IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

W.L. GORE & ASSOCIATES, INC.,)
Plaintiff,)
v.	Civil Action No. 11-515-LPS-CJB
C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,)))
Defendants.)

MEMORANDUM ORDER

In this action filed by Plaintiff W.L. Gore & Associates, Inc. ("Gore" or "Plaintiff") against Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard" or "Defendants"), Gore alleges infringement of United States Patent No. 5,735,892 (the "asserted patent" or the "patent-in-suit"). Presently before the Court is Defendants' *Daubert* motion ("Motion") to exclude the testimony of Plaintiff's patent office expert, Nicholas Godici. (D.I. 250) For the following reasons, the Court GRANTS-IN-PART the Motion.²

I. BACKGROUND³

Gore also originally asserted infringement of U.S. Patent No. 8,221,487, but is no longer asserting that patent. (D.I. 191 at 1-2) It also was asserting infringement of U.S. Patent No. 5,700,285, but that patent is no longer at issue following the District Court's adoption of the Court's recommendation to grant summary judgment of non-infringement of the patent. (D.I. 405 at 10-11; D.I. 423)

Under the circumstances here, the resolution of this *Daubert* Motion is properly treated as non-dispositive, and is resolved by the Court pursuant to 28 U.S.C. § 636(b)(1)(A) and D. Del. LR 72.1(a)(2). *See, e.g., Withrow v. Spears*, 967 F. Supp. 2d 982, 987 n.1 (D. Del. 2013) (citing cases).

The Court will assume familiarity with the background facts and procedural history detailed in its previously-issued Report and Recommendations. (*See, e.g.*, D.I. 221, 361, 369, 428, 429, 435, 436)

On June 10, 2011, Gore commenced this action. (D.I. 1) On November 29, 2011, this case was referred to the Court by Chief Judge Leonard P. Stark to hear and resolve all pretrial matters, up to and including the resolution of case dispositive motions. (D.I. 20) On January 10, 2014, Bard timely answered Gore's Second Amended Complaint, asserting, *inter alia*, counterclaims seeking a declaratory judgment of unenforceability due to inequitable conduct (the "counterclaims"), (D.I. 189), which Gore has answered, (D.I. 194).

Bard's counterclaims assert that the applicants committed inequitable conduct by failing to disclose "material, non-cumulative information" from two physicians who invented intraluminal grafts, Dr. Peter Lee and Dr. Christian Vallbracht. (D.I. 189 at ¶¶ 18-68; *see also* D.I. 251 at 6 n.4) Bard's allegations can be divided into four categories relating to the following submissions: (1) U.S. Patent No. 5,123,917 ("Lee patent") (the applicants mischaracterized the Lee patent's disclosures by grouping it with another reference in the asserted patent's specification); (2) material referred to as "Other Lee Work" (the applicants withheld this material, non-cumulative information from the United States Patent and Trademark Office ("PTO")); (3) DE 3918736 ("Vallbracht patent") (the applicants misled the PTO by submitting an inaccurate translation of the German-language Vallbracht patent that omitted one sentence containing key information); and (4) material referred to as "Other Vallbracht Work" (the applicants withheld this material, non-cumulative information from the PTO). (D.I. 189 at ¶¶ 18-68; *see also* D.I. 251 at 6 n.4; D.I. 293 at 2-3)

Gore retained Mr. Godici as an expert in connection with this action, and his expert report relates to Bard's counterclaims regarding inequitable conduct. (D.I. 252, ex. A (hereinafter, "Godici Report") at ¶ 1) Mr. Godici had a 40-year career at the PTO, beginning as a patent

examiner and serving as the Commissioner for Patents during his last five years of employment there. (Godici Report at ¶¶ 4-6) He is not an attorney. (D.I. 252, ex. B (hereinafter, "Godici Dep.") at 10)

On September 11, 2014, Bard filed the instant Motion. (D.I. 250) Briefing on the Motion (and various other *Daubert* and summary judgment motions filed by the parties) was completed on November 12, 2014. (D.I. 331) A 10-day trial is set to begin on December 7, 2015. (D.I. 362)

II. STANDARD OF REVIEW

The admissibility of expert testimony is a question of law governed by Rule 702 of the Federal Rules of Evidence. *See Daubert v. Merrell Dow Pharm., Inc.*, 113 S. Ct. 2786 (1993). Under Rule 702, "(1) the proffered witness must be an expert; (2) the expert must testify to scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995). The admissibility of expert testimony is within the discretion of the Court. *See Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

Overall, "Rule 702 embodies a 'liberal policy of admissibility." *B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 222 (D. Del. 2010) (quoting *Pineda*, 520 F.3d at 243). However, expert testimony regarding legal conclusions is not permissible. *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006); *The Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, No. Civ.A. 04-940-JJF, 2006 WL 2241018, at *1 (D. Del. Aug. 4, 2006). The burden is placed on the party offering expert testimony to show that it meets each of the standards for admissibility. *B. Braun Melsungen AG*, 749 F. Supp. 2d at 222 (citing *Daubert*,

III. DISCUSSION

According to Mr. Godici's report, he proposes to offer opinions regarding issues raised by Bard's inequitable conduct allegations,⁵ as well as certain practices and procedures of the PTO. (Godici Report at ¶ 1) Bard seeks the exclusion of Mr. Godici's testimony in its entirety. Specifically, Bard moves to exclude his opinions relating to (1) the law of inequitable conduct, (2) the applicants' state of mind, (3) the examiner's state of mind, (4) the technology at issue, and (5) the ultimate issue of inequitable conduct. Bard asserts that these opinions are beyond the

Although Bard requested oral argument on its then-pending summary judgment and *Daubert* motions, (which the Court held), (D.I. 343), neither party sought an evidentiary hearing as to this *Daubert* motion or suggested that the factual record was insufficiently developed such that a hearing of that type was required. The United States Court of Appeals for the Third Circuit has held that a trial court need not conduct an evidentiary hearing on a *Daubert* challenge if the record is sufficient to allow the Court to make a determination on the issues in dispute. *See, e.g., Oddi v. Ford Motor Co.*, 234 F.3d 136, 151-55 (3d Cir. 2000); *Maldonado v. Walmart Store No. 2141*, Civil Action No. 08-3458, 2011 WL 1790840, at *13 n.10 (E.D. Pa. May 10, 2011). Here, Mr. Godici's expert report was provided to the Court, as was his deposition testimony regarding the report. The parties also ably addressed issues relating to Mr. Godici's report in their briefing. Under such circumstances, and in light of the legal questions at issue, the Court has determined that the record before it is sufficient to allow for a decision on the admissibility of Mr. Godici's testimony under *Daubert. See, e.g., Furlan v. Schindler Elevator Corp.*, 516 F. App'x 201, 205-06 (3d Cir. 2013); *Oddi*, 234 F.3d at 151-55; *Maldonado*, 2011 WL 1790840, at *13 n.10.

Applicants for patents and their legal representatives have a duty to prosecute patent applications with candor, good faith and honesty. See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 999 (Fed. Cir. 2007); 37 C.F.R. § 1.56(a). A breach of this duty constitutes inequitable conduct. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). A finding of inequitable conduct renders the entire patent unenforceable. Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988). "The ultimate determination of inequitable conduct is committed to the trial judge's discretion[.]" Molins, 48 F.3d at 1178. To prevail on an inequitable conduct claim, the accused infringer must establish, by clear and convincing evidence, that "the applicant misrepresented or omitted material information with the specific intent to deceive the PTO." Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc).

scope of Mr. Godici's expertise. (D.I. 251, 331) Bard additionally contends that Mr. Godici's remaining testimony relating to PTO practices and procedures is unhelpful and unnecessary given the Court's familiarity with such matters, and should be excluded to the extent the Court agrees. (D.I. 251 at 1-2, 17)

For its part, Gore asserts that Mr. Godici's report does not offer opinions regarding the law of inequitable conduct, the intent of the applicants, the state of mind of the examiner, ultimate legal conclusions, or stent graft technology. (D.I. 293 at 1) Instead, Gore argues, Mr. Godici "applies his expertise on PTO practice and procedure to the evidence in the record and analyzes issues such as whether the record objectively indicates that the Gore applicants made attempts to meet their duties to the PTO, and whether the record establishes that the allegedly withheld information meets the procedural prior art and materiality standards of the PTO." (*Id.* at 1-2) In other words, Gore characterizes *all* of Mr. Godici's testimony as relating to PTO practice and procedure. (*See id.* at 7-15 (including all of Mr. Godici's testimony under the umbrella of "PTO Practice and Procedures"))

As both parties appear to recognize, this Court has a strong and consistent view with respect to the admittance of the testimony of "patent law experts." (See D.I. 251 at 7-8; D.I. 293 at 6) This Court has at times permitted testimony from such experts, including with regard to inequitable conduct allegations, so long as the testimony clearly related to the ins and outs of internal PTO practices and procedures. See, e.g., Brigham & Women's Hosp. Inc. v. Teva

The decision is a discretionary one for this Court, however, and in some instances, even this type of testimony has been excluded. *See, e.g., AstraZeneca UK Ltd., IPR v. Watson Labs., Inc. (NV)*, C.A. No. 10-915-LPS, 2012 WL 6043266, at *2 (D. Del. Nov. 14, 2012) (excluding the testimony of a patent law expert regarding, *inter alia*, "procedures at the PTO[,]" concluding that it "w[ould] not be helpful to the Court"); *Corning Inc. v. SRU Biosys.*, Civil

Pharm. USA, Inc., Civil Action No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) (explaining that "[t]he law permits experts in patent cases to offer [] testimony" regarding "the practices and procedures of the PTO") (citing cases); The Proctor & Gamble Co., 2006 WL 2241018, at *1 (restricting patent law expert's testimony to PTO practice and procedures). However, this Court has routinely excluded the testimony of patent law experts reaching beyond the scope of that narrow topic, including as to other issues relating to inequitable conduct (largely because such testimony frequently amounts to the proffering of impermissible legal conclusions). See, e.g., AstraZeneca UK Ltd., IPR v. Watson Labs., Inc. (NV), C.A. No. 10-915-

Action No. 03-633 JJF, 2004 WL 5523178, at *1 (D. Del. Nov. 5, 2004) (granting the defendants' motion to exclude the expert report and testimony of the plaintiffs' patent law expert, which dealt "primarily with internal patent office procedures"); *Syngenta Seeds, Inc. v. Monsanto Co.*, No. Civ.02-1331-SLR, 2004 WL 2106583, at *1-2 (D. Del. Sept. 8, 2004) (excluding the opinions of patent law expert which included, *inter alia*, general overviews of patent law and the PTO because "the jury is shown a Federal Judicial Center video about patent law, PTO policies and procedures" that "is a sufficient basis for instructing jurors").

Other district courts likewise permit this type of testimony from patent law experts. See, e.g., Wright Asphalt Prods. Co., LLC v. Pelican Ref. Co., LLC, Civil Action No. H-09-1145, 2012 WL 1936416, at *7 (S.D. Tex. May 29, 2012) (noting that "[c]ourts do allow former patent examiners to testify generally about the patent-application process before the [PTO]") (citing cases); Nisus Corp. v. Perma-Chink Sys., Inc., No. 3:03-CV-120, 2005 WL 6112992, at *4 (E.D. Tenn. May 27, 2005) ("Expert testimony regarding general procedures of the patent application process may be helpful to a jury and is therefore admissible.") (citing cases); Pharmacia Corp. v. Par Pharm., Inc., Civil Action No. 01-6011(SRC), 2004 WL 5614917, at *2 (D.N.J. Feb. 18, 2004) ("In patent cases, courts generally have determined that testimony by a patent law expert may include information regarding patent prosecution procedures and policies and practices followed by the PTO[.]").

The Court has also set out additional reasons for this practice. For instance, a patent law expert's testimony regarding inequitable conduct can implicate an inventor's or examiner's supposed "intent, motive, or state of mind" which is beyond the bounds of permissible expert testimony. See, e.g., AstraZeneca UK Ltd., IPR v. Watson Labs., Inc., C.A. No. 10-915-LPS, 2012 WL 6043266, at *3 (D. Del. Nov. 14, 2012) (internal quotation marks and citations omitted). This Court has also explained that it "is presumed to be the patent law expert" in explaining why it does not generally regard this type of expert testimony to be helpful to the

LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012) ("[T]he judges in this District have a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances.") (citing cases); *Brigham & Women's Hosp. Inc.*, 2010 WL 3907490, at *2 ("The law of this district is clear that experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on 'substantive issues of patent law.'") (citing cases); *In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) (excluding patent law expert's opinions and testimony regarding the intent prong of inequitable conduct); *Revlon Consumer Prods. Corp. v. L'Oréal S.A.*, Civil Action No. 96-192 MMS, 1997 WL 158281, at *3 (D. Del. Mar. 26, 1997) (concluding that while the proffered patent law expert could testify with respect to "matters of PTO practice and procedure[,]" it would not allow him "to testify as an expert on inequitable conduct; to do otherwise would usurp the respective functions of the . . . Court").

Here, the Court will permit Mr. Godici's opinions and proposed testimony regarding general PTO practice and procedure.⁹ As indicated above, this Court has sometimes permitted such testimony to be offered, and it might be helpful to the fact-finder here. And the Court will likewise permit Mr. Godici's summary of the prosecution history of the asserted patents.¹⁰ Such

trier of fact. Software AG v. BEA Sys., Inc., Civil Action No. 03-739-GMS, D.I. 234 (transcript of pretrial conference), at 20 (D. Del. Apr. 4, 2005) (D.I. 252, ex. C).

⁹ Mr. Godici's opinions relating to this topic are found in Paragraphs 14-34 and 81 of his report. (Godici Report at ¶¶ 14-34, 81; see also D.I. 251 at 7)

This summary is found in Paragraphs 38-39, 47, 51-54, and 56-59 of Mr. Godici's Report. (Godici Report at \P 38-39, 47, 51-54, 56-59; *see also* D.I. 251 at 7)

testimony is sometimes admitted and sometimes excluded. *Compare Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, Civil Action No. 05-CV-1887 (DMC), 2009 WL 3754170, at *8 (D.N.J. Nov. 5, 2009) (permitting patent law expert to testify regarding "the underlying facts regarding the prosecution of the [asserted patent applications]"), *with Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, Civil Action No. 05-700 (JJF), D.I. 197 (transcript of pretrial conference), at 16-21 (D. Del. Feb. 7, 2008) (D.I. 252, ex. E) (precluding "walk-through" of file histories provided by a patent law expert). But here, it appears harmless, and it could be helpful to hear this case-specific summary of what was filed when in context with Mr. Godici's discussion of general PTO procedures that relate to such filings. Of course, it may well be that the District Court (who will hear the evidence relating to inequitable conduct and will ultimately decide the inequitable conduct issue) will ultimately determine that even these two categories of testimony will not be particularly "helpful" to it. *AstraZeneca UK Ltd.*, 2012 WL 6043266, at *2. But the Court will not exclude them at present.

Beyond those topics, however, the Court determines that the remaining portions of Mr. Godici's expert report (i.e., the majority of the report) is the just the sort of testimony that this Court routinely excludes. After his overview of the patent application and examination process, and his discussion of a patent applicant's duties to the PTO, (Godici Report at ¶¶ 14-34), "Godici then reviews the prosecution records of the patent[]-in-suit and explains how these records objectively indicate that the Gore applicants made attempts to meet their duties to the PTO[,]" (D.I. 293 at 3 (citing Godici Report at ¶¶ 40-60)). For example, Mr. Godici notes that the "applicants specifically called the examiner's attention to the Lee [] patent by referencing it in the specification[,]" and therefore opines that "according to established PTO practices and

procedures, patent applicants are not required to discuss the prior art in their specification at all, so the fact that applicants here chose to call the examiner's attention to the Lee [] patent . . . is a further indication that applicants in this case were attempting to fulfill and exceed their duties to the PTO." (Godici Report at ¶ 43)

The remainder of Mr. Godici's report provides his analysis and opinions regarding Bard's allegations of inequitable conduct. (Id. at ¶¶ 61-108) He first considers the Lee patent and explains that the applicants had no obligation to mention the Lee patent in the specification at all, and that there does not appear to be any affirmative mischaracterization of the Lee patent by the applicants in the '892 patent's specification, nor any evidence that the examiner was actually misled by its placement in the specification. (Id. at ¶¶ 62-69) Next, Mr. Godici considers the Other Lee Work and opines that the patent examiner would not have considered the information to be prior art to the asserted patents. (Id. at ¶¶ 70-86) He then assumes that the Other Lee Work is prior art and discusses why, in his opinion, the examiner would have found the information to be immaterial and cumulative. (Id. at ¶¶ 87-94) Lastly, he examines Bard's allegations of inequitable conduct relating to Dr. Vallbracht. (Id. at ¶¶ 95-108) With respect to the missing sentence from the Vallbracht patent's translation, he opines that its omission was not a violation of the applicants' duty of disclosure because they were only required to submit a translation of the abstract (from which the omitted sentence did not come) or an explanation of the relevance of the reference. (Id. at \P 96-98) Moreover, he opines that the omission was not a violation of the applicants' duty of candor and good faith because there was no evidence that they were aware of the error; he also asserts that the omission was cumulative of other information already submitted. (Id. at ¶¶ 99-101) As for the Other Vallbracht Work, Mr. Godici opines that the

inventors were not involved in the correspondence making up this category of material, that there is no evidence indicating they knew of this information, and that therefore, they did not violate any duty of disclosure. (Id. at ¶¶ 102-07) He adds that Gore's expert Dr. Criado has opined that the Other Vallbracht work is immaterial and cumulative of information submitted to the PTO, and that it therefore was not required to be submitted. (Id. at ¶ 108)

Despite Gore's attempt to paint it as such, this is not testimony about "PTO practices and procedures" of the type the Court has sometimes permitted in the past. Rather, Bard is correct that the majority of Mr. Godici's opinions constitute "an improper attempt to offer opinions from a legal expert about what the facts of the record 'indicate' to him about materiality, intent, and what the examiner would have done had circumstances been different." (D.I. 331 at 2) Indeed, during his deposition, Mr. Godici agreed that his "analysis is to provide opinions on what would have happened in the [PTO] if certain information that was not disclosed . . . had been disclosed to the [PTO]." (Godici Dep. at 136) This testimony is infused to too great a degree with what sounds like legal opinion, or with speculation as to what may have been in another's mind—evidence that is either unhelpful to the fact-finder or that which the expert is not qualified to give. In line with the consistent practice of this Court (and many others), the Court will not permit Mr. Godici to offer such testimony here. See, e.g., S.O.I. TEC Silicon On Insulator Techs., S.A. v. MEMC Elec. Materials, Inc., 745 F. Supp. 2d 489, 507 n.16 (D. Del. 2010) (denying the defendant's motion to admit the expert testimony of a patent law expert who proposed to testify regarding, *inter alia*, how the applicants misused certain PTO procedures, where the expert had no specific knowledge of the patent applicants at issue or the examiner's treatment of same); In re Rosuvastatin Calcium Patent Litig., 2009 WL 4800702, at *8

(excluding patent law expert's testimony which was directed to the "supposed state of mind or intent" of the patent applicants); *Software AG v. BEA Sys., Inc.*, Civil Action No. 03-739-GMS, D.I. 234 (transcript of pretrial conference), at 17-25 (D. Del. Apr. 4, 2005) (D.I. 252, ex. C) (granting the plaintiff's motion to exclude the testimony of a former patent prosecutor and PTO examiner whose proposed testimony related to inequitable conduct and, *inter alia*, offering opinions regarding "the materiality of [certain] references"); *Ondeo Nalco Co. v. EKA Chems., Inc.*, No. Civ.A. 01-537-SLR, 2003 WL 1524658, at *3 (D. Del. Mar. 21, 2003) (finding that patent law expert's "walk[] through' [of] the file history of the [asserted patent] and [opinions] as to how the [PTO] would have responded had certain prior art been disclosed to it during the prosecution of the [asserted] patent. . . . exceeds the permissible scope of a patent law expert's testimony").¹¹

IV. CONCLUSION

For the reasons set out above, the Court hereby ORDERS that Bard's Motion be GRANTED-IN-PART. Specifically, the Court will permit Mr. Godici's testimony regarding

See also Degelman Indus. Ltd. v. Pro-Tech Welding & Fabrication, Inc., No. 06-CV-6346T, 2011 WL 6752565, at *6 (W.D.N.Y. Dec. 23, 2011) (allowing Mr. Godici to testify regarding PTO practice and procedure but precluding him from testifying on the issue of whether or not the plaintiff engaged in inequitable conduct before the PTO); Novartis Pharm. Corp., 2009 WL 3754170, at *8 (forbidding patent law expert from testifying as to the mental states of the patentees, from drawing inferences from the underlying facts of the prosecution histories with respect to the intent of such parties in presenting the patent applications at issue, and from expressing an opinion concerning whether the absence of material alleged to be prior art constitutes inequitable conduct); Pharmacia Corp., 2004 WL 5614917, at *2 (excluding the testimony of a patent law expert who intended to testify "regarding alleged inequitable conduct in connection with prosecution of [the asserted patents and] his conclusion that 'a reasonable patent examiner' would have considered particular information as important in making the decision to issue [the asserted patent]," as "[i]t is precisely this type of testimony infused with legal opinion that courts have precluded as unhelpful").

general PTO practices and procedures and a summarization of the prosecution history of the asserted patent, but will exclude the remainder of Mr. Godici's testimony.

Because this Memorandum Order may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Memorandum Order. Any such redacted version shall be submitted no later than **November 30, 2015** for review by the Court, along with a detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Order.

Dated: November 20, 2015

Christopher J. Burke

UNITED STATES MAGISTRATE JUDGE

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