WO

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Bard Peripheral Vascular, Inc., and David Goldfarb, M.D.,

Plaintiffs,

v.

W. L. Gore & Associates, Inc.,

Defendant.

No. CV 03-0597-PHX-MHM

ORDER

Before the Court is Defendant's Brief on Remand Regarding Objective Reasonableness of Defenses. (Doc. 1111 ("Def.'s Br.")). Plaintiffs have filed responsive briefing and Defendant has filed reply briefing. (Doc. 1115, Pls.' Br. in Resp. to Def.'s Br. Regarding Reconsid. of JMOL of No Willful Infringement ("Pls.' Resp. Br."); Doc. 1120, Def.'s Reply Br. on Remand Regarding Objective Reasonableness of Defenses ("Def.'s Reply Br.")). Counsel for the parties presented oral argument on June 12, 2013. (Doc. 1132).

I. BACKGROUND

This patent infringement case was tried before a jury in 2007. The patent at issue (U.S. Patent No. 6,436,135 ("'135 patent" or "Goldfarb patent")) concerns a medical device described as a prosthetic vascular graft (artificial vascular prosthesis) made from expanded polytetrafluoroethylene ("ePTFE") with a specific microstructure. In late 1969, Defendant developed a process for making PTFE very strong and very porous and from which resulted

expanded PTFE, or ePTFE. (Doc. 786 at 1737-41). In early 1971, Defendant provided samples of ePTFE to various surgeons in furtherance of the idea that it might be used to develop a vascular product. (*Id.*). The grafts "are used to bypass or replace blood vessels to assure adequate and balanced blood flow to particular parts of the body." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, 1175 (Fed. Cir. 2012) ("*Bard I*"). Between 1983 and 2001, an Interference proceeding was ongoing in the United States Patent Office ("PTO") regarding a determination of the inventor of the vascular grafts. (Doc. 790 at 2756). Defendant advanced the position that its employee Peter Cooper[1] was the prior inventor as opposed to Plaintiff David Goldfarb, M.D. *See Cooper v. Goldfarb*, 154 F.3d 1321 (Fed. Cir. 1998) ("*Cooper I*").[2] The Patent Office issued the patent to Dr. Goldfarb in 2002 as the prior inventor. *See Cooper v. Goldfarb*, 240 F.3d 1378 (Fed.Cir. 2001) ("*Cooper II*"). Plaintiffs filed this patent infringement suit against Defendant in March 2003. (Doc. 1, Compl.).

During trial, Defendant presented evidence on several defenses to the patent's validity, including anticipation, obviousness, written description, and improper inventorship, and on the issue of willful infringement. The Court submitted the issue of willfulness to the jury based on prevailing legal authority at the time. The jury returned a unanimous verdict in Plaintiffs' favor, finding that Defendant had infringed the patent, the patent was not invalid, and Defendant's infringement was willful. (Doc. 771, Jury Verdict). The jury awarded Plaintiffs lost profits and a reasonable royalty on Defendant's pre-verdict infringing activity. (*Id.*). Following the jury's verdict, Defendant's motions for judgment as a matter of law ("JMOL") on a number of issues, including its defenses and on the issue of willful

---

[1] Cooper served for a period of time as Plant Manager at Defendant's Flagstaff, Arizona facility. (Doc. 786 at 1753).

[2] Cooper filed his patent application on April 2, 1974. *Cooper I*, 154 F.3d at 1325. Dr. Goldfarb filed his patent application on October 24, 1974. *Id.* at 1326.

infringement, were denied. (Doc. 833, Order; Doc. 834, Order; Doc. 938, Order; Doc. 940, Order).

Plaintiffs moved for enhanced damages, attorneys' fees, and a permanent injunction. The Court awarded enhanced damages and attorneys' fees but declined to enjoin Defendant in light of the public health considerations concerning the medical devices at issue. (Doc. 941,Order; Doc. 942, Order; Doc. 951, Order; Doc. 1057, Redacted Order). The Court found that a compulsory license would compensate Plaintiffs for Defendant's infringement. (Doc. 1057, Redacted Order). The Court also ruled that an increase of the reasonable royalty rate set by the jury was appropriate. (Doc. 1057, Redacted Order). On August 24, 2010, the Court entered an Amended Judgment on all adjudicated issues. (Doc. 1047, Am. Judgment). Defendant appealed.

On February 10, 2012, the Federal Circuit affirmed the Court's Amended Judgment. *Bard I*, 670 F.3d at 1193. The Federal Circuit affirmed this Court's rulings denying Defendant's motions for JMOL regarding Defendant's defenses of joint inventorship, anticipation, obviousness, and written description, and on the issue of willful infringement. *Id.* at 1179-92. It also affirmed the jury's verdict finding Defendant's infringement willful and this Court's awards of enhanced damages, attorneys' fees, and ongoing royalty. *Id.* at 1189-93.

Defendant petitioned for rehearing. The Federal Circuit "denie[d] en banc review, but grant[ed] rehearing en banc for the limited purpose of authorizing the panel to revise the portion of its opinion addressing willfulness," and "return[ed] [the] appeal to the merits panel." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 476 F. App'x 747 (Fed. Cir. June 14, 2012).

The panel issued its decision in *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003 (Fed. Cir. 2012) ("*Bard II*"), *cert. denied*, 133 S.Ct. 932 (2013), "reaffirm[ing] its opinion issued on February 10, 2012, except for section E and that portion of section F relating to Section 284 and 285 of Title 35 of the United States Code allowing

for enhanced damages and attorneys' fees," which were vacated as related to willfulness. *Bard II*, 682 F.3d at 1005. In its analysis, the Federal Circuit endorsed the two-prong subjective and objective standard of *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc), but "clarified the legal standard for *Seagate's* objective willfulness prong" by holding that "the objective determination of recklessness, even though predicated on underlying mixed questions of law and fact, is best decided by the judge as a question of law subject to *de novo* review." *Bard II*, 682 F.3d at 1006-08. The Federal Circuit "remand[ed] the issue of willfulness so that the trial court may reconsider its denial of JMOL of no willful infringement in view of this holding." *Id.* at 1005. The appellate court's remand included the following instructions:

> On remand, therefore, the court should determine, "based on the record ultimately made in the infringement proceedings," whether a "reasonable litigant could realistically expect" those defenses to succeed. . . . If, in view of the facts, the asserted defenses were not reasonable, only then can the jury's subjective willfulness finding be reviewed for substantial evidence.

Id. at 1008 (citations omitted). The Federal Circuit further instructed that, "[i]f the court grants the JMOL, it should then reconsider its decisions on enhanced damages and attorneys' fees." *Id.* at 1005.

II. DISCUSSION

A. Standard of Review

This Court's review of Defendant's defenses is "'based on the record ultimately made in the infringement proceedings'" and involves a determination of "whether a 'reasonable litigant could realistically expect' those defenses to succeed." *Bard II*, 682 F.3d at 1008 (citation omitted). In *Highmark, Inc. v. Allcare Health Management Systems, Inc.*, 687 F.3d 1300 (Fed. Cir. 2012), *cert. granted*, 81 U.S.L.W. 3562 (U.S. Oct. 1, 2013) (No. 12-1163), the Federal Circuit stated that the objective prong "requires a retrospective assessment of the merits of the entire litigation determined 'based on the record ultimately made in the infringement proceedings.'" *Highmark*, 687 F.3d at 1310. Stated another way, "[t]he objective prong is a single backwards-looking inquiry into the reasonableness of the claims

in light of the full record." *Id.* at 1310-11. The *Highmark* court noted *Bard II's* explanation that "the objective reasonableness test was based on the objective prong of the standard for sham litigation," as explained in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.,* 508 U.S. 49, 60-61 (1993). *Id.* at 1309-10 n.1. As the *Highmark* court explained, "the objective reasonableness determination does not require fact finding. The question is simply whether the record established in the proceeding supports a reasonable argument as to the facts and law." *Id.*

"Judgment as a matter of law is proper when the evidence permits only one reasonable conclusion and the conclusion is contrary to that reached by the jury." *Ostad v. Or. Health Sci. Univ.*, 327 F.3d 876, 881 (9th Cir. 2003). *See Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1341 (Fed. Cir. 2011) (applying the law of the regional circuit in reviewing denial of a JMOL motion).

B. Analysis

The Court previously denied Defendant's Motion for JMOL Regarding Plaintiffs' Claim of Willful Infringement and Renewed Motion for JMOL Regarding Willful Infringement. (Doc. 833, Order at 3-4; Doc. 940, Order at 21-23). The Court now reconsiders those rulings as instructed on remand upon consideration of the parties' present briefing and based on the record made in the infringement proceedings.

Defendant contends that a review of the record demonstrates that it had a reasonable expectation of success on each of its defenses. However, for purposes of remand, Defendant has focused on two of its defenses, joint inventorship based on Cooper as joint inventor, and anticipation based on the Matsumoto reference. (Def.'s Br. at 10).

Joint inventorship is a question of law "based on underlying facts." *Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ. v. Hedrick*, 573 F.3d 1290, 1297 (Fed. Cir. 2009). "[A]nticipation is a question of fact." *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974 (Fed. Cir. 2010). "When the objective prong [of willfulness] turns on fact questions, as related, for example, to anticipation, or on legal questions dependent on the

underlying facts, . . . the judge remains the final arbiter of whether the defense was reasonable, even when the underlying fact question is sent to a jury." *Bard II*, 682 F.3d at 1007.

At the outset, the Court considers Defendant's argument that its defenses were objectively reasonable because Plaintiffs did not move for summary judgment on the patent-related defenses prior to trial. (Def.'s Br. at 4-5). Defendant also contends that Plaintiffs' JMOL motions were denied, allowing the defenses to be considered by the jury, and that the dissenting opinions in *Bard I* and *Bard II* show that its defenses were reasonable. (Def.'s Br. at 5-10). The Court has considered these arguments but finds that they are not dispositive or necessarily persuasive regarding its determination of whether Defendant's defenses were objectively reasonable. The "threshold determination of objective recklessness . . . entails an objective assessment of potential defenses based on the risk presented by the patent." *Bard II*, 682 F.3d at 1006. The Court must base its decision on the "record ultimately made in the infringement proceedings."[3]

1. Joint Inventorship

Pursuant to 35 U.S.C. § 116,

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

To succeed on a joint inventorship defense, a defendant must prove by clear and convincing evidence that a person "(1) [contributed] in some significant manner to the conception or reduction to practice of the invention, (2) [made] a contribution to the claimed

---

[3] Some courts have held that "summary judgment rulings do not automatically prove that an objectively reasonable defense has been raised." *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, No. 09-290, 2012 WL 5417552, at *2 (W.D. Pa. Nov. 2, 2012) (citing *Monsanto Co. v. E.I. DuPont de Nemours & Co.*, No. 4:09-cv-686-ERW, 2012 WL 2979080, at *2 (E.D. Mo. July 20, 2012)).

invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) [did] more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998). "Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Cooper I*, 154 F.3d at 1327. An actual reduction to practice requires the inventor to prove that: "(1) he constructed an embodiment or performed a process that met all the limitations of the [claim]; and (2) he determined that the invention would work for its intended purpose." *Id.* Joint inventorship requires "collaboration or concerted effort" such as "when the inventors have some open line of communication during or in temporal proximity to their inventive efforts." *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004).

In asserting that its defense that Cooper was a joint inventor was reasonable, Defendant emphasizes that it invented the material used in the patented device, and that Dr. Goldfarb testified that in February 1973, two of Defendant's employees, Richard Mendenhall and Peter Cooper, told him about trying ePTFE tubes as an artificial vascular prosthesis. (Def.'s Br. at 12-14, referring to Doc. 782 at 677-78). Defendant cites Dr. Goldfarb's testimony that Defendant's employees provided the tubing he used in his work and that he had no expertise in the process of manufacturing the graft, stopping short of saying that in late 1973 to 1974 he had no knowledge of how to make or fabricate ePTFE vascular grafts. (*Id.*, referring to Doc. 782 at 686). Defendant argues that its joint inventorship defense was based on Cooper's furnishing to Dr. Goldfarb the embodiment of the invention before Goldfarb conceived the invention using that embodiment. (Def.'s Reply Br. at 8).

Plaintiffs argue that Defendant's defense based on Cooper as joint inventor was unreasonable. Plaintiffs contend that, based on the evidence, Defendant merely suggested that ePTFE was potentially useful as a vascular graft and then provided ePTFE tubes to numerous other physicians, but none repeatedly made a successful graft. (Pls.' Resp. Br. at

13, referring to Doc. 1115, Ex. 6, PX1271.1-8 [shipping log showing tubes shipped to other doctors]; Ex. 3, PX116.15239 [Dr. Cohn report - grafts "bled like stink"]; PX116.17671 [Dr. Eiseman report that grafts "clotted in two attempts"]; PX116.17722 [Dr. Kelly report that grafts "completely thrombosed"]; & PX116.13101 [Dr. Eiseman report that "we are doing something wrong in the use of Goretex tubes"]). Plaintiffs cite evidence showing that in February 1973, Cooper sent to Dr. Goldfarb a box of undifferentiated ePTFE tubes "in a variety of sizes" for Goldfarb to use on his "animal artery prosthetic experiments, . . . to help you [Goldfarb] with your project." (Pls.' Resp. Br. at 14, referring to Doc. 1115, Ex. 3, PX116.13350). In April 1973, Cooper sent to Dr. Goldfarb "up-to-date-research reports" and ePTFE tubes that had the walls "penetrated . . . with many . . . 50-100 micron holes." (Pls.' Resp. Br. at 14, referring to Doc. 1115, Ex. 3, PX116.13351). These "research reports" reflected the state-of-the-art and erroneously focused on macroscopic properties. (Pls.' Resp. Br. at 14, referring to Doc. 791 at 3066 & Doc. 1115, Ex. 3, PX116.16082 & PX116.16194). Plaintiffs cite Dr. Goldfarb's testimony that "puncturing" the walls of the tubes with a sewing needle "destroy[ed] the true PTFE structure" and that he cut away the punctured portions of the tubes. (Pls.' Resp. Br. at 14, referring to Doc. 780 at 376 & Doc. 1115, Ex. 3, PX116.10211).

Plaintiffs also cite Cooper's testimony indicating that after he filed the patent application, he entered Dr. Goldfarb's laboratory and took Dr. Goldfarb's research slides, stating "we were trying to get the good research results that Dr. Goldfarb had obtained" in order to see if "there was something to be learned through the microscope that could help us decide if production of variables in the grafts were important." (Pls.' Resp. Br. at 15, referring to Doc. 1115, Ex. 3, PX116.15124). Plaintiffs contend that Cooper's action in taking Dr. Goldfarb's research slides shows that "Cooper still did not understand the invention." (Pls.' Resp. Br. at 15). Plaintiffs also argue that the evidence showed that in 1979, the patent examiner investigated Dr. Goldfarb's application to determine who among

Goldfarb, Cooper, Dan Detton,[4] and others was the proper inventor, concluding that the inventor was Dr. Goldfarb. (Pls.' Resp. Br. at 16, referring to Doc. 1115, Ex. 2, PX115.593-94 & PX115.603).

The Court has considered the parties' arguments and references to the evidence. Based on the record of the proceedings, Dr. Goldfarb was the first to discover that internodal distance was the key factor, and who further identified the requisite internodal distance necessary to make a successful vascular graft and reduce it to practice. *Cooper II*, 240 F.3d at 1380 (citing *Cooper I*, 154 F.3d at 1326-27). As found by the Federal Circuit in the *Cooper* decisions, "Cooper was focusing on the porosity of the material . . . not its fibril length." *Cooper II*, 240 F.3d at 1385 (citing *Cooper I*, 154 F.3d at 1324). The Federal Circuit noted Cooper's statements admitting his minimal contact with Dr. Goldfarb:

> Indeed, Cooper admits that, even after he conceived the importance of fibril length, he did not convey that information to Goldfarb. He also admits that he did not ask Goldfarb to use grafts with fibril lengths required by the interference count, or to determine the fibril lengths of successful grafts. While Cooper was not required to communicate his conception to Goldfarb, *Cooper I*, 154 F.3d at 1332, 47 USPQ2d at 1905, his failure to convey any information or requests regarding fibril length prevents Goldfarb's determination of the fibril lengths of the material from inuring to his benefit.

Cooper II, 240 F.3d at 1385. After a lengthy Interference, the Patent Office found, as affirmed by the Federal Circuit, that Dr. Goldfarb had rightful priority to the invention, that his reduction to practice did not inure to Cooper's benefit, and that "[t]his is not a case where a party conceives the invention, and then sends out the apparatus or compound in question to another for testing to confirm that the apparatus or compound will function to achieve the result intended by the conceiver." (Doc. 1115, Ex. 3, PX116.8381); *see Cooper II*, 240 F.3d at 1384-86.

The record shows that Defendant developed ePTFE and proposed using it to develop a vascular product. Defendant's Chairman Robert W. Gore testified that in late 1970 or early

---

[4] Detton was employed by Defendant from February 1973 until the Spring of 1974 and worked in the medical products area. (Doc. 787 at 1844).

1971, his father met Dr. Ben Eiseman at a medical conference and they came up with the idea that ePTFE might make a vascular product. (Doc. 786 at 1736, 1740-41). Cooper was put in charge of overseeing the vascular graft project. (Doc. 786 at 1742). As noted by the Federal Circuit, when Cooper sent the tubes to Dr. Goldfarb, he was not aware of the importance of fibril length. *Cooper II*, 240 F.3d at 1381. No one from Defendant, including Cooper, instructed Dr. Goldfarb on how to set up his experiments, what grafts to use, or what range of variables would produce a successful graft. (Doc. 1115, Ex. 3, PX116.9768-70). Dr. Goldfarb testified during trial that Cooper had very little to do with the projects except as a communicator to some of the laboratories, and had very little contact with Goldfarb. (Doc. 781 at 408-09). Dr. Goldfarb requested additional grafts from Defendant with certain identified specifications regarding internodal distance. (Doc. 781 at 398-400). Dr. Goldfarb confirmed that shortly after he filed his patent application in October 1974, a representative from Defendant matching Cooper's description entered his laboratory without permission and took his slides and that Cooper later admitted to this act. (Doc. 781 at 424-25).

Defendant's employee Mendenhall testified in a previous proceeding that there was "no discussion of substance" from Cooper and that it was Dr. Goldfarb who explained "the characteristics that were ideal for the synthetic artery." (Doc. 1115, Ex. 3, PX116.771-72, 777-78). Mendenhall testified that naming Cooper as inventor was "probably the most unethical thing [he had] ever seen done in [his] life. It is just not true." (Doc. 1115, Ex. 3, PX116.2103). Detton, Defendant's former employee whose credibility was thoroughly examined before the jury, testified in a previous deposition that Cooper was "a hindrance to the project" and "had certainly never been an inventor at the project." (Doc. 787 at 1942). Detton testified in another previous deposition that Cooper "didn't make any grafts" and did not "extrude any tubing that was used to make grafts." (Doc. 787 at 1938-39).

Portions of Cooper's September 2004 video deposition were admitted into evidence at trial. Cooper testified that he had developed a range of fibril lengths that would be suitable for a vascular prosthetic but he was not sure of the date. (Doc. 786 at 1757, 1760). He

claimed that he was aware of the five micron limit but he could not recall who taught it to him and thought it might have been something he had read. (*Id.* at 1757-58). Cooper did not recall telling anyone about the lower limit. (*Id.* at 1759). Cooper testified that "due to my work, these tubes were created and put into David Goldfarb's hands. So I believe that that was a contribution that I made, yes." (*Id.* at 1760).

It was not reasonable for Defendant to expect that it could succeed on its defense that Cooper was a joint inventor with Dr. Goldfarb. Substantial evidence indicated a contrary finding. Relevant to the Court's reasonableness assessment of the joint inventorship defense is whether Defendant, as an objective litigant, had a realistic argument as to the facts and the law that Cooper made a contribution to the invention that was not insignificant in quality when measured against the full invention and that he engaged in collaboration or concerted effort with Dr. Goldfarb. *Pannu*, 155 F.3d at 1351; *Eli Lilly & Co.*, 376 F.3d at 1359. The PTO and the Federal Circuit found that Dr. Goldfarb's work did not inure to Cooper or to Defendant's credit. Cooper's action of providing the ePTFE tubes to Dr. Goldfarb was insignificant as the evidence shows that he punctured the tubes, he erroneously focused on porosity, and that, after applying for the patent, he took Dr. Goldfarb's research slides to help him understand an invention that he apparently did not comprehend. Cooper did not control or direct Dr. Goldfarb's experiments and Cooper admitted that he did not convey the importance of fibril length to Dr. Goldfarb. Indeed, Defendant's steps in pursuing the joint inventorship defense can be deemed reckless. The PTO considered and rejected Defendant's contention that Cooper was the prior inventor, there was essentially no evidence that Cooper collaborated in any meaningful way with Dr. Goldfarb, and Defendant's own employees denied that Cooper contributed to the invention. Defendant could not have realistically expected to succeed on its joint inventorship defense. Therefore, Defendant's request for relief based on joint inventorship is denied.

2. Anticipation

The defense of anticipation requires the alleged infringer to prove that a single prior art reference "describe[d] every element of the claimed invention, either expressly or inherently," and that it enabled "a person of ordinary skill in the art [to] practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000).

Defendant argues that Plaintiffs' witnesses, inventor Dr. Goldfarb and expert Dr. Anderson,[5] agreed that the Matsumoto prior art reference showed a picture of an ePTFE vascular graft possessing all of the claimed characteristics of the asserted '135 patent claims. (Def.'s Br. at 16).[6] Defendant supports this argument with a chart outlining excerpts of the testimony of Drs. Goldfarb and Anderson relevant to claim 20:

> Q. Do you agree that Matsumoto describes an artificial vascular prosthesis comprising expanded porous polytetrafluoroethylene?
>
> A. Dr. Goldfarb: Yes.

(Doc. 788 at 2107).

> Q. Now, let's see if we can streamline this a little bit. Let's put up claim 20, which talked about Matsumoto. Now, let's talk at the top part here, right above the "which permits tissue ingrowth," you agree that Matsumoto discloses and describes using the words of claim 20 an artificial vascular prosthesis comprising expanded porous polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils, correct?
>
> A. Dr. Anderson: Correct.
>
> Q. Yes?
>
> A. Dr. Anderson: Yes.

(Doc. 791 at 3084).

---

[5] James M. Anderson, Ph.D., M.D., is a Professor of Pathology, Polymer Science, and Biomedical Engineering at Case Western University in Cleveland, Ohio. (Doc. 783 at 1013, 1016).

[6] Dr. Goldfarb testified that the third Matsumoto article referred to the Surgery publication in the United States. (Doc. 782 at 653, 660-61, 712). This article was published in October 1973. (Doc. 788 at 2181; *see* Doc. 1115, Ex. 7, DX3009).

Q. You agree with me, though, that the photograph that Matsumoto shows is of a microstructure consisting of nodes interconnected by fibrils, looking at Figure 1?

A. Dr. Goldfarb: That's the way it appears, yes.

Q. And Matsumoto shows that his prosthesis permitted tissue ingrowth; isn't that right?

A. Dr. Goldfarb: Yes.

(Doc. 788 at 2108).

Q. I'm going to show you again the better photocopy of the Matsumoto article open to Figure 4. From that photograph, particularly the presence of nuclei, does that clarify the fact that Matsumoto is describing that there was cellular ingrowth in the pores?

A. Dr. Goldfarb: In this picture, it does look like that, yes.

Q. And that's the same sort of cellular ingrowth that you observed in the 1973, 1974 work; is that right?

A. Dr. Goldfarb: It has the same appearance.

(Doc. 788 at 2104).

Q. And you agree that these words in Matsumoto of a well developed fibroplasia or fibroplastic proliferation in the porous layer - - through the pores may support claim 20 permits tissue ingrowth as construed by the Court, correct?

A. Dr. Anderson: Correct.

(Doc. 791 at 3089).

Q. Dr. Goldfarb, I'm going to hand you Gore's Deposition Exhibit 15 and I'm going to ask you . . . to look at the photograph which is figure 11[.]

A. Dr. Goldfarb: Yes.

Q. Would you please compare that with Figure 4 that appears in the English language Matsumoto publication, Gore Exhibit 13, and confirm for me that, apart from the size of the photograph, we're looking at the same photograph. And I can make it easier for you by giving you better copies.

A. Dr. Goldfarb: It appears the same.

Q. Okay. Now, in paragraph 13 of the declaration of Dr. Schoen, which has been marked a Gore Deposition Exhibit 14, Dr. Schoen states his determination that the ePTFE graft described in Figure 11 of the Matsumoto Japanese article - - which we've marked here as . . . Exhibit

15 - - had an internodal distance on the order of 50 microns. Do you have any reason to agree or disagree with that determination by Dr. Schoen which was filed on your behalf?

A. Dr. Goldfarb: I would say that's a reasonable approximation.

Q. Is it your position that the Matsumoto 1973 article, Exhibit 13, described an ePTFE tube as a vascular prosthesis having values of internodal distance and wall thicknesses within the range you described in your patent application?

A. Dr. Goldfarb: I don't believe - - and correct me if I'm understanding it wrong - - that he described it in this article. But the picture that he shows could possibly be interpreted as being within the range. But there's no calibration here in the Matsumoto article. So it would be hard for me to come to a definite conclusion about that.

Q. But you're willing to accept Dr. Schoen's conclusion as being reasonable for one skilled in the art; is that correct?

A. Dr. Goldfarb: His method of extrapolation is logical.

(Doc. 788 at 2105-07).

Q. And if we believe Dr. Schoen's declaration filed in your behalf, the average distance between nodes is not less than six microns and is small enough to prevent transmural blood flow; isn't that correct?

A. Dr. Goldfarb: It appears that way.

(Doc. 788 at 2108).

In contending that Defendant's anticipation defense was not reasonable, Plaintiffs argue that the Matsumoto reference said nothing about internodal distance and that Defendant before the PTO had previously argued against the Matsumoto reference being considered as prior art. (Pls.' Resp. Br. at 18-19, referring to Doc. 1115, Ex. 4, PX117.158 & Ex. 3, PX116.3828). Plaintiffs refer to evidence indicating that scientists failed to replicate Matsumoto's results. (Pls.' Resp. Br. at 19, referring to Doc. 1115, Ex. 8 [DX3205 at 40931], Ex. 3 [PX116.13192], Ex. 5 [PX1216.129:16-17], Ex. 4 [PX117.155], & Doc. 787 at 1960 (testimony of Defendant's employee Detton)). Plaintiffs argue that Matsumoto was before the PTO as prior art to Dr. Goldfarb's application in 1976, in 1984-1986, and in 2001, and each time the PTO rejected any contention that Matsumoto invalidated Goldfarb's claims. (Pls.' Resp. Br. at 19-20, citing *Bard I*, 670 F.3d at 1185 ("Matsumoto was already

before the PTO during prosecution of the '135 patent, and the PTO did not find that Matsumoto anticipated . . . ")).

Based on the Court's review of the record, Jock Wheeler, M.D., a vascular surgeon and Defendant's expert, acknowledged in his testimony that the PTO considered the Matsumoto prior art reference before issuing the patent. (Doc. 788 at 2120, 2246).[7] Dr. Wheeler agreed that the Matsumoto article never used the term "fibril length" but used "porosity" instead, which did not refer to "internodal distance." (*Id.* at 2246-47). Dr. Wheeler also acknowledged that the PTO had determined that "pore size" bore no relationship to fibril length, but said he did not agree with that conclusion. (*Id.* at 2247). Defendant's employee Detton testified at trial that "you couldn't figure anything" from the Matsumoto article "because the article itself did not define anything." (Doc. 787 at 1960). Detton further testified that there were "real problems" even with the third Matsumoto article and "that wouldn't have been enough for me to even do much with . . . so we had no idea." (*Id.*). Detton testified that Matsumoto had received industrial tubing but that they "knew nothing about what Matsumoto received except that it was Gore-Tex." (*Id.*).

Regarding the testimony cited by Defendant, Dr. Goldfarb also testified that the Matsumoto reference had been considered by the PTO which concluded it had no effect on the issuance of the patent. (Doc. 781 at 500, 502; Doc. 782 at 693, 699). Dr. Goldfarb testified that the Matsumoto reference "could possibly be interpreted as being within the range," but there was "no calibration here in the Matsumoto article." (Doc. 788 at 2106). Dr. Anderson testified that "there's not enough information" in Matsumoto to "identify the parameters that a doctor should use to create a working vascular graft with ePTFE" because Matsumoto did not disclose "[t]he characteristics of the graft material" and did not discuss internodal distance at all. (Doc. 791 at 3063-64). Dr. Anderson further testified that

---

[7] Dr. Wheeler also had served as Dean and Provost of the Eastern Virginia Medical School. (Doc. 788 at 2120-21).

Matsumoto did not recognize a connection between internodal distance and tissue ingrowth and did not show a connection in the dimensions. (*Id.* at 3089).

Other evidence shows that in October 1973, Defendant's employee noted that Matsumoto "claims 100% success on femoral arteries in dogs: but we do not know what tubes we used. So we start again." (Doc. 1115, Ex. 8, DX3205 at 40931; Doc. 787 at 1958-61). In 1973 and 1975, doctors stated they had not been able to replicate Matsumoto's results. (Doc. 1115, Ex. 3 [PX116.13174 & PX116.13192] & Ex. 4, PX117b.155). In 1975, Defendant's employee Mendenhall testified regarding the Matsumoto article that "nobody knew what was sent over" and "[n]obody was very able to reproduce that." (Doc. 1115, Ex. 5, PX1216.129). Finally, Defendant, before the PTO, argued against the Matsumoto reference. (Doc. 1115, Ex. 3, PX 116.3826-29). For example, Defendant argued in briefing before the PTO that "[o]ne is left to speculate as to whether this small portion of the Matsumoto graft is representative of the fibril length throughout the entire graft and whether other portions of the graft had tissue ingrowth." (Doc. 1115, Ex. 3, PX116.3828).

Substantial evidence supports the finding that the anticipation defense was unreasonable. In order for the defense to have been reasonable, there must have been credible evidence on which Defendant could successfully show that Matsumoto was a prior art reference that described every element of the claimed invention, either expressly or inherently, and enabled a person of ordinary skill in the art to practice the invention without undue experimentation. *Advanced Display*, 212 F.3d at 1282. Here, in contrast, scientists and physicians at the time could not replicate Matsumoto's claimed results. Defendant's own employees could not figure anything out from the Matsumoto article even though Defendant manufactured the tubing. Defendant's expert Dr. Wheeler agreed that the Matsumoto article never used the term "fibril length." Defendant, before the PTO, even argued that Matsumoto did not anticipate. The Matsumoto reference was considered by the PTO and consistently rejected. Against all of these concerns, Defendant could not have "realistically expected"

its anticipation defense to succeed based on Matsumoto. Thus, Defendant's request for relief on this basis is also denied.

3. Other Defenses

Other evidence in the infringement proceedings supports the conclusion that Defendant's other defenses also were unreasonable. Defendant relied on a November 2002 opinion letter from counsel that the patent was invalid to show Defendant's good faith in continuing to manufacture and sell its vascular graft products. (Doc. 791 at 3003-09, 3021-37). Counsel's opinion letter was based in part on Matsumoto as enabling prior art; however, the Matsumoto article was considered and rejected by the PTO. The Matsumoto article is cited on the face of the patent. (Doc. 729 at 7; Doc. 781 at 498-500, 502-503; Doc. 782 at 654-55, 693; Doc. 788 at 2264; Doc. 791 at 3031-32; PX1). Counsel's opinion letter on which Defendant relied ignored Defendant's arguments in the Interference proceedings that Matsumoto was not enabling and that Defendant could not determine the structure that was disclosed. (Doc. 729 at 8; Doc. 787 at 1957-61). Notably, the opinion letter stated that Dr. Goldfarb and Cooper were joint inventors even though Defendant argued in the Interference that Cooper was the sole inventor and made no claim that Cooper was a joint inventor. (Doc. 791 at 3032-33, 3055).

Next, Defendant contended at trial that Dr. Volder was a sole or joint inventor. (Doc. 790 at 2594-2630; Doc. 793 at 3566-75, 3582, 3587, 3595-96). However, Defendant's opinion letter claimed that only Cooper was a co-inventor. (Doc. 791 at 3032-33). The PTO made no determination regarding Dr. Volder as inventor as the issue was between Dr. Goldfarb and Cooper. (Doc. 791 at 2900, 2918-19). In July 1976, Dr. Volder submitted an affidavit to the PTO that supported Dr. Goldfarb's patent application. (Doc. 782 at 694-98). Dr. Volder stated under oath in the affidavit that "he is of the unqualified opinion that the prosthetic vascular structure conceived and developed by [Dr. Goldfarb] . . . was by no means obvious to those actively conducting research on expanded PTFE vascular structures during 1972 and 1973." (Doc. 782 at 694, 697-98). Dr. Volder never made a claim to the

PTO that he was an inventor or co-inventor. (Doc. 790 at 2646; Doc. 791 at 2903). The trial testimony indicated that Drs. Goldfarb and Volder were "independent surgical research investigators." (Doc. 781 at 408-09, 415; Doc. 788 at 2265-66). Dr. Volder's article is listed on the front page of the patent. (Doc. 781 at 499).[8] Its significance was considered and rejected by the PTO. (Doc. 781 at 502). After the Volder article, Defendant was still searching for a solution and a structure. (Doc. 788 at 2264-66). Dr. Volder did not testify at trial.

Defendant additionally presented weak arguments at best based on written description and best mode. (Doc. 756; Doc. 758; Doc. 788 at 2197, 2205-16, 2261-63). The key critical element was fibril length or internodal distance. (Doc. 791 at 3067). Complete transmural tissue ingrowth and formation of a neointima were not essential to the Goldfarb invention. (Doc. 314 at ¶ 46; Doc. 559 at 18; Doc. 782 at 668; Doc. 786 at 1622). Dr. Goldfarb testified that no specific density was required and "that wall thickness was important, but not essential." (Doc. 781 at 401, 514).

Defendant's reliance on counsel's opinion letter, its defense that Dr. Volder was a sole or joint inventor, and its written description and best mode arguments all lacked a sufficiently reasonable persuasive basis. Defendant argued that Cooper was the sole inventor before the PTO but then claimed he was a co-inventor. Defendant claimed that Dr. Volder was a sole or joint inventor, but Dr. Volder provided an affidavit to the PTO that supported Dr. Goldfarb and he never claimed the invention before the PTO as either inventor or co-inventor. These unreasonable, unrealistic arguments and Defendant's weak references to written description and best mode all are rejected by this Court just as they were by the jury. The record of the infringement proceedings does not permit a reasonable conclusion contrary to that reached by the jury. *Ostad*, 327 F.3d at 881.

---

[8] The Volder article was published in April and November 1973. (Doc. 781 at 499; Doc. 788 at 2181-82; Doc. 782 at 695). Defendant asserted obviousness in light of the Volder article. (Doc. 771 at 17; Doc. 872 at 6-10).

III. CONCLUSION

There is no dispute that Defendant had notice of the Goldfarb patent. Defendant was familiar with the patent's subject matter and pre-trial litigation history because it litigated the inventorship issue in an eighteen-year Interference in which the PTO and the Federal Circuit ultimately determined that Dr. Goldfarb was the prior inventor. Defendant relied on counsel's opinion letter even though it was based in part on prior art that had been considered and rejected by the PTO and ignored arguments that Defendant had made before the PTO. The extensive litigation history of this case shows that Defendant relied on the same references, that is, the Matsumoto and Volder articles, to support its invalidity defense that the PTO previously had considered and found were not invalidating. Defendant argued before the PTO that Cooper was the sole inventor but then later changed its position by claiming at trial that Cooper was a joint inventor or that Volder was either a sole inventor or joint inventor. Defendant's arguments asserted prior to the issuance of the '135 patent and Defendant's contradictory arguments asserted after the patent issued, and its diluted defenses, convince this Court that Defendant did not have a reasonable basis for believing in the noninfringement of the patent.

Plaintiffs contend that the facts underlying the jury's verdict of willfulness are binding on the Court with respect to its determination of whether Defendant's defenses were objectively reasonable. (Pls.' Resp. Br. at 11). Defendant, in contrast, argues that "the objective reasonableness determination does not require fact finding" and that "there is no direct role for the jury to play in that determination." (Def.'s Reply Br. at 5). Defendant's argument appears inconsistent with *Bard II's* recognition that, depending on the defense that has been asserted, the court may "allow the jury to determine the underlying facts relevant to the defense in the first instance." *Bard II*, 682 F.3d at 1008. Under either standard, it is clear to this Court, just as it was to the jury, that Defendant, as a "reasonable litigant," could not have "realistically expected" its defenses to succeed. *Id.* Defendant's incautious and

arguably reckless defenses were not objectively reasonable. It is unnecessary for the Court to reconsider its rulings on enhanced damages and attorneys' fees.

Accordingly,

IT IS ORDERED upon reconsideration pursuant to remand of this matter, Defendant is not entitled to JMOL on the issue of willful infringement.

Dated this 16th day of October, 2013

Mary H. Murguia
United States Circuit Judge
designated as United States District Judge