experimental uses. *See, e.g.*, *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990). The Manual of Patent Examining Procedure (MPEP), citing pre-*Therasense* cases, vaguely states that "[i]t may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention." MPEP (9th ed. Rev. 07.2015, Nov. 2015) § 2004 ("Aids to Complaint with Duty of Disclosure") at No. 11; *see also* MPEP (8th ed. Rev. 2, May 2004) § 2004 (same). Other cases, however, concluded the opposite. *Trading Tech. Int'l Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1362 (Fed. Cir. 2010) ("Experimental uses of the patented invention may in some instances give rise to an issue of patentability. In this case, however, the record shows that [the inventor] tested the software for his own confidential, personal purposes. The district court did not clearly err by finding that a reasonable examiner similarly would not have regarded such experimental use as material.") (internal citations omitted).

In at least one pre-*Therasense* case, the Federal Circuit found no error where the district court concluded that pre-critical date activities were not material because the court found credible the inventor's testimony that the invention was not ready for patenting until after the critical date. *See Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 978 (Fed. Cir. 2010). Under the old

standard, then, it is somewhat unclear whether Dr. Barry's experimental surgeries would have been but-for material.

Under *Therasense*, however, the court must consider and make a finding as to whether there is a preponderance of evidence showing that the withheld information would have blocked issuance of the claims. *See Am. Calcar*, 651 F.3d at 1335. As stated above, and more thoroughly explained in this court's JMOL Order, there was substantial evidence at trial that the pre-critical date surgeries were experimental uses. Dkt. 442 at 32–35. Experimental use is an underlying fact, which is to be determined under the clear and convincing evidence standard (although the court does not understand the preponderance of the evidence standard as applicable to underlying facts, even viewing the evidence under a preponderance standard, the court finds that the surgeries were experimental).

Medtronic has not established that the asserted claims would not have issued had the PTO been aware of these pre-critical date surgeries.

c. <u>Medtronic's reliance on the Manual of Patent Examining Procedure (MPEP) is unavailing</u>

In an effort to refute the evidence of experimental use and confidentiality, Medtronic cites Sections 2133.03(e)(2)-(e)(5) of the MPEP to suggest that, under PTO procedure, "patients receiving a purchased invention must at a minimum be aware of the intent to experiment," Dkt. 353-1 at ¶ 20, and because patients were allegedly not made aware of experimentation, Dr. Barry's surgeries do not qualify as experimental use. The most relevant portions of the MPEP upon which Medtronic relies, with the most relevant language in italics, appears below:

> The significant determinative factors in questions of experimental purpose are the extent of supervision and control maintained by the inventor over an invention during an alleged period of experimentation, *and the customer's awareness of the experimentation.*

> When sales are made in an ordinary commercial environment and the goods are placed outside the inventor's control, an inventor's secretly held subjective intent to 'experiment,' even if true, is unavailing without objective evidence to support the contention. Under such circumstances, *the customer at a minimum must be made aware of the experimentation.*

MPEP (8th ed. Rev. 2, May 2004) §§ 2133.03(e)(5); 2133.03(e)(2).[20] As to the first paragraph, it seems self-evident that if the patient is aware of the system and method to be used, a confidentiality agreement would be needed. But these patients were sedated. There is no evidence they ever saw the assembled derorators or were told of the methods.

The second provision, by its own terms, applies to ordinary commercial sales. The surgical suit is not an "ordinary commercial environment." The jury did not find that the derotators were "outside of the control" of Dr. Barry or those who considered themselves bound to confidentiality.

Perhaps, upon reading of this case, inventors of medical systems and methods and their legal advisors will in the future take greater efforts to document confidentiality. But the quoted passages, even if a lay person like Dr. Barry was expected to have read them, do not provide guidance that is clear enough to establish that the pre-critical date surgeries were but-for material so that they should have been disclosed.

The two primary cases cited in the MPEP, *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066 (Fed. Cir. 1992) and *Paragon Podiatry Lab., Inc. v. KLM Labs, Inc.*, 984 F.2d 1182 (Fed. Cir. 1993),[21] are distinguishable. Both involved the commercial sale of goods,

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[20] Medtronic cites in its Proposed Findings and Conclusions a 2008 version of the MPEP. *See* Dkt. 353-1 at ¶ 3, n.3. However, the court is to view the evidence through the lens of the PTO examiner at the time of prosecution. Therefore, the court cites the version of the MPEP available at the time that Dr. Barry started prosecuting the '358 Patent. Substantively, there is no difference in the language of the sections cited.

[21] Another MPEP section cites, for a similar proposition, *Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co.*, 417 F.3d 1203, 1214–1215 (Fed. Cir. 2005).

not the use of surgical methods and systems. In *LA Bounty*, it was virtually undisputed that the goods at issue, shears, were placed outside of the inventor's control. 958 F.2d at 1074. The court's reasoning emphasized testimony that established that "the sale to the customer was contingent upon the customer's satisfactory trial of the shear 'to do' the job which the customer had asked for the shear." *Id*. at 1072. The "testing" of the shears by the customers and public users was "for the benefit of the customers, who wanted to determine whether to purchase one of the shears, and did not constitute experimental use for the benefit of the inventor." *Id*. at 1074.

This is different than the present case, where the precise techniques and instruments to be used varies from patient to patient and the surgeon making decisions after the first incision. Medtronic did not present either clear and convincing evidence, or in the court's view a preponderance of evidence, that the system and method was placed outside of Dr. Barry's control. Certainly, the system or method was not in the purview of a customer, who would have been under anesthesia while the surgery was performed on his or her back. Here, there are also other indicia such as expectation of confidentiality, the normal fee for the surgery, and the degree of control exercised by Dr. Barry, indicating that the use and "sale" were experimental rather than invalidating commercial activity or public use. As noted above, the witnesses consistently testified that the surgeries were performed in a controlled environment with implicit confidentiality obligations imposed on those in the operating room.

However, in *Electromotive*, the inventor "made no attempt to monitor the conditions" in the testing conditions and the district court found that the inventor "exercised no control" over another's use of the invention. *Id*. at 1215. This made the court's conclusion that the use could not have been experimental easier to reach than this case, where the jury reached the opposite conclusion as does the court.

Paragon cites *LA Bounty* for the "requirement" that customers be made aware of the experimentation, but there again, the case involved goods—orthotics—that were ultimately and indisputably placed outside the control of the inventor.[22] 984 F.2d at 1184, 1186–87. Orthotics are also plainly visible, unlike the use and method of a surgical method. As discussed by the court during the trial, a corset brace or an orthotic given to a customer without a confidentiality agreement would be wholly outside of the inventor's control, and not an experimental use. *See* Tr. at 1058:4–1062:3. A procedure performed on a patient's back under sedation in a controlled access operating room, absent evidence of other disclosure or failure to control, would remain under the inventor's control. Here, there was no evidence that the systems or methods were explained to any patient.

Further, the MPEP does not suggest to this court that the PTO is attempting to insert itself into the field of medical ethics, or attempting to establish regulations on whether failure to obtain a certain medical consent form affects the patentability of the method or system. Medtronic's reliance on the MPEP is therefore unavailing.

d. <u>The pre-critical date surgeries are not but-for material.</u>

The court agrees with the jury's refusal to find that the pre-critical date surgeries invalidated any of the claims under Section 102(b). Of course this was under a clear and convincing standard. But, given its finding that the surgeries were experimental, as discussed above, the court finds that, even under the preponderance of the evidence standard for materiality, the PTO would not have refused to issue the patents-in-suit had any or all of these this pre-critical date

[22] Other facts in *Paragon* are also distinguishable. *See* Dkt. 442 at 33 n.20.

experimental uses been disclosed. Therefore, the court concludes that the pre-critical date surgeries are not but-for material to patentability. *See* Findings ## 22, 23, 24.

e. Additional reasons why the surgeries are not but-for material under the on-sale bar

To prove materiality pursuant to its on-sale bar theory, Medtronic also had to prove that Dr. Barry commercially sold the invention for a greater than an incidental benefit prior to the critical date. Because the only evidence is that Dr. Barry charged his normal surgical fee during the pre-critical date surgeries, Medtronic did not present sufficient evidence that Dr. Barry commercially exploited the invention through the surgeries.

Under the on-sale bar, a sale can still be experimental in nature if the inventor receives only an incidental benefit as a result. In at least one other District Court case, the normal surgical fee for an operation, without other signs of commercial exploitation, did not give rise to the on-sale bar. *See McGuire v. Acufex Microsurgical, Inc.*, 868 F. Supp. 388, 396 (D. Mass. 1994) ("It is undisputed that the patient paid [the doctor] his normal surgical fee for the March 30, 1988 operation. Payment alone, however, does not make a *per se* case of a section 102(b) bar.") (citing *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1564 (Fed. Cir. 1987)). Medtronic explicitly agreed with this aspect of the on-sale bar during the jury charge conference. Tr. at 1988:2–13. Dr. Barry testified that he received payment for doing the surgeries (Tr. at 430:11–12), but there was no evidence that he received anything other than his standard fee. There was no showing that he charged any more than he would have using older techniques and equipment. The same applies to those that worked with Dr. Barry in the surgical theater. Therefore, Medtronic failed to prove that an actual "sale" occurred. Without proof of a sale, this allegedly material activity cannot be but-for material. *See* Findings ## 22, 23, 24.

f. No specific intent to deceive the PTO with regards to the surgeries

Though it was undisputed that Dr. Barry did not disclose the surgeries to the PTO during prosecution (Tr. at 2262:18–23), neither Dr. Barry nor Mr. Henry had the requisite specific intent to deceive the PTO.[23] *See* Finding # 21. Turning to Mr. Henry first, Medtronic failed to establish Mr. Henry's knowledge of the pre-critical date surgeries at the time of filing, which undercuts a specific intent finding. Mr. Henry credibly testified that he was unaware of the allegedly invalidating activity, which comports with Dr. Barry's testimony that Dr. Barry did not reveal information about that activity to Mr. Henry. *See* Finding # 18; *see also supra* note 8. Medtronic did not present clear and convincing evidence to the contrary. Because Mr. Henry was not aware of the references, he was not under a duty to disclose them to the PTO, and his omission cannot be the basis for Medtronic's inequitable conduct defense.

Medtronic also did not prove either that Dr. Barry knew that the surgeries were but-for material or that he withheld information about them with intent to deceive. Applicants are instructed not to inundate the PTO with marginal or repetitive references. MPEP (8th ed. Rev. 2, May 2004) § 2004, No. 13 (Aids to Compliance with Duty of Disclosure) ("It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information."). Dr. Barry is not a patent attorney and testified that he thought he "felt like he had a [sic] invention" in *2004*. Tr. at 2238 (emphasis added). If this was Dr. Barry's impression, there would be no reason for him to appreciate the relevance of the pre-critical date surgeries, which were 2003 activities. The court found Dr. Barry's testimony

[23] Medtronic more generally asserted specific intent to deceive across all its theories (Dkt. 353-1 at 49–52), but those allegations primarily consist of conclusory recitations of what is required to establish specific intent, not specific factual allegations supported by credible evidence. The court makes its best attempt to match up specific factual allegations with what might be probative for each of Medtronic's various theories.

on this point, basically a laymen's assessment of what is important to disclose to his prosecutor, credible.

Medtronic failed to rebut this. It did not question Dr. Barry about what led him to withhold discussing those surgeries with Mr. Henry. Instead, Dr. Barry testified that his patent attorney never told him to disclose the activity. Tr. at 2262:9–23. With regards to Mr. Henry, Dr. Barry admitted that he never disclosed the surgeries to Mr. Henry when he approached him about filing the patent. Mr. Henry's testimony comports with this. Tr. at 2230:16–21, 2199:12–15, 2197:15–21. It is plausible, and in fact likely, that Mr. Henry took Dr. Barry at his word when Dr. Barry did not discuss the surgeries in their initial conversations. While Dr. Barry's assumption that Mr. Henry would ask the right questions, and Mr. Henry's corollary assumption that Dr. Barry would tell him about relevant activity, may amount to negligence, it does not amount to an intent to deceive. *See, e.g.*, *Mettler-Toledo, Inc. v. Fairbanks Scales, Inc.*, Civ. Action No. 9:06-CV-97-KFG, slip op. at *6–7 (E.D. Tex. Nov. 9, 2010) (Dkt. 259, Findings of Fact and Conclusions of Law). These numerous plausible explanations make an intent to deceive far from the "single most reasonable inference" to be drawn.

Medtronic identifies a memo (DX 105) produced by Dr. Barry that supposedly informed Dr. Barry of his general duty to disclose material information to the PTO to support its assertion that Dr. Barry was aware of materiality of his surgeries. *See* Finding # 24; *see also* Dkt. 436 at 14 (*citing* DX 105). The memo discloses that patentees have a duty to disclose certain documents and information relating to the claimed invention, such as "information regarding sales, uses or public disclosures of the invention or products similar to the invention." It does not describe experimental uses in that list of activities. Moreover, Medtronic was not able to establish through testimony that Mr. Henry sent the memo, that Dr. Barry received the memo prior to application,

or that Dr. Barry read the memo. The fact that the memo was produced through Dr. Barry's production is not alone sufficient to establish Dr. Barry's knowledge of the memo or that pre-critical date activities that did not practice all limitations of his invention would be material. Awareness about a general duty to disclose material information[24] is not the same as awareness of the materiality of experimental uses. Medtronic's evidence did not establish the latter.

To the extent that Medtronic alleges that Mr. Henry did not conduct "even minimum diligence" in investigating into the surgeries, including the dates, Mr. Henry's actions were sufficient to meet the minimum standard of diligence. *See* Finding # 4. While there is a duty of diligence on the part of a prosecutor, it is well-established that a "duty to investigate does not arise where there is no notice of the existence of material information" and a patent attorney need not "pursue a fishing expedition to obtain information" but may instead reasonably rely on information provided by his client. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1382 (Fed. Cir. 2001). Mr. Henry testified about the diligence he did exercise when Dr. Barry approached him about applying for a patent. He conducted his typical questionnaire in order to ascertain information from Dr. Barry. Tr. at 2183:20–2184:15. While Mr. Henry's methodology may not be perfect and he did not engage in a fishing expedition, he was not required to.

Because Medtronic did not establish that Mr. Henry or Dr. Barry had the requisite intent to deceive with regards to his withholding mention of the pre-critical date surgeries (*see* Finding # 21), and alternatively because those surgeries were not proven to be but-for material even by a preponderance of the evidence (*See* Findings ## 22, 23, 24), these surgeries cannot be the basis for Medtronic's inequitable conduct claim.

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[24] Dr. Barry does not contest that he was made aware about the general duties he and/or Mr. Henry owed the PTO. Tr. at 2237:23–2238:3.

2. The IMAST Abstract

The court first provides some background factual information regarding the IMAST Abstract. On February 1, 2004, Dr. Barry submitted an abstract for the International Meeting on Advanced Spine Techniques (IMAST) that described his interim findings to-date, including the results of the 21 surgeries that occurred prior to the critical date. During this litigation, Dr. Barry submitted a sworn declaration to the PTAB through IPR proceedings in which he represented that the IMAST abstract describes his invention as set out in the claims of the '358 patent and included a claim chart showing where each element of the '358 claims is described in the IMAST abstract. DX 27. The IPR declaration also states that he had "conceived of the inventions claimed in the '358 Patent" by February 1, 2004, the date on which he submitted the IMAST abstract. DX 27.

Findings

25. The IMAST Abstract, which was submitted after the critical date on February 1, 2004, discloses the claim limitations of the '358 Patent. DX 27 (Dr. Barry's IPR Declaration).

26. Medtronic did not establish that Dr. Barry was aware that he was required to submit the IMAST Abstract to the PTO during prosecution.

27. Mr. Henry was not aware of the IMAST Abstract at the time of filing the application. Tr. at 2199:12–22.

28. Medtronic did not prove, under the PTO's preponderance of the evidence standard, that the PTO would have failed to find any of the '358 Patent claims unpatentable had the PTO been aware of the IMAST Abstract.

29. Medtronic did not prove, under the PTO's preponderance of the evidence standard, that the IMAST Abstract is but-for material.

30. Medtronic did not prove by clear and convincing evidence that Dr. Barry or Mr. Henry had a specific intent to deceive in failing to disclose the IMAST Abstract.

It is undisputed that Dr. Barry was aware of the IMAST Abstract (PX 21); he prepared it for the 2004 IMAST Conference. *See* Tr. at 197:10–198:7; 202:8–19.[25] What is disputed is whether the IMAST Abstract was but-for material, and if so, whether Dr. Barry was aware of its materiality and intended to deceive the PTO by withholding the reference. On all of these points, Medtronic failed to carry its burden.

Medtronic seems to claim that the IMAST Abstract is but-for material because it is an invalidating printed publication under Section 102(b). In other words, Medtronic claims that the abstract is but-for material because it discloses each limitation of the '358 patent by describing pre-critical date surgeries that were "predictable and reproducible." Dkt. 436 at 19. Yet, Medtronic did not assert the IMAST Abstract as prior art at trial. Even by a preponderance of the evidence standard, when a party abandons a reference in its invalidity case during litigation, it is difficult for this court to conclude that the reference is but-for material. *See* Findings ## 28, 29.

Even if the IMAST Abstract was material, Medtronic did not prove by clear and convincing evidence that Dr. Barry was aware of its materiality, meaning this court cannot find a specific intent to deceive. *See* Finding # 30. The MPEP reminds us that the knowledge must exist during the pendency of the application. MPEP (8th ed. Rev. 2, May 2004) § 2001.04 ("the duty applies to contemporaneously or presently known information . . . . The duty to disclose information . . . extends until a patent is granted on that application."). To show Dr. Barry's awareness, Medtronic identifies Dr. Barry's December 2015 IPR declaration and his testimony that the abstract "appears to" contain a table that shows where each element of the '358 Patent claims is described in the

[25] The court does not dwell here on the conduct or failure to disclose by Mr. Henry. Similar to the pre-2004 surgeries, Mr. Henry was not aware of the IMAST Abstract or the IMAST presentation. *See* Finding # 27. Therefore, Mr. Henry's conduct cannot constitute a failure to disclose.

IMAST Abstract. *See* Dkt. 436 at 19; Tr. at 2256:2–2259:1. But that qualified statement does not establish that each claim of the '358 Patent was described. *See* Tr. at 2259:2–14. And the 2015 PTAB declaration is not probative of whether Dr. Barry was aware *during prosecution* of the materiality of the IMAST Abstract. Medtronic did not elicit testimony from Dr. Barry on this crucial point.

Again, Medtronic does not allege factual allegations supporting a specific intent to deceive specific to the IMAST Abstract by itself. *See* Finding # 22. Therefore, the court assumes that Medtronic must rely on the same general allegations regarding Dr. Barry's and Mr. Henry's deceit and, for the same reasons that those allegations were rejected with regard to other references, the court rejects Medtronic's specific intent allegations with regards to the IMAST Abstract.

On the part of Mr. Henry, just as was the case with other alleged prior art, Mr. Henry testified that he was unaware of the existence of the abstract during prosecution; Dr. Barry admits that he never discussed the reference with Mr. Henry. *See* Finding # 27. The court finds both witnesses' testimony credible on this point, and as such, Medtronic's theory as to Mr. Henry fails. *See* Finding # 30.

3. Dr. Barry's interactions with medical device companies

Findings

31. Medtronic did not establish that Dr. Barry was aware at the time of application that he was required to disclose to the PTO his interactions with medical device companies SpineVision, Interpore Cross International, or DePuy as potentially invalidating prior uses, offers for sale, or sales.

32. Mr. Henry was not aware at the time of prosecution of Dr. Barry's interactions and discussions with medical device companies prior to the critical date. Tr. at 2206:10–2207:15.

33. Medtronic did not prove, under the PTO's preponderance of the evidence standard, that the PTO would have failed to find any of the '358 Patent claims unpatentable had the PTO been aware of Dr. Barry's pre-critical date interactions with medical device companies.

34. Medtronic did not prove, under the PTO's preponderance of the evidence standard, that the interactions with medical device companies are but-for material.

35. Medtronic did not prove by clear and convincing evidence that Dr. Barry or Mr. Henry had the specific intent to deceive by failing to disclose Dr. Barry's interactions with medical device companies.

Medtronic also alleges that Dr. Barry's interactions with medical device companies were but-for material to patentability as invalidating offers for sale under the on-sale bar of Section 102(b).[26] At trial, Medtronic relied on these interactions as prior art. It claimed that they were invalidating activities pursuant to 35 U.S.C. § 102(b) as prior public disclosures and under the on-sale bar. The jury received a detailed instruction on the on-sale bar, including an instruction that incidental benefit derived from a "sale" does not amount to an invalidating commercial activity. Dkt. 414 at 25–26. The jury did not find that any of the claims were invalid under either theory. Dkt. 411 (Jury Verdict), Questions ## 5, 6. In its Order on Medtronic's motions for JMOL, the court found that there was substantial evidence to support the jury's findings. Dkt. 442 at pp 35–39. As the court understands *Therasense,* these would be underlying factual determinations, for which Medtronic had the burden of proof under a clear and convincing standard.

Based on the evidence and the court's evaluation of the credibility of the witnesses, the court also finds under a preponderance of the evidence standard that Dr. Barry's activities with

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[26] Given the broad array of theories advanced by Medtronic based on several sets of discrete activities, the specific grounds for each of its inequitable conduct theories is unclear. Even at trial, the jury heard about several sets of potentially invalidating activities, and during closing argument, Medtronic left it to the jury to fit the activities into a particular category of prior art—which the jury obviously refused to do. To the extent that Medtronic argues that Dr. Barry's interactions with medical device companies were also invalidating public disclosures, there was no evidence that Dr. Barry disclosed each and every limitation during any of these alleged "disclosures." Also, at least one such representative testified that these types of meetings were held in confidence, debunking the idea that these meetings may have been public disclosures. Therefore, the court cannot reach a finding that these meetings would be but-for material even as potential public disclosures.

medical device companies were not but-for material to patentability. *See* Findings ## 33, 34. The evidence does not establish that Dr. Barry's interactions with medical device companies like DePuy and SpineVision were "offers for sale" that would invoke the on-sale bar. As this court pointed out in its prior Order on JMOL, Medtronic tried and failed to elicit testimony that Dr. Barry approached these companies with an offer to perform his method for them or sell his method or system to them for any purpose. Dkt. 442 at 36–38. Instead, Dr. Barry stated that he "didn't think he was ready to sell it" and called at least one of those meetings "a preliminary meeting to talk about" his "system that was in evolution." Tr. at 437:7–13. If the discussions were not offers for sale of his invention, those discussions could not have been but-for material.

To the extent that Medtronic alleges that these were public disclosures about his invention, the evidence did not establish that Dr. Barry discussed or publicly disclosed each and every claim limitation in front of third-party sales representatives. In fact, there is credible testimony from Mr. Pfefferkorn, an uninterested witness, that those interactions occurred in confidence. Tr. at 679:1–681:1 (Pfefferkorn testifying about a specific 2003 meeting with DePuy was confidential). Therefore, Dr. Barry had no duty to disclose those discussions to the PTO, and this activity cannot serve as the basis for an inequitable conduct failure to disclose claim.[27] *See* Finding # 35. Additionally, for the same reasons discussed previously, Medtronic failed to prove a specific intent to deceive. *Id.* These activities therefore cannot constitute the basis of Medtronic's inequitable conduct claim.

[27] As with Medtronic's other theories related to failure to disclose material prior art, Mr. Henry credibly testified that he was unaware of the allegedly invalidating activity (*see, e.g.*, Tr. at 2212:13–24). Medtronic did not present clear and convincing evidence to the contrary. Because Mr. Henry was not aware of the references, he was not under a duty to disclose them to the PTO, and his omission cannot be the basis for Medtronic's inequitable conduct defense.

4. Dr. Lawrence Lenke's allegedly invalidating activity[28]

Findings

36. Medtronic did not establish by clear and convincing evidence that either Dr. Barry or Mr. Henry were aware of Dr. Lenke's work on a similar invention prior to filing his patent application.

37. The earliest date on which Dr. Barry was aware of Dr. Lenke's use of *unlinked* multiple derotators is "prior to the filing date of the '358 patent, December 30, 2004." *See* Tr. at 2241. Medtronic did not establish that Dr. Barry was aware of *linked* multiple derotators prior to the filing of the '358 patent. *See* Tr. at 347–48 (Dr. Barry testifying that he knows "now" (after the lawsuit) that Dr. Lenke was doing multiple derotations surgery in the early 2000s or possibly 2002).

Medtronic included this theory in its Proposed Findings of Fact but did not include it in post-trial briefing (Dkt. 436). This was prudent. As the court pointed out during the course of the bench trial (*see* Tr. at 2243:1–2244:11), there is no evidence that Dr. Barry was aware that Dr. Lenke worked on potentially invalidating work, let alone appreciated the materiality of that work. *See* Finding # 36. Dr. Barry testified that he became aware of Dr. Lenke's work in using *unlinked* derotators prior to the date of the filing the '358 patent. *See* Finding # 37; Tr. at 2241. Dr. Barry did not testify that he knew about linked derotators prior to filing for his patents. When pressed for more on this point by the court during the bench trial, Medtronic could not respond. Tr. at 2243:3–2244:11. This nullifies Medtronic's failure to disclose theory. *Therasense* requires knowledge of a reference (which Medtronic did not establish) before it requires knowledge of the reference's materiality. Medtronic did not cite, and the court has not found, a case in which a

[28] At trial, Medtronic relied on Dr. Lawrence Lenke's alleged prior invention, namely his development of and work on the "apical derotator project" as prior art. It claimed that work was invalidating pursuant to 35 U.S.C. § 102(g)(2) as a prior invention. The jury did not find that any of the claims were invalid due to prior invention. Dkt. 411 (Jury Verdict) at pp. 8–9 (Question No.7).

challenger raised an inequitable conduct claim based on a reference where no evidence supports the preliminary finding that the patentee was aware of that reference. Without evidence of Dr. Barry's or Mr. Henry's awareness of the alleged prior art, Dr. Lenke's allegedly invalidating activity cannot serve as the basis for Medtronic's inequitable conduct claim, regardless of materiality.

IV. CONCLUSION

Despite its shotgun approach, Medtronic failed to establish by clear and convincing evidence, for any of its theories, the required specific intent to deceive. As to the materiality prong of inequitable conduct, Medtronic failed to establish requisite underlying facts by clear and convincing evidence, and in most, perhaps all, cases, even by a preponderance of the evidence. Likewise, Medtronic did not establish by a preponderance of the evidence that had the PTO been aware of the acts or references in question, the PTO would have rejected any of the asserted claims.

In the end, each of Medtronic's inequitable conduct theories rests on the unproven *ipse dixit* conclusion that Dr. Barry and/or Mr. Henry knowingly intended to deceive the PTO; therefore, had the PTO known of this deceit, the PTO, more likely than not, would have rejected the claims. The court must reject this logical fallacy.

It is THEREFORE ORDERED that Medtronic's affirmative defense of inequitable conduct is DENIED, and Medtronic's Counterclaim III, entitled "Unenforceability of the Asserted Patent Due to Inequitable Conduct" (Dkt. 77 at 24–25), is DISMISSED WITH PREJUDICE.

So **ORDERED** and **SIGNED** this **24** day of **March, 2017.**

Ron Clark, United States District Judge