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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Bard Peripheral Vascular, Inc., and David) Golfarb, M.D., Plaintiff, vs. W.L. Gore & Associates, Inc., Defendant.	No. CV 03-0597-PHX-MHM ORDER
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Currently pending before the Court is Defendant's Motion Under Rule 50(b) Seeking Entry of Judgment that Goldfarb Patent Claims 20-27 are Invalid Under 35 U.S.C. § 103 for Obviousness. (Dkt.#848). After reviewing the pleading and holding oral argument, the Court issues the following Order.

I. Whether Defendant's Should be Permitted to Raise an Argument That Was Not Presented To The Jury And The Appropriate Standard of Review

On July 29, 2008, this Court addressed Defendant's Motion for Judgment as a Matter of Law that claim 20 was obvious in light of the publication by Dr, Volder, among others, titled "A-V Shunts Created in New Ways." (Dkt.#834.) In this Order, the Court determined that the invalidity defense of obviousness was an issue of law for the Court to determine at the post-trial stage—specifically through the procedural mechanism of a Renewed Motion for Judgment as a Matter of Law (RJMOL). See Id. at 7; see also KSR Int'l Co. v. Teleflex,

1 Inc., 550 U.S. 398 (2007); Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337 (Fed. Cir.
2 2008); Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337 (Fed. Cir. 2007). The Court further noted
3 that obviousness would be submitted to the jury, but that the jury's verdict with respect to
4 this issue would be treated only as "advisory" by the Court. (Dkt.#834 at 2.) Lastly, the
5 Court held that "any renewed JMOL motion Gore chooses to file as to obviousness shall not
6 be limited to claim 20 and the Volder article." Id. at 7. Given the Court's July 2008 Order,
7 there are two issues that must be addressed before the Court can make an ultimate ruling.

8 First, Plaintiffs argue that Gore has improperly raised an issue in their JMOL relating
9 to obviousness that was not first presented to the jury. The issue in question is whether the
10 Goldfarb patent is obvious based on the Matsumoto article alone. Plaintiffs contend that,
11 under Fed. R. Civ. P. 50, the Court cannot review an issue that was not first presented to the
12 jury. On the other hand, Defendant contends that because obviousness is a question of law,
13 the Court cannot limit itself to what was presented to the jury; additionally, the question of
14 obviousness based on the Matsumoto article alone was preserved for later determination
15 when Mr. Maledon, Defendant's trial counsel, noted at closing argument that Goldfarb's
16 patent was "obvious and anticipated by" the Matsumoto and Volder publications. (12/6/07
17 Tr. 3614-16). The Court recognizes that there has been some dispute among the Parties
18 regarding the proper procedure for determining obviousness. The Court also notes that while
19 the July 2008 Order permitted Defendant to raise issues beyond the narrow focus of their
20 JMOL, the Court did not specifically address whether Defendant would be permitted to raise
21 questions of obviousness that were not presented to the jury at all. Irrespective of whether
22 the July 2008 Order contemplated Defendant's novel argument regarding the Matsumoto
23 article, the Court will in an abundance of caution rule on this issue. The Court will not, as
24 Plaintiffs argue, deem the issue as waived.

25 Next, Defendant argues that Plaintiffs have not briefed the question of obviousness
26 under the appropriate standard of review. Defendants contend that under KSR, the Court
27 must perform a de novo review and make a determination as a matter of law, regardless of
28 the jury's findings. KSR Int'l, 127 S.Ct. At 1734. Plaintiffs contend that, although the legal

1 conclusion is reviewed de novo, the jury's explicit and implicit factual findings are owed
2 "due deference" and are reviewed to determine if they are supported by "substantial
3 evidence." See Agризap, Inc. v. Woodsteam, Corp., 514 F. Supp. 2d 714, 720-21 (E.D. Pa.
4 2007). The Court acknowledges that the jury's determination on obviousness is owed
5 deference. In ruling on Defendant's Obviousness JMOL, the Court held that the jury's
6 verdict would be taken under advisement while the Court conducting its own de novo
7 determination. However, the Court cannot agree that all that is left for it to do is review the
8 record and determine whether the jury's obviousness determination is supported by
9 "substantial evidence." Such an inquiry would eviscerate the independent nature of the
10 Court's obviousness determination and would run the risk of confusing the unique review
11 that is to be conducted here with the type of deferential review performed by a trial court
12 under a traditional RJMOL. See Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506,
13 1515 (Fed. Cir. 1984) (noting that the trial court is the "ultimate arbiter" on the question of
14 obviousness). Therefore, even if the Court were to assume, arguendo, that Gore did not
15 properly present their argument that Goldfarb's patent was obvious in light of the Matsumoto
16 article standing alone, the Court would still review such a claim. The Court will therefore
17 review the issue of obviousness de novo, and make the determination as a matter of law.

18 **II. Merits and Analysis of Defendant's Obviousness Argument**

19 A party seeking to establish that patent claims are invalid must overcome statutory
20 presumption of validity set forth in 35 U.S.C. § 282 by clear and convincing evidence.
21 Nystrom v. TREX, Co., Inc., 424 F.3d 1136, 1149 (Fed. Cir. 2005). This presumption of
22 validity exists at every stage of the litigation. Cannon Computer Sys., Inc. v. Nu-Kote Int'l,
23 Inc., 134 F.3d 1985, 1088 (Fed. Cir. 1998), and "is never annihilated, destroyed or even
24 weakened regardless of what facts are of record." ACS Hosp. Sys., Inc. v. Montefiore Hosp.,
25 732 F.2d 1472, 1574-75 (Fed. Cir. 1984).

26 A patent claim is invalid if the invention recited in the claim would have been obvious
27 to a person of ordinary skill in the field of the invention at the time it was made. Model
28 Patent Jury Instruction for the Northern District of California § 4.3b. The ordinary skilled

1 person is a person of average education and training in the field of the invention and is
2 presumed to be aware of all of the relevant prior art. Id.

3 In addition, under Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350
4 (Fed. Cir. 1984), where the matter alleged to be invalidating was expressly considered by the
5 PTO, the party challenging validity has the “added burden . . . of overcoming the deference
6 that is due to a qualified government agency presumed to have properly done its job, which
7 includes one or more examiners who are assumed to have some expertise in interpreting the
8 references and to be familiar with their work with the level of skill in the art and whose duty
9 it is to issue only valid patents.” Id. at 1359.¹

10 Under KSR, the Court first looks to the primary factors: the scope and content of the
11 prior art, the differences between the prior art and the claims at issue, and the level of
12 ordinary skill in the pertinent art. KSR, 127 S. Ct. at 1734; (Dkt.#769 at 35.) The Court also
13 may consider the following secondary factors: (1) the commercial success of a product due
14 to the merits of the claimed invention; (2) a long felt need for the solution provided by the
15 claimed invention; (3) unsuccessful attempts by others to find the solution provided by the
16 claimed invention; (4) copying of the claimed invention by others; (5) unexpected and
17 superior results from the claimed invention; (6) acceptance by others of the claimed invention
18 as shown by praise from others in the field or from the licensing of the claimed invention;
19 (7) other evidence tending to show nonobviousness; (8) independent invention of the claimed
20 invention by others before or at about the same time as the named inventor thought of it; and

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22 ¹To the extent Gore classifies the Supreme Court’s decision in KSR as lowering their
23 burden or proof or requiring the Court to use a less stringent standard in “overcoming the
24 presumption of validity,” that argument is hereby rejected. The Court instructed the jury on
25 the applicable law without Gore’s objection—on December 4, 2007, Gore endorsed the
26 Court’s instruction, including the standard under Am. Hoist, as “absolutely correct.”
27 (12/04/07 Tr. At 3129-30.) Incidentally, the Supreme Court decided KSR on April 30, 2007,
28 months before the instructions were finalized. The instant motion is neither the appropriate
time nor place to raise a belated objection to a jury instruction that was never thought to be
in contention. In any event, the Court’s unobjected instruction on obviousness was legally
accurate, as it was based on Graham v. John Deere, 383 U.S. 1 (1966), which the Supreme
Court in KSR noted, “continues to define the inquiry that controls.” KSR, 127 S. Ct. At 1734.

(9) other evidence tending to show obviousness. KSR, 127 S. Ct. at 1734; (citing Graham v. John Deere, 383 U.S. 1, 17-18 (1966)); (Dkt#769 at 35.)

The Court will now review the record in light of the relevant primary and secondary factors. Before doing so, the Court must first explain its organizational structure. With respect to the scope and content of the prior art² and the differences between the prior art and the claims at issue, these factors are discussed within the context of each of the three individual arguments raised by Defendants. With respect to the proper level of skill, that factor can be disposed of rather quickly. Defendant argues that the level of ordinary skill in the art as of Dr. Goldfarb's filing date would have been a surgeon with vascular surgery experience, and that the issue was undisputed among the Parties experts. (Wheeler 11/28/07 Tr. 2138:14-16; Anderson 12/04/07 Tr. 3077:25-3078:12). Plaintiffs disagree, noting that one need only look to the jury instructions and the different contentions each side advanced as to the qualifications of one of ordinary skill. Turning to the jury instruction, the Parties did indeed proffer different instructions, both of which were submitted to the jury on the issue of the level of ordinary skill. Gore asked the jury to determine that the level of ordinary skill was "a person involved in and familiar with the design, development, and use of vascular grafts." (Dkt.# 769 at p. 59.) This is not the same definition that Gore now claims was undisputed among the experts at trial. If the level of skill was indeed undisputed at trial, it is unclear why Gore requested a jury instruction that significantly deviated from the unquestioned opinion of both Parties experts. In any event, the Court will review the question of obviousness under the both definitions that Gore has submitted. The Court finds that Gore's argument fails under either standard.

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²The Court is unmoved by Defendant's argument that there was "no dispute" as to the scope and content of the prior art. While both the Volder and Matusmoto articles are indeed prior art to the Goldfarb patent, the scope and content of these two articles was heavily debated throughout trial, and even in the briefing submitted by the Parties on the instant motion.

A. Obviousness of Claims 20-24 and 27 in Light of the Volder Article

The evidence presented at trial supports the legal conclusion that Claims 20-24 and 27 of the Goldfarb patent would not have been obvious to a person of ordinary skill based on the Volder article. First, the significance of the Volder article was repeatedly considered by the PTO before, during and after Gore's interference. See Am. Hoist, 725 F.2d at 1359 (noting the burden that arises when the PTO has considered the same contention). In fact, Gore repeatedly distinguished the Volder article from Dr. Goldfarb's invention in the PTO:

- March 24, 1975: Gore disclosed the Volder article to the PTO, stating that it does not disclose a devise for "replacing body parts by expanded porous PTFE having fibrils exceeding a critical minimum of 5 microns in length." (PX117.90)
- February 26, 1976: Gore submitted a declaration to the PTO stating that the "term 'pore size' [as used in the Volder article] is meaningless without further qualification." (PX117.155)
- June 24, 1977: Gore stated to the PTO that the Volder article was "irrelevant to the subject invention." (PX117.2114)

Besides Gore's own admissions before the PTO,³ in Dr. Volder's un rebutted affidavit, he stated under oath 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." (PX115.310).

Evidence was also presented at trial that researchers were unable to invent a successful graft even after the Volder and Matsumoto articles were published. For example, Gore's discredited inventor, Peter Cooper, testified in 1975 that despite ready access to Dr. Volder, his work and article, Cooper was compelled to steal Dr. Goldfarb's histology slides to determine why "other research centers . . . had not been successful." (11/07/07 Tr. 424-425; 11/08/07 Tr. at 643, 691-692).

³After interference was resolved, the PTO once again considered and rejected the Volder article in *ex parte* prosecution. (PX115.1599) "When an attacker simply goes over the same ground traveled by the PTO, part of the burden is to show that the PTO was wrong in its decision to grant the patent." Am. Hoist, 725 F.2d at 1360.

1 In addition, the actual inventor of devise at issue, Dr. Goldfarb, testified at trial that
 2 neither Volder nor Matsumoto articles taught his invention. (11/07/07 Tr. at 499). Plaintiff's
 3 expert Dr. Anderson testified that he would have been unable to create a working graft in
 4 1973 based on the Volder and Matsumoto articles because "[he]'d have to do a lot of
 5 experimentation. . . . [T]here wasn't enough in either of those articles to point me and reduce
 6 the time and money factor to create something in a reasonable amount of time." (12/04/07
 7 Tr. At 3066).

8 Lastly, with respect to the skill of one in the art at the time of invention, the Court
 9 must reject—just as the jury did—Gore's flawed contention that "pore size" and "internodal
 10 distance" were synonymous. Record evidence, such as that reproduced below, directly
 11 contradicts such a finding:

- 12 ○ Gore's statement to the PTO that the Volder article does not disclose a devise
 13 "having fibrils exceeding a critical minimum of 5 microns in length." (PX117.90)
- 14 ○ Gore's declaration, that "pore size does not predict fibril length." (PX116.3890)
- 15 ○ Dr. Campbell's declaration, in which he declared that the "term 'pore size' is
 16 meaningless without further qualification." (PX117.155)
- 17 ○ The Federal Circuit's adoption of the Parties agreement that "pore size bears
 18 no relationship to fibril length." (PX116.7637)
- 19 ○ Gore's founder's declaration that "'pore size' is not synonymous with 'fibril
 length" in the Volder article. (PX117.2134)
- 20 ○ Dr. Volder's own statements, which this Court has previously recognized in
 its July 2008 Order as evidence that the Volder article does not render the
 Goldfarb patent as obvious.

21 When viewing the record evidence in light of the relevant KSR factors, the Court can
 22 only conclude that the Volder article did not render the Goldfarb patent obvious to one
 23 skilled in the art.

24 **B. Obviousness of Claims 25 and 26 in Light of the Combination of the** 25 **Matsumoto and Volder Article**

26 Turning to the next issue, Gore's contention that Claims 20-27 of the Goldfarb patent
 27 are obvious in light of the Matsumoto and Volder publications is likewise without merit.
 28 Like the Volder article, the Matsumoto article was also repeatedly considered by the PTO
 during the pendency of the Goldfarb application.

- 1 ○ October 24, 1974: Dr. Goldfarb notes in his patent application that “[ePTFE] has been used . . . without clinically meaningful or reproducible success,” citing the Matsumoto article. (PX1, col.4)
- 2 ○ April 21, 1975: Dr. Goldfarb submits the Matsumoto article stating that “none of the above-cited references [including Matsumoto] anticipate or otherwise render obvious the combination covered by the claims.” (PX115.57)
- 3 ○ February 26, 1976: Gore states in a declaration that “[e]fforts in this country to duplicate the results of Matsumoto have met with failure . . .” (PX117.155)
- 4 ○ October 29, 1984: Gore argues that “the uncontroverted fact is that Matsumoto I did not teach anyone how to make an expanded PTFE graft that would enable tissue ingrowth,” and 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 . . .” (PX116.3828-29)

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10 In addition, other doctors, including those working for Gore, were unable to crack the problem with graft development after the publication of both the Volder and Matsumoto articles were published. In 1975, Peter Cooper, Gores discredited “inventor,” testified that despite the fact that Gore had access to Dr. Volder and his research, and despite the fact that Gore manufactured the tubing used by Matsumoto, it could not figure out why researchers—other than Dr. Goldfarb—were failing. (DX 3009; PX116.15122-23; 11/07/07 Tr. at 424-25; 11/08/07 Tr. at 643, 691-692.)

16 The record also demonstrates that other researchers could not determine the structure disclosed in the Matsumoto article or use the article to create a working vascular graft:

- 18 ○ October 22, 1973: Gore reported that the “Japanese paper [the Matsumoto article] claims 100% success on femoral arteries in dogs: but we do not know what tubes were used. So we start again.” (DX3205 at WLG5005927.)
- 19 ○ December 7, 1973: Dr. Kelly, one of the other researchers working with Gore, wrote to Dr. Matsumoto noting that “[u]sing what is presumably identical material, . . . all of the grafts have occluded within 4 weeks . . . It is difficult to resolve the apparent conflict in your results.” (PX116.13174.)
- 20 ○ July 16, 1975: Gore employee Richard Mendenhall testified regarding the Matsumoto article that “nobody knew what was sent over; therefore, if you didn’t know what was sent, you would have a very hard time duplicating it from a manufacturing point of view . . . Nobody was very able to reproduce that.” (Mendenhall Tr., 7/19/75 at 129 (PX117.1718).)

22 Then there is the testimony from trial, which further confirms the nonobviousness of the Matsumoto article. Dr. Goldfarb testified that the Volder and Matsumoto articles did not teach his invention. (11/07/07 Tr. at 499.) Even Gore’s paid fact witness, Mr. Detton, whom the Court noted in a previous Order lacked credibility, confirmed that Gore researchers had

1 “no idea” what type of ePTFE vascular graft Matsumoto used. (11/27/07 Tr. at 1959-61.)
 2 The record also reveals substantial proof that the Matsumoto article failed to disclose the key
 3 parameter of internodal distance. This evidence includes Gore’s own damaging admissions:

- 4 ○ “Matsumoto I doesn’t even mention fibrils or fibril length . . . Not only does
 5 Matsumoto I fail as an inherent anticipation, but given its silence as to fibril
 length, Matsumoto I does not render the invention unpatentable on any
 ground.” (PX 116.3825-26.)
- 6 ○ Those skilled in the art of making vascular prosthetics were not taught by
 7 Matsumoto I how to make successful grafts . . . The fact is that Matsumoto I
 includes no mention of fibril length, let alone that fibril length is a relevant
 8 parameter. One looking at Matsumoto I is left to guess at the physical
 properties of the grafts responsible for producing success.” (PX116.3827.)
- 9 ○ “Even assuming that Matsumoto I shows a small portion of a graft having
 10 fibrils greater than about 5 microns in length with tissue ingrowth, Matsumoto
 I is completely silent as to the structure of the remainder of the graft. One is
 11 left to speculate as to whether this small portion of the Matsumoto graft is
 representative of fibril length throughout the entire graft and whether other
 portions of the graft had tissue ingrowth.” (PX116.3828-29.)

12 Thus,. When the record evidence is viewed in light of the relevant KSR factors, the
 13 Court can only conclude that the Volder and Matsumoto articles did not render the Goldfarb
 14 patent obvious to one skilled in the art.

15 **C. Obviousness of Claims 20-27 in View of the Mutsumoto Article Alone**

16 For reasons identical to those recited in the previous section of this Order, the Court
 17 has no basis to find Claims 20-27 of the Goldfarb patent obvious in light of the Matusmoto
 18 article, standing alone.

19 **III. Conclusion**

20 In sum, this issue is not a close call. In the instant motion, Gore has no valid
 21 evidentiary basis for meritoriously arguing that Claims 20 through 27 of the Goldfarb patent
 22 are, by clear and convincing evidence, obvious. In fact, the overwhelming weight of the
 23 evidence presented at trial can only be understood as supporting a finding of
 24 nonobviousness—to argue otherwise is nothing more than an attempt to swim against a great
 25 and unrelenting current. The Court also notes that the jury returned a verdict that found the
 26 Goldfab patent nonobvious in light of the Volder and/or Matsumoto publications. The jury
 27 also resolved every single dispute that was at issue in the case in Plaintiffs’ favor, including
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1 a finding that Gore was a willful infringer. (See Dkt.# 771 at 17.) The Court is mindful of
2 the critical role played by the jury in this case.

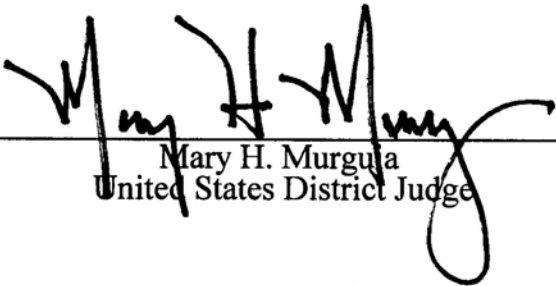
3 As such, the Court rules, as a matter of law, that Claims 20 through 27 of the Goldfarb
4 patent are not obvious in light of the Volder publication, the Matsumoto publication, or any
5 combination thereof.

6 **Accordingly,**

7 **IT IS HEREBY ORDERED** denying Defendant's Motion Under Rule 50(b) Seeking
8 Entry of Judgment that Goldfarb Patent Claims 20-27 are Invalid Under 35 U.S.C. § 103 for
9 Obviousness. (Dkt.#848.)

10 DATED this 31st day of March, 2009.

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Mary H. Murgula
United States District Judge