No. _____

In the Supreme Court of the United States

W.L. GORE & ASSOCIATES, INC.,
Petitioner,

v.

BARD PERIPHERAL VASCULAR, INC., DAVID GOLDFARB, M.D., C.R. BARD, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

The second paragraph of 35 U.S.C. § 261 provides, with emphasis added:

> Applications for patent, patents, or any interest therein, shall be assignable in law **by an instrument in writing**. The applicant, patentee, or his assigns or legal representatives may **in like manner** grant and convey an **exclusive right** under his application for patent, or patents, to the whole or any specified part of the United States.

The question presented is:

Does Section 261 require that a grant or conveyance of an exclusive patent license be in writing?

PARTIES TO THE PROCEEDING

Petitioner W.L. Gore & Associates, Inc. was the defendant and appellant in the proceedings below.

Respondents Bard Peripheral Vascular, Inc. and David Goldfarb, M.D. were the plaintiffs and appellees in the proceedings below.

Respondent C.R. Bard, Inc. was the counterclaim defendant and appellee in the proceedings below. C.R. Bard, Inc. was not a plaintiff in the proceeding below.

CORPORATE DISCLOSURE STATEMENT

Petitioner W.L. Gore & Associates, Inc. has no parent corporation and is not publicly traded. No publicly held company owns 10% or more of its shares.

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PETITION FOR WRIT OF CERTIORARI

Petitioner W.L. Gore & Associates, Inc. ("Gore") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

The primary question presented in this petition is whether under 35 U.S.C. § 261 an exclusive patent license must be in writing in order to be effective. Section 261 states that "[a]pplications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing," and "in like manner," the holder of these rights may "grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." The plain language of this statute mandates that an exclusive right (i.e., an exclusive license) in a patent may only be granted or conveyed "by an instrument in writing" (i.e., "in like manner" as an assignment of a patent). Despite this clear statutory mandate, the Federal Circuit has developed a body of case law approving of oral and implied transfers of exclusive patent rights, despite the fact that there is no written instrument transferring the exclusive rights. Gore requests that this Court grant its petition for certiorari to correct the Federal Circuit's misinterpretation of the Patent Act, and make clear that a grant or conveyance of an exclusive license must be in writing.

This case provides a poignant example of the importance of correcting the Federal Circuit's interpretation of Section 261. The plaintiff in this

case—IMPRA/BPV[1]—received a $1 billion-plus patent infringement judgment, even though IMPRA/BPV did not possess the exclusive rights in the asserted patent and thus did not have standing by itself to enforce the asserted patent. *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1344 (Fed. Cir. 2006) ("For the same policy reasons that a patentee must be joined in any lawsuit involving his or her patent[s], there must be joinder of any exclusive licensee.") (citing *Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 466 (1926)). Rather, the only entity that possessed the exclusive patent rights in the asserted patent was a different entity—Bard—which was not a plaintiff in the case and never executed a written instrument transferring its exclusive rights to IMPRA/BPV.

The district court and Federal Circuit nonetheless concluded that IMPRA/BPV had acquired the exclusive rights in the asserted patent from Bard in one of two ways, either (1) by an alleged oral or implied agreement—which was based on hearsay testimony of IMPRA/BPV's president—or (2) a subsequent "memorialization" of the oral or implied transfer in a patent license "amendment" between the named inventor (Goldfarb) and IMPRA/BPV. App. 8-9. But neither of these alleged mechanisms could possibly transfer an exclusive license from Bard to IMPRA/BPV, because the alleged oral or implied agreement is not an

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[1] BPV is a subsidiary of C.R. Bard, Inc. ("Bard"), and it was named IMPRA, Inc. ("IMPRA") until 2003, when it underwent a name change and became BPV. D. Ariz. Dkt. 124. At the time the complaint in this action was filed, March 28, 2003, this entity was still named IMPRA. D. Ariz. Dkt. 1. Accordingly, Gore generally refers to this entity as "IMPRA/BPV."

"instrument in writing" under Section 261, and Bard was not a party to and did not sign the subsequent "affirmation" of the alleged transfer.

What is more, the Federal Circuit is entrenched in its interpretation of Section 261. Sitting *en banc* twenty years ago in *Rite-Hite Corp. v. Kelley Co.*, the Federal Circuit explicitly ruled that exclusive licenses may be "express or implied." 56 F.3d 1538, 1552 (Fed. Cir. 1995) (en banc). Subsequently, another Federal Circuit panel seemed to acknowledge the potential flaw in the court's reading of Section 261, but concluded that it was "bound to follow our precedent, and thus we hold that an exclusive license need **not** be in writing for the licensee to have standing if the patentee or assignee is also joined." *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 288 Fed. Appx. 697, 706 (Fed. Cir. 2008) (emphasis added). And the Federal Circuit in this case held that it is now "**well established** that the **grant** of a license **does not need to be in writing**." App. 8 (emphasis added).

It is important both for this case and the patent system that the Court correct the Federal Circuit's misinterpretation of Section 261, and confirm that exclusive licenses may only be transferred by a written instrument. The Federal Circuit's acceptance of oral and implied transfers of exclusive patent rights undermines the critical public policy of promoting certainty and transparency of ownership and control of patent rights.[2] It also serves to facilitate the ability of

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[2] Promoting transparency is one of the main topics Congress is currently considering in connection with proposed legislation for addressing and preventing abusive patent enforcement. *See, e.g.*,

patent plaintiffs to engage in "revisionist history" as to patent standing in order to manipulate proceedings to meet their financial goals. *See Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998). Gore therefore respectfully requests that the Court grant this petition for certiorari to decide whether Section 261 requires that an exclusive license must be in an "instrument in writing."

OPINIONS BELOW

The post-trial opinion of the district court denying Gore's Motion for JMOL on Plaintiffs' Lack of Standing (App. 91-118) is unreported. The opinion of the district court denying Gore's Motion Pursuant to Fed. R. Civ. P. 12(b)(1) and 12(h)(3) to Dismiss Plaintiffs' Complaint for Lack of Standing or in the Alternative Renewed Motion for Judgment as a Matter of Law (App. 59-90) is unreported. The district court's amended final judgment naming Goldfarb and IMPRA/BPV as the parties to the infringement judgment (App. 45-58) is unreported.

The district court's orders in remanded proceedings, following a Federal Circuit appeal on issues relating to the appropriate legal standard for finding willful patent infringement, ordering that Gore is not entitled to reconsideration of JMOL on the issue of willful infringement, denying Gore's motion for a new trial, and granting IMPRA/BPV and Goldfarb's motion for

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H.R. 9, 114th Cong. § 4 (2015) (as introduced, Feb. 5, 2015) (a section titled "Transparency of Patent Ownership" would amend the Patent Act to require patent plaintiffs to disclose additional information about ownership of asserted patents when filing a complaint for patent infringement).

leave to execute the district court's August 24, 2010 Amended Clerk's Judgment dated October 16, 2013 (App. 41-44) and October 30, 2013 (App. 35-40) are unreported.

The January 2015 opinion of the Court of Appeals for the Federal Circuit (App. 1-34) is reported at 776 F.3d (Fed. Cir. 2015). The order of the Court of Appeals for the Federal Circuit denying Gore's petition for rehearing en banc of the issues decided in the January 2015 opinion (App. 119-120) is not reported.[3]

JURISDICTION

The court of appeals entered its judgment on January 13, 2015, and denied a petition for rehearing on April 8, 2015. App. 119-120. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Patent Act, 35 U.S.C. §§ 1, *et seq*. are reproduced at App. 121-124.

STATEMENT OF THE CASE

A. Statutory Background.

The current version of Section 261 was enacted as part of the Patent Act of 1952. Section 261 sets forth the requirements for a transfer of a patentee's rights in the patent to another, either through an assignment of an interest in the patent, or through a grant and

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[3] Gore previously filed a petition for certiorari in this case to review the Federal Circuit's judgment on a different and unrelated issue (joint inventorship). The Supreme Court denied that petition on January 14, 2013. 133 S. Ct. 932.

conveyance of an exclusive right in the patent. The second paragraph of Section 261 states:

> Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.

It is clear from the plain language of this paragraph that the only way to grant or convey an exclusive right in a patent is through an "instrument in writing." The first sentence of the paragraph states that any interest in a patent may be assigned through an "instrument in writing." The second sentence then states that the "applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." An exclusive patent license is an "exclusive right" under the patent. Thus, under Section 261, any grant or conveyance of an exclusive patent license must be executed "in like manner" as an assignment—through an "instrument in writing."

B. The Federal Circuit's Interpretation of Section 261.

The Federal Circuit has ignored the plain language of Section 261 and instead developed a body of case law allowing grants and conveyances of exclusive licenses without an instrument in writing. However, this was not always the case. In an unpublished decision in

1994, the Federal Circuit recognized that under Section 261, exclusive licenses must be in writing. *Quieden Co. v. Cent. Valley Builders Supply Co.*, No. 94-1098, 1994 WL 393811, at *1 (Fed. Cir. 1994) ("Because there was never a valid, written agreement transferring rights under the patent to Quieden Company, Inc., the corporation did not have standing to bring the present lawsuit."). But less than a year later, sitting *en banc* in *Rite-Hite Corp. v. Kelley Co.*, the Federal Circuit ruled that exclusive licenses may be "express or implied." 56 F.3d at 1552. Since *Rite-Hite*, the Federal Circuit has acknowledged that Section 261 might apply to exclusive licenses, but nonetheless stated, without analyzing the statute, that it was bound by its precedent allowing oral or implied exclusive licenses. *Aspex v. Altair*, 288 Fed. Appx. at 705 ("While Altair is correct that none of these cases expressly analyzes the 'in like manner' language in Section 261, we are bound to follow our precedent, and thus we hold that an exclusive license need not be in writing for the licensee to have standing if the patentee or assignee is also joined."). And the panel in this case held that it is now "well established that the grant of a license does not need to be in writing." App. 8.

The importance of Supreme Court review is also shown by the fact that while the Federal Circuit's interpretation of Section 261 is largely consistent with the Ninth Circuit, it appears inconsistent with the Seventh Circuit—the other circuit courts that have expressly analyzed Section 261 as it pertains to exclusive licenses. The Seventh Circuit has acknowledged that Section 261 applies to exclusive licenses. *Moraine Prods. v. ICI Am., Inc.*, 538 F.2d 134, 143 (7th Cir. 1976). In *Moraine Products*, the Seventh

Circuit reviewed the history of Section 261 and determined that it was originally enacted to apply to "grants," which only differ from exclusive patent licenses in their "formal . . . nature." It then reached the conclusion that "[t]he bare language of § 261 . . . allow[s] a patentee or his assignee to grant an exclusive license to make, use, or sell the patented invention." *Id.* The Ninth Circuit, on the other hand, reviewed the history of Section 261 but reached a different conclusion and decided that the statute applies only to an "ownership interest" and not to licenses. *In re Cybernetic Servs. Inc.*, 252 F.3d 1039, 1049 (9th Cir. 2001). The inconsistent interpretations between the Seventh and Ninth Circuits further warrants review by this Court.

C. Factual Background.

1. 1974—Goldfarb files application for the '135 patent.

The application for the asserted patent in this case, U.S. Patent No. 6,436,135 ("the '135 patent" or "the asserted patent"), was filed by Dr. David Goldfarb ("Goldfarb") on or about October 24, 1974. '135 patent. Fed. Cir. App. A108-20. The '135 patent is titled "Prosthetic Vascular Graft" and has 27 patent claims directed to expanded polytetrafluoroethylene vascular grafts. *Id.* It names Goldfarb as the only inventor and issued in his name on August 20, 2002. *Id.*

2. 1980—Goldfarb grants Bard an exclusive license to the '135 patent.

In 1980, Goldfarb and C.R. Bard, Inc. ("Bard")[4] executed a license agreement (the "1980 Agreement") in which Goldfarb granted Bard an exclusive license to his inventions, including U.S. Patent App. No. 517,415, the application which eventually issued as the asserted '135 patent. App. 125-149.

Section 1.4 of the 1980 Agreement granted Bard a "worldwide, exclusive license[], with the right to sublicense, to make, use and sell products covered by" the '135 patent:

> 1.4 **Grant**. DR. GOLDFARB hereby grants to USCI [BARD] worldwide, exclusive licenses, with the right to sublicense, to make, use and sell products covered by PATENTS [including the '135 patent] except HEART VALVES.

App. 127, ¶ 1.4 (brackets added for clarity). Bard also enjoyed "sole discretion to file, control, defend and settle" all claims and actions relating to the granted "PATENTS." App. 137, ¶ 5.3. Bard could, but was not required to, request that Goldfarb assist in litigation filed by Bard seeking to enforce a patent or assist in an action brought by a third party seeking to declare a patent invalid. *Id.*

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[4] The 1980 Agreement transfers rights from Goldfarb to "USCI Surgical Products Division, C. R. Bard, Inc. ('USCI')." App. 125. For the purposes of clarity, Gore refers to Bard, not USCI, as the receiving entity. Bard apparently sold its USCI division to another company after September 1996. Fed. Cir. App. A41.

3. 1996—Bard allegedly transfers its exclusive rights to IMPRA/BPV.

In 1996, Bard acquired IMPRA. Despite the acquisition, IMPRA is a separate corporate entity from Bard. App. 65. IMPRA later changed its name to Bard Peripheral Vascular, Inc. ("BPV"). When the acquisition occurred or sometime thereafter, Bard allegedly transferred its exclusive rights in the 1980 Agreement to IMPRA/BPV. It is undisputed that there is no written instrument for this alleged 1996 transfer of exclusive rights.

4. 1997—Goldfarb and IMPRA/BPV (but not Bard) enter agreement purporting to amend the 1980 Agreement.

On February 21, 1997, Goldfarb and IMPRA/BPV executed an "Agreement Amending Licensing Agreement" (the "1997 Amendment"), in which Goldfarb and IMPRA/BPV purported to amend the 1980 Agreement. App. 150-156. One of the "WHEREAS" clauses at the beginning of the 1997 Amendment states that "on September 16, 1996, BARD acquired IMPRA and thereafter assigned and transferred the [1980] License Agreement to IMPRA." App. 151. Bard, however, is not a party to the 1997 Amendment. Nor is the "WHEREAS" clause a transfer of rights—at most it is an acknowledgement of what Goldfarb and IMPRA believe resulted from the alleged 1996 oral or implied transfer of rights. Thus, although the 1997 Amendment mentioned Bard and purported that Bard had, at some prior date, "assigned and transferred" the 1980 Agreement to IMPRA, the 1997 Amendment was not signed by Bard—the signature

block does not even include a space for execution by a Bard representative—and was not effective to transfer any rights from Bard to IMPRA. App. 151, 154.

5. 1997-2000s—Bard continues to represent that it owns exclusive rights to the '135 patent.

After the purported September 1996 transfer of the 1980 Agreement from Bard to IMPRA/BPV, Bard continued to represent to the public that it possessed exclusive rights in the '135 patent. For example, on January 31, 1997, Bard filed a declaratory judgment action in the District of New Jersey seeking to terminate an option it had given Gore to sublicense the '135 Patent.[5] Bard's complaint stated that "Bard granted Gore an option ['the Gore Option'] to obtain, in the future, a license to any patent issued or thereafter issuing to **Bard** as a result of a then-pending patent application **owned by Bard** ('the Goldfarb application')." Fed. Cir. App. A4145, ¶ 10 (emphasis added).[6]

Bard repeatedly represented throughout the New Jersey litigation that Bard owned the rights to the '135

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[5] Bard gave Gore the option to license the '135 patent as part of a settlement agreement for a separate patent litigation dispute between Bard and Gore that took place in the 1980s.

[6] Bard's failure to mention IMPRA/BPV's now-purported interest in the '135 patent did not stem from a view in 1997 that IMPRA was merely a subsidiary of Bard. Bard emphasized that IMPRA was a separate corporate entity in its complaint and in a declaration from Bard's general counsel. Fed. Cir. App. A4146, ¶13; Fed. Cir. App. A4133, ¶16.

patent. In November 1998, Bard Vice President and General Counsel Richard A. Flink verified an interrogatory response in which Bard stated that "it has valid patent rights in the Goldfarb application." Fed. Cir. App. A4210, No. 14; A4216. In April 1999, Flink then testified as the corporate representative of Bard during a Rule 30(b)(6) deposition that "**I have no knowledge of an assignment from Bard to IMPRA**, so if my knowledge is correct, then **Bard** is still the licensee." Dep. of C.R. Bard, Inc., by its designee R. Flink, Apr. 8, 1999 (Fed. Cir. App. A4220), 79:3-7 (emphasis added).

In appeals to the Federal Circuit during interference proceedings over the subject matter in the '135 patent, counsel for Goldfarb and Bard also listed in Certificates of Interest in Goldfarb's appeal briefs that Bard was the real party in interest, because, as counsel stated, Bard was "the licensee of the application." Fed. Cir. App. A27900; Fed. Cir. App. A29291; Fed. Cir. App. A29499.

6. 2003—Goldfarb and IMPRA/BPV sue Gore for patent infringement.

Despite Bard's representations that it held the exclusive license to the '135 patent, in 2003, Goldfarb and IMPRA/BPV filed suit against Gore for infringing the '135 patent. After the case was filed, Gore brought claims against Bard as a counterclaim defendant. D. Ariz. Dkt. 4 at 6. Bard, however, answered the counterclaims on May 12, 2003 and specifically stated that "Bard denies that it has asserted in this litigation that Gore infringes the '135 patent." D. Ariz. Dkt. 20, ¶ 96. Moreover, in four separate interrogatory responses, Bard specifically denied that it contended

Gore infringed the '135 patent: "Counterdefendant **Bard is not a plaintiff** in this action and has not alleged that Gore infringes the '135 patent." Fed. Cir. App. A4246, at No. 1; A4257, at No. 1 (emphasis added); *see also* A4237-38, at No. 2; A4297, at No. 6.

In January 2007, ten months prior to the start of trial, Goldfarb assigned his rights in the '135 patent to IMPRA/BPV. App. 157-164. The 2007 assignment did not mention that Bard possessed any rights in the '135 patent. *Id.* Nor is there any evidence other than IMPRA/BPV's own testimony that Goldfarb terminated the 1980 Agreement with Bard prior to the 2007 assignment.

A jury trial was then held between November 2, 2007 and December 11, 2007 in the District of Arizona. The jury reached a verdict finding that Gore infringed the '135 patent. D. Ariz. Dkt. 771. The district court then entered an amended final judgment awarding IMPRA/BPV damages. D. Ariz. Dkt. 1047 at 2. The district court also entered an order granting a compulsory license requiring Gore to pay royalties to IMPRA/BPV for the remainder of the life of the '135 patent, which expires on August 20, 2019. *Id.*

Under the district court and the Federal Circuit's judgments, Gore has to date paid Bard over $1,063,914,846.90. *See* D. Ariz. Dkts. 1152, 1153, 1164 & 1165 (this number does not include Gore's quarterly compulsory royalty payments after October 2013).

D. Proceedings Below.

This case has a long and detailed history, but the only issue before the Court relates to whether IMPRA/BPV obtained exclusive rights to the '135

patent from Bard, and, therefore, had standing to enforce the '135 patent against Gore. This is because if IMPRA/BPV did not acquire the exclusive rights in the '135 patent from Bard, then IMPRA/BPV lacked standing to enforce the '135 patent. *Aspex v. Miracle*, 434 F.3d at 1344 ("For the same policy reasons that a patentee must be joined in any lawsuit involving his or her patent[s], there must be joinder of any exclusive licensee.") (citing *Indep. Wireless*, 269 U.S. at 466); *see also Alfred E. Mann Found. For Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1359-60, 1363 (2010). In the proceedings below, Gore raised the issue of Goldfarb and IMPRA/BPV's lack of standing at least three times.

First, on November 16, 2007, Gore brought a Motion for JMOL Regarding Plaintiffs' Lack of Standing. D. Ariz. Dkt. 652. Gore argued that Goldfarb and IMPRA/BPV's complaint should be dismissed for lack of subject matter jurisdiction because Goldfarb had granted an exclusive license to Bard and there was no evidence that there was ever a written transfer of that exclusive license from Bard to IMPRA/BPV. *Id.* at 3. It asserted that the lack of a writing meant that IMPRA/BPV did not have standing at the outset of the case. Moreover, because Goldfarb had assigned the right to enforce the '135 patent to Bard, Goldfarb retained only naked title to the patent and could not maintain the suit in his own name. *Id.* at 4. The district court denied Gore's Motion for JMOL in post-trial rulings on July 29, 2008. App. 91-118.

Second, on August 12, 2008, Gore again raised the standing defect by filing a Motion to Dismiss Plaintiff's Complaint for Lack of Standing or in the Alternative

for Judgment as a Matter of Law. Fed. Cir. App. A4082. The district court denied Gore's motion on March 31, 2009 (App. 59-90), and it entered an amended final judgment August 24, 2010, naming Goldfarb and IMPRA/BPV as the parties to the infringement judgment (App. 45, ¶1.0).

Third, Gore appealed the issue of the plaintiffs' lack of standing to the Federal Circuit, arguing that the 1980 Agreement transferred all substantial rights in the '135 patent from Goldfarb to Bard and thus constituted a virtual assignment. Because the 1980 Agreement constituted a virtual assignment, Goldfarb lacked standing to bring suit against Gore. Moreover, since there was never an adequate written agreement between Bard and IMPRA/BPV transferring the 1980 Agreement, IMPRA/BPV also lacked standing.

The Federal Circuit issued its opinion on January 13, 2015. App. 1-34. The court stated that the 1980 Agreement was not a virtual assignment, but only an exclusive license, because "Goldfarb retained significant reversionary rights, there was a field of use restriction, and Goldfarb retained the right to share in damages." App. 9. On this basis, the panel stated that no written instrument was necessary to transfer the exclusive license from Bard to IMPRA/BPV because "[i]t is well established that the grant of a license does not need to be in writing." App. 8. The panel went on to find that, even though Bard was not a party to the 1997 Amendment, "there is no question that in 1997, there *was* a written agreement **between the parties** affirming Bard's transfer of its rights to BPV." App. 9 (emphasis added). The court did not mention, nor attempt to explain, the interpretation and evidentiary

issues with the 1997 Amendment, including the fact that Bard was not a party to the 1997 Amendment and that the 1997 Amendment itself is not a transfer of exclusive rights but, rather, only mentions the alleged oral or implied transfer in a "whereas" recital. App. 151. Nor did it address or even mention Bard's repeated representations after 1997 that Bard was still the exclusive licensee of the '135 patent.

Gore petitioned for rehearing, and rehearing *en banc* was denied on April 8, 2015.

REASONS FOR GRANTING CERTIORARI

I. The Federal Circuit's Allowance of Oral or Implied Transfers of Exclusive Patent Rights Is Contrary to the Statutory Requirement of 35 U.S.C. § 261 That Such Transfers Be in Writing.

The Federal Circuit's decision in this case adds to its established body of case law holding, contrary to the explicit wording of the Patent Act, that exclusive licenses do not need to be in writing. The court below found that plaintiff IMPRA/BPV had standing to bring suit for patent infringement because there was an oral or implied transfer of an exclusive license to the '135 patent from Bard to IMPRA/BPV in 1996. This finding contradicts the requirement of 35 U.S.C. § 261 that a patentee or his assigns may only "grant and convey an exclusive right" under his patent "by an instrument in writing."

A. Under The Plain Language of Section 261, a Grant or Conveyance of an Exclusive Patent License Must Be "By an Instrument in Writing."

Section 261 governs the manner in which an "applicant, patentee,[7] or his assigns or legal representatives" may assign any interest in a patent or grant and convey exclusive rights in the patent. The first sentence sets forth the requirements for assigning any ownership interest in a patent or patent application, and the second sentence sets forth the requirements for granting or conveying an exclusive right under a patent or patent application:

> Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.

35 U.S.C. § 261.

Under the plain language of Section 261, any transfer of exclusive patent rights must be executed by an appropriate "instrument in writing." The first sentence of Section 261 states that "[a]pplications for patent, patents, or any interest therein, shall be assignable in law by an **instrument in writing**." *Id.*

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[7] Section 100(d) defines "patentee" as "includ[ing] not only the patentee to whom the patent was issued but also the successors in title to the patentee."

(emphasis added). The second sentence then states that "[t]he applicant, patentee, or his assigns or legal representatives may **in like manner** grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." *Id.*

The second sentence's use of the phrase "in like manner" refers back to the first sentence's use of the phrase "by an instrument in writing." Indeed, the only manner for transferring a patent interest identified anywhere in Section 261 is "by an instrument in writing." Thus, the phrase "may in like manner grant and convey an exclusive right under his application for patent, or patents" means "may [by an instrument in writing] grant and convey an exclusive right under his application for patent, or patents." Accordingly, the plain language of Section 261 confirms that a grant or conveyance of an exclusive patent right may only be done "by an instrument in writing." *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) ("And where the statutory language provides a clear answer, it ends there as well.") (citing *Conn. Nat'l. Bank v. Germain*, 503 U.S. 249, 254 (1992)).

It bears emphasizing that Section 261's "written instrument" requirement applies to assignments **and** grants and conveyances of exclusive patent rights, namely a grant of an exclusive license. This is important because, as discussed below, the Federal Circuit has failed to acknowledge that the written instrument requirement of Section 261 applies to exclusive licenses.

B. The Federal Circuit's Decision Allowing Oral or Implied Transfers of Exclusive Patent Licenses Is Not Permitted by Section 261.

The Federal Circuit's ruling in this case directly contradicts the plain meaning of Section 261. In its decision, the Federal Circuit found that no written instrument was necessary for Bard to transfer its exclusive license to IMPRA/BPV.[8] App. 8-9. First, the court noted that IMPRA/BPV's argument was that it was "an exclusive licensee with the right to sue for infringement." *Id.* It then stated: "It is **well established** that the grant of a license **does not** need to be in writing." *Id.* (emphasis added) (citing *Waymark Corp. v. Porta Sys. Corp.*, 334 F.3d 1358, 1364 (Fed. Cir. 2003); *Rite-Hite*, 56 F.3d at 1552. The panel offered no explanation for how its ruling was permissible under Section 261, except for its citation to the *Waymark* case, in which another Federal Circuit panel held that Section 261 was inapplicable to exclusive licenses.

The decision below stems from the Federal Circuit's confusing and inconsistent case law on the circumstances under which an exclusive license must be in writing. The Federal Circuit recognized on at least one occasion in an unpublished decision that Section 261 requires an exclusive license be in a

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[8] As discussed later in this petition, the 1997 Amendment purporting to memorialize the oral or implied transfer is not sufficient to constitute the written instrument required by Section 261 because Bard was not a party to that agreement—the agreement was only between Goldfarb and BPV.

"written agreement" to establish standing. *Quieden Co. v. Cent. Valley Builders Supply Co.*, No. 94-1098, 1994 WL 393811, at *1 (Fed. Cir. 1994) ("Because there was never a valid, written agreement transferring rights under the patent to Quieden Company, Inc., the corporation did not have standing to bring the present lawsuit."). But about a year later, the Federal Circuit, sitting *en banc*, held that to "be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee's **express or implied promise** that others shall be excluded from practicing the invention within that territory as well." *Rite-Hite*, 56 F.3d at 1552 (emphasis added). Later, in *Waymark*, the Federal Circuit held with almost no analysis that "[o]nly assignments need be in writing under 35 U.S.C. § 261" and that "Licenses may be oral." 334 F.3d at 1364. The Federal Circuit now uniformly holds that exclusive licenses do not need to be in writing. *See, e.g.*, *Waymark*, 334 F.3d at 1364; *Rite-Hite*, 56 F.3d at 1552; *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc.*, 748 F.3d 1354 (Fed. Cir. 2014) (exclusive licensee had standing based on implied license); *Aspex v. Altair*, 288 Fed. Appx. at 705 ("[A]n exclusive license need not be in writing for the exclusive licensee to have standing to sue with the patentee as a co-plaintiff.").

The panel in *Aspex* seemed to acknowledge the potential flaw in the Federal Circuit's previous understanding of Section 261, noting that *Rite-Hite* and other Federal Circuit cases had not "expressly analyze[d] the 'in like manner' language in Section 261," but concluded that the court was "bound to follow our precedent, and thus we hold that an exclusive license need not be in writing for the licensee to have

standing if the patentee or assignee is also joined." *Aspex v. Altair*, 288 Fed. Appx. at 706 (referring back to *Waymark*, 334 F.3d at 1364; *Rite-Hite*, 56 F.3d at 1552; and *Weinar v. Rollform, Inc.*, 744 F.2d 797, 806-07 (Fed. Cir. 1984)).

The Federal Circuit's incorrect interpretation of Section 261 is further shown from a dichotomy it has created between what it refers to as exclusive licenses that are "virtual assignments" and exclusive licenses that are not "virtual assignments." The Federal Circuit holds that exclusive licenses known as "virtual assignments" must be in writing, but that other types of exclusive licenses that do not rise to the level of a "virtual assignment" do not need to be in writing. *See, e.g.*, *Enzo*, 134 F.3d at 1093 ("While we acknowledge that a license may be written, verbal, or implied, if the license is to be considered a virtual assignment to assert standing, it must be in writing."). There is no basis for the Federal Circuit's distinction between different types of "exclusive licenses" under Section 261, which provides that all grants of "exclusive rights" must be made "in like manner" as assignments. Moreover, the Federal Circuit's distinction unnecessarily complicates the application of Section 261 and undermines the policy of promoting certainty of patent ownership.

In reaching its decision in this case, the Federal Circuit relied on its prior decisions in *Waymark* and *Rite-Hite* for the proposition that an oral or implied exclusive patent license is sufficient and that such an oral or implied license may establish standing to participate in a patent suit against an alleged infringer. The Federal Circuit, for example, stated that

"BPV's position is only that it was an exclusive licensee with the right to sue for infringement. It is well established that the grant of a license does not need to be in writing." App. 8 (citing *Waymark*, 334 F.3d at 1364; *Rite-Hite*, 56 F.3d at 1552). The Federal Circuit's holding is contrary to Section 261 and must be vacated. Patent rights are "created by the act of Congress; and no rights can be acquired in it unless authorized by statute, and in the manner the statute prescribes." *Gayler v. Wilder*, 51 U.S. 477, 494 (1850); *see Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 40 (1923); *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1336-37 (Fed. Cir. 2007).

C. The Seventh and Ninth Circuits' Inconsistent Interpretations of Section 261.

The Seventh and Ninth Circuits are the only other circuit courts that have expressly analyzed whether Section 261 applies to exclusive licenses, although they have not directly addressed the question of whether an exclusive patent license must be transferred in a written instrument. The Seventh Circuit has concluded that although Section 261 was historically intended to apply only to "assignments" and "grants," Section 261 also applies to exclusive licenses because they differ from "grants" only in their "formal . . . nature." *Moraine*, 538 F.2d at 143. In contrast, the Ninth Circuit has concluded that Section 261 applies only to "ownership interests," not licenses. *In re Cybernetic Servs. Inc.*, 252 F.3d 1039, 1049 (9th Cir. 2001). The differences between the Ninth and Seventh Circuit analyses highlight the importance of granting

certiorari to address the scope and meaning of Section 261.

1. Seventh Circuit: *Moraine Prods. v. ICI Am., Inc.*

In *Moraine Products*, the Seventh Circuit addressed Section 261 in the context of a decision about whether it is an antitrust violation "for the assignee of a patent in licensing a competitor to agree with that competitor that with the exception of another competitor the assignee will not license anyone else although retaining the right to use the patent itself and the first licensee will not grant any sub-licenses." *Moraine*, 538 F.2d at 138.

The Seventh Circuit acknowledged that the phrase "in like manner" means in a "written instrument." It quoted the statutory text of Section 261 and placed "in an instrument in writing" in parentheses after "in like manner":

> 35 U.S.C. § 261 provides in relevant part: The applicant, patentee, or his assigns or legal representatives may in **like manner (by an instrument in writing)** grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.

Id. at 143 (parentheses in original; emphasis added).

The Seventh Circuit then noted an apparent historical distinction between a "grant" and an "exclusive license" and stated that the quoted language of Section 261 was originally not intended to apply to assignments and exclusive licenses, but only to

"grants." *Id.* However, the Seventh Circuit concluded that "the difference between a 'grant' and an exclusive license is merely formal in nature." *Id.* Under this analysis, the Seventh Circuit stated that "**[t]he bare language of § 261** does allow a patentee or his assignee to **grant an exclusive license** to make, use, or sell the patented invention." *Id.* (emphasis added).[9] Thus, although it did not explicitly address the question, it follows from the logic of the Seventh Circuit in *Moraine Products* that the written instrument requirement of Section 261 applies to exclusive licenses.

2. Ninth Circuit: *In re Cybernetic*.

In contrast, the Ninth Circuit has decided that Section 261 applies only to "transfer[s] of an ownership interest," and not to licenses. *Cybernetic*, 252 F.3d at 1049.

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[9] The Seventh Circuit is not alone in concluding that Section 261 applies to exclusive licenses. Other circuit courts—including one Ninth Circuit opinion that appears to conflict with *In re Cybernetic* discussed below—have stated that Section 261 applies to exclusive licenses. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304-05 (11th Cir. 2003) ("[A] patentee can choose to . . . grant exclusive territorial licenses carving up the United States among its licensees, see 35 U.S.C. § 261."); *Dunlop Co. v. Kelsey-Hayes Co.*, 484 F.2d 407, 417 (6th Cir. 1973) ("[T]erritorial licenses granted by a patentee . . . are permitted by 35 U.S.C. § 261."); *Brownell v. Ketcham Wire & Mfg. Co.*, 211 F.2d 121, 128 (9th Cir. 1954) (citing to "grant and convey exclusive rights" language of Section 261 in stating that "[i]t is fundamental rule of patent law that the owner of a patent may license another and prescribe territorial limitations").

The Ninth Circuit addressed Section 261 while ruling on the question of "whether [Section 261] or Article 9 of the [UCC], as adopted in California, requires the holder of a security interest in a patent to record that interest with the federal [PTO] in order to perfect the interest as against a subsequent lien creditor." *Id.* at 1044.

Like the Seventh Circuit, the Ninth Circuit explained that historically a "grant" was a distinguishable type of right in a patent different from an assignment or license. *Id.* at 1050. However, unlike the Seventh Circuit, the Ninth Circuit concluded that a "grant and conveyance" involves the transfer of an ownership interest in the patent or patent application:

> The types of transactions referred to in § 261's second paragraph—(1) the assignment of a patent, and (2) the grant or conveyance of an exclusive right in a patent in the whole or part of the United States—track the historical definitions of assignment, grant, and conveyance that we just discussed—transactions that all involve the transfer of an ownership interest in a patent.

Id. at 1050-51. Thus, according to the Ninth Circuit's reasoning, Section 261 would not apply to licenses, including an exclusive license, because it only applies to "ownership interest[s]." *Id.* at 1050-51.

The inconsistency between the Seventh and Ninth Circuits' interpretation of the scope of Section 261 further confirms that it is necessary for the U.S. Supreme Court to grant certiorari.

D. Federal Circuit Precedent Permitting Oral or Implied Transfers of Exclusive Patent Licenses Can Be Corrected Only By This Court.

This Court is the proper Court to correct the Federal Circuit's entrenched body of case law finding oral and implied exclusive licenses sufficient to establish standing. Although the question of whether Section 261 requires a written instrument has been raised before, the Federal Circuit has stated that it believes it is bound by its own precedent. In *Aspex Eyewear, Inc. v. Altair Eyewear*, a Federal Circuit panel recognized that the oft-cited decisions in *Waymark* and *Rite-Hite* do not "expressly analyze[] Section 261." 288 Fed. Appx. at 706. However, the panel stated that it was "bound to follow our precedent," and "thus [held] that an exclusive license need not be in writing to have standing if the patentee or assignee is also joined." *Id.* Thus, even when the Federal Circuit has recognized that the written instrument requirement of Section 261 may be applicable to exclusive licenses, it has nonetheless felt constrained to follow its own precedent without further analysis of the statute. And in this case the Federal Circuit explained that it is now "well established that the grant of a license does not need to be in writing." App. 8.

It is therefore necessary for this Court to address the contradiction between Federal Circuit case law and the statutory requirement in Section 261 that transfers of exclusive patent rights be "by an instrument in writing."

II. The Written Instrument Requirement of Section 261 Is Important for Promoting Certainty and Transparency in Control of Patent Rights.

The Federal Circuit drew the wrong line when it endorsed the validity of oral or implied exclusive patent licenses to establish standing. The line it drew places certain types of exclusive licenses, categorized as "virtual assignment[s]," on the "instrument in writing" side of the divide, *see Enzo*, 134 F.3d at 1093, while all other exclusive licenses fall in a category that can be oral or implied. The plain language of Section 261 establishes a different line—one that places all exclusive licenses in the "written instrument" category and only permits oral or implied licenses when they are non-exclusive. The line that Section 261 draws is clear from its emphasis on "exclusive rights" in the plain language of the statute and also comports with the public policy of encouraging transparency in who has the right to enforce a patent.

The Federal Circuit itself has explained the critical importance to the patent system of "the certainty provided by the writing requirement of section 261":

> [T]he licensing arrangement conferring [standing on licensees who are virtual assignees] must, logically, resemble an assignment in both form and substance. Under the 35 U.S.C. § 261 (1994), '[a]pplications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing.' If we were to expand the exception to include verbal licenses, the exception would swallow the rule. Parties would be free to engage in revisionist history,

> circumventing the certainty provided by the writing requirement of section 261 by claiming to be patentee by virtue of a verbal licensing arrangement.

Enzo, 134 F.3d at 1093; *cf. Moraine*, 538 F.2d at 145 ("Where licensing practices suppress incentives to attack patent validity, to invent around the patent, or to employ available technology, they can hardly be considered a legitimate exercise of patent rights . . . .").

The certainty concerns discussed in *Enzo* apply to **all** exclusive licenses, not just exclusive licenses that are deemed "virtual assignments." Indeed, this case is an example of exactly the type of revisionist history that the written instrument requirement of Section 261 is meant to guard against. For years after the alleged oral or implied transfer by Bard to IMPRA/BPV of the exclusive license in the 1980 Agreement, Bard continued to hold itself out as the owner of the '135 patent and the exclusive rights to it. Bard's own general counsel testified in 1999 that "I have no knowledge of an assignment [of the 1980 Agreement] from Bard to IMPRA, so if my knowledge is correct, then **Bard is still the licensee**." Dep. of C.R. Bard, Inc., by its designee R. Flink, Apr. 8, 1999 (Fed. Cir. App. A4240, 79:3-7) (emphasis added). Bard's statements under oath in litigation in the late 1990s and 2000s shows that it did not believe that it had transferred its license to IMPRA/BPV. Yet when it came time for enforcement of the '135 patent against Gore in this case in 2003, Bard and IMPRA/BPV chose to have IMPRA/BPV enforce the patent, not Bard, by claiming for the first time that Bard had granted an unwritten exclusive license to IMPRA/BPV in 1996.

The obvious question, then, is why did Bard and IMPRA/BPV choose to have IMPRA/BPV enforce the patent instead of Bard? The answer is money. IMPRA/BPV, not Bard, is the entity that competed directly with Gore and sold products that competed with Gore. It was therefore IMPRA/BPV, not Bard, that was potentially eligible for lost profits, a higher royalty, and a greater amount of damages if Gore was found to infringe the '135 patent. That is why, when it came time to file the complaint in this litigation, Bard and IMPRA/BPV made a strategic decision to name IMPRA/BPV as the plaintiff, not Bard. But IMPRA/BPV cannot by itself be a patent plaintiff unless it possesses exclusive rights in the patent. And when Gore challenged IMPRA/BPV on its failure to acquire exclusive rights in the '135 patent, IMPRA/BPV resorted to self-serving oral testimony to try to establish the existence of an implied or oral transfer of an exclusive license from Bard to IMPRA/BPV. This is exactly the "revisionist history" that *Enzo* warned against, which allowed IMPRA/BPV to obtain a $1 billion-plus damages award based on a patent it had no right to enforce.

III. This Case Is a Superior Vehicle For Addressing a Fundamental Question of Proof of Ownership of Patent Rights That Warrants This Court's Immediate Review.

This case is a superior vehicle for the U.S. Supreme Court to address whether the "written instrument" requirement of Section 261 applies to exclusive licenses.

A. There Is No Written Instrument Transferring Bard's Exclusive License To IMPRA/BPV.

There is no dispute that Bard and IMPRA/BPV did not execute a written instrument in September 1996.[10] Nonetheless, the court decided that a written instrument was not necessary to effectuate this transfer because "BPV's position is only that it was an exclusive licensee with the right to sue for infringement," and "[i]t is **well established** that the grant of a license **does not need to be in writing**." App. 8 (emphasis added).

In addition to the lack of a written instrument in 1996, there was also never a subsequent written instrument whereby Bard transferred its exclusive rights to IMPRA/BPV. The Federal Circuit found the 1997 Amendment (executed by Goldfarb and IMPRA/BPV) to be a valid after-the-fact confirmation of the 1996 oral or implied transfer. But **Bard was not a party** to the 1997 Amendment, nor did the "WHEREAS" clause itself transfer any rights.

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[10] The only evidence of this purported transfer is oral hearsay testimony. *See* App. 65 ("[A]s Mr. McDermott testified, because Impra was the sole C.R. Bard entity manufacturing ePTFE grafts, all rights and obligations under the 1980 Agreement were transferred to it.").

B. The Failure of Bard to Effectively Transfer Its Exclusive License to IMPRA/BPV Has Significant Implications On This Case.

Lack of standing. The absence of Bard—the exclusive licensee of the '135 patent—as a plaintiff created a fundamental standing problem that requires dismissal of the case.[11] This is because, "[f]or the same policy reasons that a patentee must be joined in any lawsuit involving his or her patent[s], there must be joinder of any exclusive licensee." *Aspex v. Miracle*, 434 F.3d at 1344 (citing *Indep. Wireless*, 269 U.S. at 466); *see also Alfred E. Mann*, 604 F.3d at 1359-60, 1363. Thus, Goldfarb, as the patentee, needed to include Bard from the outset of the case because he had granted Bard the exclusive right to sue for patent infringement. *See* App. 137, ¶ 5.3. Moreover, adding Bard to the case as a third party defendant did not solve the standing problem, because Bard specifically stated that it was not alleging that Gore infringed the '135 patent and expressly disclaimed status as a plaintiff in the case. Bard's Reply to Counterclaims ¶ 96 (D. Ariz. Dkt. 20 at 14 ("Bard denies that it has asserted in this litigation that Gore infringes the '135 patent."); Supp. Interrog. Resp. No. 1 (Fed. Cir. App.

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[11] At the Federal Circuit, Bard argued that the plaintiffs' alleged possession of standing had become the law of the case. However, "law of the case cannot bind this Court in reviewing decisions below. A petition for writ of certiorari can expose the entire case to review." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (citing *Panama R. Co. v. Napier Shipping Co.*, 166 U. S. 280, 283-84 (1897)). Moreover, this Court has not previously ruled on the issues raised in this petition.

A4246) ("Counterdefendant Bard is **not a plaintiff** in this action and has not alleged that Gore infringes the '135 patent.") (emphasis added); Fed. Cir. App. A4257 (same); Fed. Cir. App. A4237-38, at No. 2 (same); Fed. Cir. App. A4297, at No. 6 (same).

The damages award. The entire $1 billion-plus damages award was also based on the incorrect understanding that the plaintiff—IMPRA/BPV—had the right to exclude Gore and others from using the '135 patent. Even setting aside the standing problem, this too requires remand.

C. Issue for Consideration on Remand.

This case presents a superior vehicle for this Court to address a straightforward legal issue: Does Section 261 require that the grant or conveyance of an exclusive patent license be in writing? If the answer to this question is yes, the Court should remand to the lower court for reconsideration of whether there is a writing that effectively transfers Bard's exclusive rights in the '135 patent to IMPRA/BPV.

For these reasons, the Court should grant certiorari to resolve the uncertainty created by the Federal Circuit's interpretation and application of Section 261, and confirm that exclusive licenses must be transferred "by an instrument in writing."

CONCLUSION

For the reasons set forth above, this Court should grant the petition for certiorari.

Respectfully submitted,

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July 7, 2015

APPENDIX

APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2014-1114

[Filed January 13, 2015]

BARD PERIPHERAL VASCULAR, INC., AND DAVID GOLDFARB, M.D.,
Plaintiffs-Appellees,

AND

C.R. BARD, INC.,
Counterclaim Defendant-Appellee,

v.

W.L. GORE & ASSOCIATES, INC.,
Defendant-Appellant.

Appeal from the United States District Court for the District of Arizona in No. 2:03-CV-00597-MHM, Judge Mary H. Murguia.

Decided: January 13, 2015

MICHAEL W. MCCONNELL, Kirkland & Ellis LLP, of Washington, DC, argued for plaintiffs-appellees and counterclaim defendant-appellee. With him on the brief were JOHN C. O'QUINN, WILLIAM H. BURGESS, DENNIS J. ABDELNOUR and LIAM P. HARDY; STEVEN C. CHERNY,

of New York, New York; and JOHN L. STRAND, Wolf, Greenfield & Sacks, P.C., of Boston, Massachusetts.

JAMES W. PORADEK, Faegre Baker Daniels LLP, of Minneapolis, Minnesota, argued for defendant-appellant. With him on the brief were TIMOTHY E. GRIMSRUD; JARED B. BRIANT and LESLIE B. PRILL, of Denver, Colorado; and MICHAEL E. FLOREY and DEANNA REICHEL, Fish & Richardson P.C., of Minneapolis, Minnesota.

Before PROST, *Chief Judge,* NEWMAN and HUGHES, *Circuit Judges.*

Opinion for the court filed by *Chief Judge* PROST.

Concurring opinion filed by *Circuit Judge* HUGHES.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

PROST, *Chief Judge*.

W.L. Gore & Associates, Inc. ("Gore") appeals from the judgment of the United States District Court for the District of Arizona of willfulness in the infringement of U.S. Patent No. 6,436,135 ("'135 patent"). For the reasons stated below, we affirm.

I

This dispute began with the filing of the 1974 patent application from which the '135 patent eventually issued—twenty-eight years later. The technology and patent claims that have been at issue are thoroughly discussed in this court's previous decisions involving the '135 patent and underlying application. *See Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171 (Fed. Cir. 2012)

("*Bard I*"); *Cooper v. Goldfarb*, 240 F.3d 1378 (Fed. Cir. 2001) ("*Cooper II*"); *Cooper v. Goldfarb*, 154 F.3d 1321 (Fed. Cir. 1998) ("*Cooper I*").

Briefly, the '135 patent relates to prosthetic vascular grafts made of highly-expanded polytetrafluoroethylene ("ePTFE"). The ePTFE material is made of solid nodes of PTFE connected by thin PTFE fibrils. It is sold by Gore under the brand name "Gore-Tex." The patent generally covers a vascular graft formed by ePFTE that is thus homogeneously porous—a structure that allows uniform cell regrowth to establish a firm integration of the graft into the body. The different claims of the patent are directed to grafts made of ePTFE with varying internodal distances, which are also called fibril lengths.

In 2003, Bard Peripheral Vascular, Inc. ("BPV") and Dr. David Goldfarb filed suit against Gore for infringement of the '135 patent. A jury found the '135 patent valid and that Gore willfully infringed, and, in December 2010, the district court denied Gore's motions for judgment as a matter of law ("JMOL") reversing the verdict. Gore appealed, and, in February 2012, the panel affirmed. *Bard I*, 670 F.3d at 1193. The en banc court denied review but granted rehearing "for the limited purpose of authorizing the panel to revise the portion of its opinion addressing willfulness." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 476 F. App'x 747 (Fed. Cir. June 14, 2012) (en banc). The panel accordingly vacated the parts of its opinion discussing willfulness and allowing enhanced damages and attorneys' fees. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1005 (Fed.

Cir. 2012) ("*Bard II*"). It held that as to the threshold determination of willfulness, "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." *Id.* at 1007. The panel remanded "so that the trial court may apply the correct standard to the question of willfulness in the first instance." *Id.* at 1008.[1]

On remand, the district court again found that, in view of *Bard II*, it was "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." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 03-0597, 2013 WL 5670909, at *12 (D. Ariz. Oct. 17, 2013) (order denying JMOL on willful infringement) ("*Bard III*"). Gore appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II

Gore argues that at the time of suit, neither BPV nor Goldfarb had standing to sue for infringement of the '135 patent. Gore thus seeks to vacate the district court's judgment in its entirety and to have the case dismissed for lack of jurisdiction. The crux of Gore's argument is that at the time the suit was filed, *only* C.R. Bard, Inc. ("Bard Inc.") could have possessed standing to sue. We reject that argument.

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[1] Gore sought to appeal the question of inventorship under 35 U.S.C. § 116 to the Supreme Court, which denied its petition for certiorari. *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 133 S. Ct. 932 (2013).

In 1980, Goldfarb—who was the inventor and original assignee of the '135 patent's application—entered into a license agreement with Bard Inc. involving the application and any patents that might issue. Gore argues that in that agreement, Goldfarb granted all substantial rights to the patent—thereby resulting in a virtual assignment to Bard Inc. In 1996, Bard Inc. acquired IMPRA, which later became a wholly owned subsidiary, BPV, and in September, Bard Inc. transferred its interest in the 1980 agreement to BPV. Gore argues that because there is no evidence of a written instrument effecting the transfer of the interest to BPV, BPV did not in fact acquire standing to sue for infringement. In sum, Gore contends that both plaintiffs lacked standing: Goldfarb, because he had virtually assigned his rights to Bard Inc., and BPV, because Bard Inc. had not properly transferred its rights.

Gore raised this argument on standing twice before at the district court—prior to its first appeal in this case. Gore first filed a pre-trial JMOL motion on standing, which the district court denied. Gore again raised the issue as a post-trial JMOL motion, which the district court again denied. The district court's discussion of the standing issue and denial of Gore's motion was contained in the same March 31, 2009 opinion and order denying Gore's various other JMOL motions that Gore appealed to this court. In that appeal, although the issue was not raised in briefing, the panel confirmed that the district court had jurisdiction under 28 U.S.C. § 1338(a). *Bard I*, 670 F.3d at 1178.

Gore does not claim that there exists any material difference between the argument it raised before the district court then and that it now raises on this appeal. Indeed, in its first appeal, Gore conceded that the district court had jurisdiction. Brief for Appellant at 1, *Bard I*, 670 F.3d 1171 (Fed. Cir. 2012) (No. 10-1542), 2010 WL 4853331. Instead, Gore contends that we are not bound by the prior panel's determination on standing, based on the fundamental principle that "[t]he question of standing is not subject to waiver" because "[t]he federal courts are under an independent obligation to examine their own jurisdiction." *See United States v. Hays*, 515 U.S. 737, 742 (1995).

The "party invoking federal jurisdiction bears the burden of establishing" standing at any stage of the litigation. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). In this case, Gore challenged the plaintiffs' standing at the district court. The district court determined that the plaintiffs met their burden and had established standing. On appeal, this court again confirmed that the plaintiffs had standing. Gore argues that because it did not brief the issue on appeal, and the prior panel did not discuss the issue of standing, the standing issue has yet to be resolved with finality.

As an initial matter, however, we have no reason to assume that the prior panel did not weigh standing. This was not a case in which a standing issue remained dormant in facts buried deep in the record, or which was not recognized by either party or the trial court. While Gore's briefs in that appeal did not raise the standing issue, the district court's opinion discussing Gore's standing challenge were attached to the opening brief as required pursuant to Federal Circuit Rule

28(a)(12). Had the prior panel seen merit in Gore's standing challenge, it could have asked for additional briefing, as this court has done in other cases. *See, e.g.*, *Consumer Watchdog v. Wis. Alumni Research Found.*, No. 13-1377 (Fed. Cir. Nov. 14, 2013) (order requesting supplemental briefing on the issue of appellant's standing) ECF No. 29. We are bound, therefore, by the prior panel's determination that the plaintiffs had standing and that the district court had jurisdiction. *See Gould, Inc. v. United States*, 67 F.3d 925, 930 (Fed. Cir. 1995) ("The law of the case is a judicially created doctrine, the purposes of which are to prevent the relitigation of issues that have been decided and to ensure that trial courts follow the decisions of appellate courts.").

To be sure, there are exceptional circumstances in which a panel may not adhere to the decision in a prior appeal in the same case, when "(1) the evidence in a subsequent trial is substantially different; (2) controlling authority has since made a contrary decision of the law applicable to the issues; or (3) the earlier ruling was clearly erroneous and would work a manifest injustice." *Id.* This is not such a case. Gore raises no new facts in this appeal and seeks only to relitigate the same standing theory that the district court rejected before. Gore does not point to any change in the relevant law. This is also not a case in which the district court made findings on remand that "undermine" the prior appellate affirmance of standing. *Pub. Interest Research Grp. of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 117 (3d Cir. 1997). And, we see no clear error in the previous decision on standing that would warrant an extraordinary review at this stage.

Indeed, on the merits, this is an easy question. We review de novo the district court's determination of a party's standing, while reviewing any factual findings relevant to that determination for clear error. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1377 (Fed. Cir. 2007). Gore's argument hinges on the absence of a written instrument transferring to BPV what it contends was the virtual assignment from Goldfarb to Bard Inc. *See Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000) (holding that a written instrument was needed to document the "transfer of proprietary rights" to support standing to sue for patent infringement); 35 U.S.C. § 261 ("Applications for patent, patents, or any interest therein, shall be *assignable* by law in an instrument *in writing*.") (emphases added). However, BPV has never claimed that in 2003 it had all substantial rights to the '135 patent.[2] BPV's position is only that it was an exclusive licensee with the right to sue for infringement. It is well established that the grant of a license does not need to be in writing. *See Waymark Corp. v. Porta Sys. Corp.*, 334 F.3d 1358, 1364 (Fed. Cir. 2003) ("Only assignments need be in writing under 35 U.S.C. § 261. Licenses may be oral."); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995) (en banc) (holding that to be an exclusive licensee a party may rely on either an express or implied promise of exclusivity). In any event, in 1997 there was a

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[2] In 2007, Goldfarb assigned his remaining interests in the '135 patent to BPV. Gore argues that this assignment was illusory since Goldfarb had already granted all substantial rights to Bard Inc. in 1980. We note that at most this transfer corroborates BPV's position that the parties clearly understood that BPV was Goldfarb's licensee at the time the suit was filed.

memorialized transfer of the exclusive license from Goldfarb and Bard Inc. to BPV's predecessor. We agree with the district court that this 1997 agreement between the parties settles BPV's right to sue at the time of the complaint as Goldfarb's exclusive licensee. *Bard III*, at 19-20.

BPV and Goldfarb thus readily meet their burden to establish standing. For Gore to prevail, it would have to establish each of the following propositions: (1) the 1980 agreement that was styled as an "exclusive license" between Goldfarb and Bard Inc. was in fact a virtual assignment, and (2) Bard Inc.'s transfer of its rights to BPV under the agreement failed because it was not in writing. We see no error in the district court's well-reasoned analysis on the first point—inter alia, Goldfarb retained significant reversionary rights, there was a field of use restriction, and Goldfarb retained the right to share in damages. *See id.* at 15. There was no basis, therefore, to conclude that Goldfarb had transferred "all substantial rights" to Bard. *See Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1132 (Fed. Cir. 1995) (finding that even limited rights retained by the patentee made it a necessary party in any subsequent infringement suit). But even if Gore could get past those first shoals, it would founder at the second. Gore argues that since Bard represents that it transferred its entire interest in the 1980 agreement to BPV, if that interest were a virtual assignment, then the transfer would fail without a written agreement. But, there is no question that in 1997, there *was* a written agreement between the parties affirming Bard's transfer of its rights to BPV. Gore argues that our case law prevents such a retroactive agreement—but for support of this

proposition, all Gore cites is precedent in which we considered agreements that were executed *after* the suit was filed, such as *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359 (Fed. Cir. 2008). Here, by contrast, the 1997 memorialization occurred years before the suit was filed. The 1997 agreement was not a nunc pro tunc written agreement that occurred *after* the complaint. *Compare, e.g.*, *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1366-67 (Fed. Cir. 2010); *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998). Accordingly, the plaintiffs had standing at the time of the complaint, and the district court had jurisdiction pursuant § 1338(a). We turn, then, to Gore's appeal on the merits.

III

To establish willful infringement, the patentee has the burden of showing "by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc) *cert denied* 552 U.S. 1230 (2008). "The state of mind of the accused infringer is not relevant to this objective inquiry." *Id*. Only if the patentee establishes this "threshold objective standard" does the inquiry then move on to whether "this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." *Id.* While this second prong of *Seagate* may be an issue of fact, the threshold determination of objective recklessness requires "objective assessment" of the accused infringer's defenses. *Bard II*, 682 F.3d at

1006. In *Bard II* we held that objective 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." *Id.* at 1007.[3] Even when underlying factual issues were sent to the jury in the first instance—such as in this case—"the judge remains the final arbiter of whether the defense was *reasonable*." *Id.* at 1008 (emphasis added).

Accordingly, under *Bard II*, we review de novo the district court's determination whether Gore's "position is susceptible to a reasonable conclusion of no infringement." *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1310 (Fed. Cir. 2011). Objective recklessness will not be found where the accused infringer has raised a "substantial question" as to the validity or noninfringement of the patent. *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1319 (Fed. Cir. 2010); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1336 (Fed. Cir. 2009).

On remand, the district court evaluated several defenses raised by Gore and determined that none of

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[3] The district court's opinion suggests that it rejected Gore's argument because "substantial evidence" was contrary to a finding that Gore had a reasonable expectation of success in its defense. *Bard III*, at 11. Gore argues that this suggests that the district court inappropriately relied on findings of fact in determining the objective reasonableness of its defense. Gore's position overstates the significance of the district court's reference to "substantial evidence." Rather, the district court correctly followed *Bard II*, reviewing the facts in the record produced in the litigation and evaluating whether, on the basis of those facts, Gore had raised a reasonable defense. *See id.* at 19.

them were objectively reasonable. On appeal, Gore appeals only its determination with respect to Gore's inventorship defense. This defense arises from the decades-long record, which includes parallel examination of Gore's and Goldfarb's patent applications on vascular grafts made of ePTFE, an interference declared in 1983 between the applications, which we reviewed in *Cooper I* and *Cooper II*, as well as the infringement proceedings in this case that were finally resolved—except as to the issue of willfulness—in *Bard I*. Gore's argument is based on the fact that its employee, Peter Cooper, supplied the particular ePTFE tubing that Goldfarb used in making his successful vascular graft (the "2-73 RF" graft). In Gore's view, Cooper furnished to Goldfarb "the embodiment of the invention before Goldfarb conceived the invention using that embodiment." *Bard III*, at 7.

As an initial matter, we reject Gore's argument that the mere fact a member of the previous panel dissented on this issue indicates that its position was reasonable. Gore does not point to any previous case in which we followed this principle. To the contrary, in *Paper Converting Machine Co. v. Magna-Graphics Corp.*, 785 F.2d 1013, 1016 (Fed. Cir. 1986), for example, we noted that despite the existence of a dissenting opinion in a prior opinion affirming infringement, the same panel could still affirm willfulness in a later appeal. Otherwise, we would be imposing a rule that any single judge's dissent on the merits could preclude the determination of willful infringement.

Turning to the merits, Gore claimed that its employee, Peter Cooper, was a joint inventor of the '135 patent. Therefore, Gore argued that the patent is

invalid for nonjoinder of Cooper as a co-inventor. Gore now argues that even though it did not prevail, its argument was still reasonable in light of the facts in the record and the law of joint inventorship.

Issued patents are presumed to correctly name the inventors; therefore, "[t]he burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence." *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997) (quoting *Garrett Corp. v. United States*, 190 Ct. Cl. 858, 870 (1970)). By statute,

> [i]nventors 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.

35 U.S.C. § 116(a). "Because conception is the touchstone of inventorship, each joint inventor must generally contribute to the conception of the invention." *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). Conception is precisely defined as existing "when a definite and permanent idea of an operative invention, including every feature of the subject matter sought to be patented, is known." *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994). In other words, conception is only complete when the "idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994).

As to the required degree of contribution to conception, we have recognized that "[t]he determination of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). The underlying principle from our case law is that a joint inventor's contribution must be "not insignificant in quality, when that contribution is measured against the dimension of the full invention." *Id.* Of particular relevance to this case, we have held that if an individual supplies a component essential to an invention, that is an insufficiently significant contribution if the component and the principles of its use were known in the prior art. *Hess*, 106 F.3d at 981; *see also Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998) (explaining that a joint inventor is required to "do more than merely explain to the real inventors well-known concepts and/or the current state of the art"). Moreover, while joint inventors need not "physically" work together under § 116, "the statutory word 'jointly' is not mere surplusage." *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., Inc.*, 973 F.2d 911, 917 (Fed. Cir. 1992). We require that "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). Critically, "each inventor must contribute to the *joint arrival* at a definite and permanent idea of the invention as it will be used in practice." *Burroughs*, 40 F.3d at 1229 (emphasis added); *see also Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1308 (Fed. Cir. 2010) ("[C]o-inventors must collaborate and work together to collectively have a definite and permanent idea of the complete invention.").

In sum, the two questions for objectively assessing Gore's defense are (1) what constitutes the "definite and permanent idea" of the invention at issue and (2) whether Cooper and Goldfarb acted in concert to jointly arrive at that idea. With respect to these questions, the factual record and inferences from the record were raised in the interference proceeding that preceded the issuance of the '135 patent and this litigation—and were reviewed by this court in *Cooper I* and *Cooper II*.

As to the first, we note that the invention at issue was not merely the use of ePTFE in vascular grafts. Rather, each claim of the '135 patent includes, as its key limitation, specified dimensions of fibril length that are essential for a successful graft. *See Cooper II*, 240 F.3d at 1380 (noting that the invention "relates to the fibril length of certain material used for vascular grafts"). While Cooper identified ePTFE as a promising material for vascular grafts, many grafts that were made of ePTFE failed. *Cooper I*, 154 F.3d at 1325. Prior to the invention, Cooper and others in the art believed that pore size was the key parameter for success. *Id.* at 1324. We affirmed the Board's finding that prior to Cooper's providing the lot of ePTFE tubes that ultimately led to the successful 2-73 RF graft, "he had not yet recognized the importance of the fibril length required by the interference, i.e., he had not yet conceived the invention, and he was not aware of the fibril lengths of the material he was sending to Goldfarb." *Cooper II*, 240 F.3d at 1381. What Cooper told Goldfarb was, more generally, that "he expected the material to be suitable as a vascular graft." *Id.* at 1384. In other words, Cooper "had not conceived the

fibril length limitation before he sent the material to Goldfarb." *Id.* at 1385.

To be sure, in those prior appeals we held that Cooper "had conceived of the invention, including the fibril length limitation" before Goldfarb evaluated the 2-73 RF graft and reduced the invention to practice. *Id.* at 1384-85 (citing *Cooper I*, 154 F.3d at 1326). However, we agree with the district court that the record—established in proceedings prior to the litigation—shows that Cooper had "minimal contact" with Goldfarb on the subject of the fibril length limitation:

> 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.

Bard III, at 9 (quoting *Cooper II*, 240 F.3d at 1385). Based on the record established in *Cooper I* and *II*—that we reviewed—Cooper and Goldfarb *independently* conceived of the fibril length limitation. While *Cooper I* and *II* concerned inurement in the context of interference, they established that—barring Gore's introduction of new evidence or theories—Cooper and Goldfarb did not collaborate, communicate,

nor in any way jointly arrive at the recognition that fibril length was significant for graft success. Even if Cooper had achieved conception prior to Goldfarb, *Cooper II* definitively held that Goldfarb arrived at conception on his own, and, thus, his reduction to practice did not inure to Cooper. 240 F.3d at 1386.

This is an unusual case. Forty years have passed since Goldfarb filed for the patent at issue in this case. Gore tried to get a patent on the subject matter of the patent on which it was sued. The subsequent decades of prior proceedings shaped what defenses Gore could raise once it was sued for infringement. Once it failed and the '135 patent issued, Gore was left with an exceptionally circumscribed scope of reasonable defense.

In the current proceedings, Gore relied on those facts which showed that the invention was based on a material that Gore invented and that Cooper may have conceived of the invention prior to Goldfarb (though Goldfarb won the patent because he was the first to reduce it to practice). But even if it could have persuaded a jury—which it did not—Gore could not have evaded the legal requirements of joint inventorship. Ultimately, to have stood a reasonable chance of prevailing on this issue, Gore needed to raise new evidence or theories that were not considered in *Cooper I* and *II*. However, as the prior panel noted, "Gore's argument remains unchanged and there is still no evidence that Cooper either recognized or appreciated the critical nature of the internodal distance and communicated that key requirement to Goldfarb before Goldfarb reduced the invention to

practice." *Bard I*, 670 F.3d at 1182.[4] Within the backdrop of the extensive proceedings prior to this litigation, therefore, we agree with the district court that Gore's position was not susceptible to a reasonable conclusion that the patent was invalid on inventorship grounds.

IV

For the aforementioned reasons, we affirm the district court's determination that the plaintiffs established standing and that the '135 patent was willfully infringed.

AFFIRMED

[4] Indeed, if anything, the evidence presented in the litigation further bolstered the plaintiffs' position. For example, as the district court noted, shortly after Goldfarb filed his patent application in October 1974, Cooper admitted to entering Goldfarb's laboratory without permission and took his histological slides. *Bard III*, at 10. Other evidence suggested that Cooper did so because Cooper still did not understand what parameters mattered for successful grafts. *Id.* at 10-11.

HUGHES, *Circuit Judge*, concurring.

I agree that when reviewed de novo, the evidence in this case shows that Gore's defenses were not objectively reasonable. I write separately to reiterate my belief that the full court should review our willfulness jurisprudence in light of the Supreme Court's recent decisions in *Highmark Inc. v. Allcare Health Management Sys., Inc.*, 134 S. Ct. 1744 (2014) and *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014). Those decisions call into question our two-part test for determining willfulness, *In Re Seagate Tech., LLC*, 497 F.3d 1360 (2007) (en banc), and our de novo standard for reviewing the district court's willfulness determination, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1006–07 (Fed. Cir. 2012) (*Bard II*). *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1383 (Fed. Cir. 2014) (O'Malley, J., concurring).

This case demonstrates why de novo review of willfulness is problematic. The panel is divided over the strength of Gore's joint inventorship defense. Each side advances a sound argument about whether the evidence in this case raises a "substantial question" of joint inventorship. And the district court, likewise, provided a thorough and well-reasoned opinion. If one of these several reasonable opinions must ultimately govern, it should be the opinion of the district judge, whose assessment of litigation positions is informed by trial experience and who has "lived with the case over a prolonged period of time." *Highmark*, 134 S. Ct. at 1748.

A more deferential standard of review would be consistent with the standards for reviewing mixed

questions of law and fact in other contexts. *See, e.g.*, *Highmark*, 134 S. Ct. at 1748–49 (holding abuse of discretion is the proper standard for reviewing award of attorney fees in patent cases, "[a]lthough questions of law may in some cases be relevant . . . ."); *Pierce v. Underwood*, 487 U.S. 552, 558 (1988) (holding abuse of discretion is the proper standard for reviewing determinations of whether a litigant's position is "substantially justified" for purposes of fee-shifting under the Equal Access to Justice Act, although the determination frequently turns on a purely legal issue). It would also be consistent with the standard for reviewing a finding of willful copyright infringement. *See Dolman v. Agee*, 157 F.3d 708, 715 (9th Cir. 1998) ("The district court's finding of willful [copyright] infringement is reviewed for clear error.").

NEWMAN, *Circuit Judge*, dissenting.

This case returns to the Federal Circuit on appeal of a district court decision on remand from an en banc decision of this court. The issue is willful infringement and its consequences, which this en banc court remanded for de novo determination as a matter of law, vacating the judgment entered on the jury verdict.

The en banc court changed the standard and procedure for determination of willful infringement and its consequences in order to bring reasonable national uniformity to application of this penalty. The court held that the objective reasonableness of a defense to infringement is a legal question to be determined by the judge, and is decided de novo on appeal. The court held that willful infringement is not a jury question, and vacated the judgment of willful infringement and punitive damages that the district court had entered on the jury verdict.

On remand, the district court re-entered its prior judgment in its entirety, reciting the evidence that in its view supported the judgment. Again here on appeal, my colleagues on this panel repeat the district court's exercise, do not apply de novo standards of review, and do not apply the clear precedent which requires determination of whether Gore acted with "objective recklessness" *In re Seagate Techs., LLC,* 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). Nor do my colleagues attempt to meet the court's responsibility to impart reasonable consistency and objective standards to the penalty aspect of "willful" activity, although this was the reason why the en banc court established a system of de novo determination of this question of law applied to the facts of the particular case.

Precedent establishes that the objective prong of willful infringement "tends not to be met where an accused infringer relies on a reasonable defense to a charge of infringement." *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.,* 620 F.3d 1305, 1319–20 (Fed. Cir. 2010). When there is a "substantial question of invalidity or unenforceability" of the patent, willful infringement cannot arise, as a matter of law. *Seagate,* 497 F.3d at 1371. The panel majority does not review the evidence and apply the law objectively; the court merely searches for and recites adverse evidence.

The majority ignores that Gore's employee Cooper was the first to conceive of the invention – by final ruling of the patent interference tribunal and this court; the majority ignores that the '135 patent was pending for twenty-eight years, while Gore developed this Gore-Tex® prosthetic product; the majority ignores that the district court refused to enjoin Gore's provision of these prosthetic products after this litigation, citing the "potentially devastating public health consequences"[1]; the court does not mention the inequitable conduct that pervades Dr. Goldfarb's actions in obtaining the patent, including confessed perjury of a key witness; the court does not mention the action for misappropriation of Gore's trade secrets by Gore ex-employees who now testify against Gore; the court does not mention the solid support for the theory that there is at least joint invention.

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[1] *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 03-CV-0579-PHX-MHM, 2009 WL 920300, at *5 (D. Ariz. March 31, 2009).

I start with the history of this conflict, for it is relevant to both willful infringement and the award of punitive damages.

I. The Interference

The saga of Bard versus Gore started forty-one years ago, when Gore's employee Peter Cooper, manager of the Gore plant in Flagstaff, Arizona, invited Dr. David Goldfarb at the Arizona Heart Institute to participate in an ongoing study of Gore's product, expanded polytetrafluoroethylene ("ePTFE"), for use as a vascular prosthesis, i.e., as a graft to repair and replace blood vessels.

Gore's ePTFE polymer, (brand name Gore-Tex®), has unique properties based on its microporous and fibrous structure, as well as the adaptability of that structure to various uses. Gore employees sought to develop new applications for ePTFE, and continued to modify its structure in studying new uses. Beginning around 1970, Peter Cooper led the development of ePTFE vascular prosthetic grafts.

Cooper and other Gore employees collaborated with vascular surgeons in the United States and Japan, who surgically inserted Gore's ePTFE vascular tubes of varying porous and fibrous structure into the arteries of dogs and sheep. Compatibility of ePTFE with human tissue and its effectiveness as mammalian grafts were demonstrated. In addition to scientific publications and the PTO interference record, details of this history may be found in this court's opinions in the interference appeals, reported at *Cooper v. Goldfarb*, 154 F.3d 1321 (Fed. Cir. 1998) ("*Cooper I*") and *Cooper v. Goldfarb*, 240 F.3d 1378 (Fed. Cir. 2001) ("*Cooper II*").

In 1973 Cooper, along with Gore employee Richard Mendenhall, contacted Dr. Goldfarb, who had recently arrived at the Arizona Heart Institute, and invited him to participate in the ePTFE vascular study. Cooper gave Dr. Goldfarb the reports of surgeons who had previously evaluated ePTFE tubes as vascular grafts, and gave him samples of the most effective ePTFE tubes based on the prior evaluations. A letter from Cooper to Dr. Goldfarb accompanying these samples stated that they "represent the latest attempt to achieve satisfactory patency rates in small artery prosthetics." *Cooper II*, 240 F.3d at 1384.

Dr. Goldfarb tested the Gore samples by inserting them in blood vessels of dogs and inspecting their structure by microscope. On October 24, 1974 Dr. Goldfarb filed a patent application on the structure of the most effective of the samples he tested. Cooper had previously filed a patent application covering the same structure, and the PTO declared an interference between the Cooper and Goldfarb applications.

In its interference decision, the PTO held that Cooper was the first to conceive the subject matter of the interference count, ruling that Cooper "had conceived all the limitations of the count" and "had established conception as of June 5, 1973." *Cooper I*, 154 F.3d at 1328. However, the PTO also held that Goldfarb was the first to reduce the count to practice, declining to credit Cooper with the prior reductions to practice by the surgeons to whom Cooper had previously provided ePTFE tubes and grafts for testing and evaluation. Although the record contains extensive evidence of these tests, reports, and continued collaboration, the PTO tribunal also did not permit

Cooper to show diligence to his filing date, on the ground that diligence had not been pleaded in the interference. Thus the PTO awarded priority to Goldfarb.

On appeal, this court affirmed the PTO ruling that Cooper was the first to conceive the subject matter of the count. This court found error in the PTO's refusal to consider whether Goldfarb's work "inured" to Cooper's benefit. The PTO had stated that the issue of inurement had not been raised at final hearing, but this court found that inurement had been raised "in several places in the final hearing brief," *Cooper I*, 154 F.3d at 1332, and remanded to the PTO to consider inurement. On remand the PTO held that Goldfarb's work did not inure to Cooper's benefit, relying on affidavits of a Gore employee, Dan Detton, who later admitted to perjury.[2] *Cooper II*, 240 F.3d at 1380–81.

The PTO awarded the patent to Dr. Goldfarb, and U.S. Patent No. 6,436,135 ("the '135 patent") issued on August 20, 2002. Meanwhile, during the twenty-eight years of patent pendency, Gore developed ePTFE grafts for a variety of prosthetic uses, and achieved medical and commercial success.

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[2] Counsel: Is your testimony there knowingly false or truthful?
Mr. Detton: No, that was inaccurate testimony.
Counsel: Was it knowingly false?
Mr. Detton: Yes, it was.
Counsel: Perjury?
Mr. Detton: Yes, it was.

Trans. 1915:5–15, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 03-CV-0579-PHX-MHM, (D. Ariz. Nov. 27, 2007), ECF No. 787.

II. The Infringement Litigation

On March 28, 2003, Dr. Goldfarb and exclusive licensee Bard sued Gore for infringement of the '135 patent. Although Gore attempted to raise several defenses of invalidity and enforceability, at trial and by motion, the district court and the jury were told repeatedly that the Federal Circuit had finally adjudged that Dr. Goldfarb was entitled to the patent.

The jury rendered a verdict of willful infringement, and assessed damages measured as Bard's lost profits on Gore's products for which Bard had a competing product. The jury also awarded a royalty to Bard at rates ranging from 10% to 18%, for Gore sales of ePTFE products for which there was no competing Bard product. These damages totaled $185,589,871.02. Then, based on the jury's finding of willful infringement, the district court doubled the damages, and awarded Goldfarb and Bard their attorneys' fees and costs. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 586 F. Supp. 2d 1083 (D. Ariz. 2010) ("*Bard I*"). A split panel of the court affirmed. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.,* 670 F.3d 1171 (Fed. Cir. 2012) ("*Bard II*"). Gore requested rehearing.

III. Rehearing en banc

The Federal Circuit granted rehearing en banc on the issue of willful infringement and the award of punitive damages and attorneys' fees. The en banc court vacated these district court rulings, stating that "the opinion of the court accompanying the judgment is modified, in accordance with the panel opinion accompanying this order." *Bard Peripheral Vascular,*

Inc. v. W.L. Gore & Assocs., Inc., 476 Fed. App'x 747, 748 (Fed. Cir. 2012) (en banc) ("*Bard III*"). The court cited the need for consistency and reasonable predictability in resolving the pervasive issue of willful infringement, and ruled that willful infringement is "a question of law based on underlying mixed questions of law and fact and is subject to de novo review," *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1005 (Fed. Cir. 2012) ("*Bard IV*").

The court remanded for de novo determination of willful infringement. The court explained that willful infringement contains objective and subjective components, and that the objective component requires proof of objective recklessness in the face of a high likelihood of infringing a patent known to be valid. *Bard IV*, 682 F.3d at 1006. This objective component receives de novo review, as a matter of law.

The objective prong of willful infringement is not met when there is a reasonable defense to the charge of infringement. *Spine Solutions,* 620 F.3d at 1120; *see also Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1382 (Fed. Cir. 2014); *Advanced Fiber Techs. (AFT) Trust v. J & L Fiber Servs., Inc.*, 674 F.3d 1365, 1377 (Fed. Cir. 2012). Then, if a district court holds the objective defenses to be objectively unreasonable, the jury's subjective findings can be reviewed. *Bard IV*, 682 F.3d at 1008.

After clarifying the legal principles, this court remanded to the district court for redetermination of willful infringement. The district court reviewed the issues and reinstated its prior judgment of willful infringement, double damages, and attorneys' fees. The district court stated that the evidence supported the

prior judgment. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.,* No. 03-0597, 2013 WL 5670909 (D. Ariz. Oct. 17, 2013) ("*Bard V*"). Today's majority now affirms.

IV. This Appeal

The panel majority, while mentioning that willful infringement is now a matter of law, does not undertake the required de novo review. Determination of a matter of law requires consideration of the positions of both sides, with due attention to the burdens and standards of proof. As stated in *Seagate Techs.*, a ruling of willful infringement requires objective recklessness in the face of a high likelihood of infringing a patent known to be valid and enforceable.

The question for the reviewing court is not whether the district court's decision of law can be found supported by substantial evidence. The question of willful infringement is whether the accused infringer raised a substantial question of invalidity or unenforceability regarding the '135 patent. *In re Seagate*, 497 F.3d at 1371. Willful infringement cannot lie "when a reasonable defense is raised," *Advanced Fiber*, 674 F.3d at 1377, "[although] the record contains substantial evidence to support the jury's implicit finding" of validity and enforceability. *Spine Solutions,* 620 F.3d at 1319. The required showing of objective recklessness is not met, as a matter of law, when the patent is reasonably subject to challenge.

It cannot be disputed that Gore raised several substantial questions challenging the validity and enforceability of the '135 patent. I have previously

outlined some of the grounds on which the '135 patent was vulnerable:

> (1) the ruling of the Patent and Trademark Office, affirmed by the Federal Circuit, that Gore's employee Cooper was the first to conceive of the invention that was patented by Goldfarb; (2) the fact that Cooper provided Goldfarb with the Gore–Tex® tubes that Goldfarb patented; (3) the fact that Goldfarb tested the tubes in dogs at Cooper's request; (4) the fact that others had previously tested the Gore–Tex® tubes in dogs and sheep, and had reported and published the same results that Goldfarb later patented; (5) the fact that the Goldfarb application was pending for 28 years, leaving doubt as to the outcome in the Patent Office. It is not irrelevant that the eventual allowance of the Goldfarb application included the admitted perjured affidavit of Detton, an affidavit that Detton asked Goldfarb to withdraw, and was refused.

Bard III, 682 F.3d at 1009 (Newman, J., dissenting in part). These are all substantial questions of validity and enforceability of the '135 patent, weighing against reckless disregard.

Gore also presented by motion seven grounds of unenforceability of the '135 patent, quoted by the district court as follows:

> 1. Plaintiffs and their attorneys failed to advise the Patent Office of Dr. Volder's connections with Impra in his 1976 affidavit in which he expressed his opinion on the issue of

obviousness as a presumably impartial person skilled in the art.

2. Plaintiffs and their attorneys failed to advise the Patent Office at any time prior to withdrawal of the rejection of Claims 1 to 10 of the Goldfarb patent application, that in 1978 Lenox Baker, M.D., withdrew and repudiated paragraph 6 of his 1976 affidavit filed with the Patent Office.

3. The filing of and reliance on two 1976 affidavits from D. Dan Detton, notwithstanding Mr. Detton's repudiation of those affidavits before they were filed, and Plaintiffs' subsequent failure to advise the Patent Office of Mr. Detton's 1978 repudiation of his 1976 affidavits.

4. Plaintiffs' reliance on an error that the Patent Office made in connection with the Matsumoto publication in Surgery, in which the Patent Office Examiner mistakenly interpreted the wall thickness in that publication to be 1 millimeter ("mm") rather than 0.5 mm.

5. Plaintiffs and their attorneys failed to provide information to the Patent Office about Dr. Volder's work and his possible role as an inventor or co-inventor, including the failure to disclose the existence of and the subsequent destruction of the Volder notebook.

6. Plaintiffs and their attorneys failed to comply with the Patent Office order requiring production of material information from the *Goldfarb v. Impra* litigation.

> 7. Plaintiffs and their attorneys failed to advise the Patent Office Examiner of the existence of the Gore shipping log, which contained information about prior art vascular graft wall thicknesses that was inconsistent with the 1976 affidavits of Harold Green and Mr. Detton, and inconsistent with the argument made by Dr. Goldfarb and Mr. Sutton in persuading the Patent Office Examiner to withdraw the November 1975 rejection of Claims 1 to 10.

Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., 573 F. Supp. 2d 1170, 1173–74 (D. Ariz. 2008).

Each asserted ground of inequitable conduct was summarily dismissed by the district court, which stated that, even if Dr. Goldfarb misrepresented or intentionally withheld information from the PTO and despite the admitted perjury, the false information was "not material to the prosecution of the '135 patent." *Id*. at 1215. That reasoning cannot be sustained.

In addition, Gore's argument of incorrect inventorship, or at least joint invention, is quite viable, and raises a substantial question of validity, which requires correct inventorship. Given the PTO's findings that Cooper was the first to conceive the invention, and this court's prior affirmance that Cooper conceived of the invention including the fibril length limitation before Goldfarb evaluated the 2-73 RF graft, *see Cooper II*, 240 F.3d at 1384–85 (citing *Cooper I*, 154 F.3d at 1326), Goldfarb's reduction to practice of the material that Cooper made and presented for patenting, at least raises a substantial question of "joint inventorship." The statute is clear, and surely presents enough of a

question that joint invention could be reasonably raised in defense:

> *Joint Inventors* -- . . . 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.

35 U.S.C. §116(a) (2012).

The panel majority rules that Gore's joint invention defense fails because Gore cannot show "collaboration" between Cooper and Goldfarb as to every limitation in the claims. Joint invention does not require collaboration as to every limitation, as the statute makes clear. Moreover, when the PTO's interference procedures are removed from the deferential review status they enjoyed in *Cooper I* and *Cooper II*, the correctness of these rulings can reasonably be challenged in the infringement context.

In all events, the question as it relates to willfulness is whether the defense of invalidity could reasonably be raised, not whether it eventually succeeded. The flaws in the Goldfarb patent and the way it was obtained provided sufficiently reasonable defenses to both validity and enforceability. On the entirety of the premises and applying the correct legal standards, the judgment of willful infringement cannot stand.

V. Damages

Even when willful infringement is found, it does not follow that punitive damages must be imposed, or that

the damages must be doubled. The public benefit of Gore's product cannot be ignored. Punitive damages are intended to discourage bad behavior, not life-saving medical devices. This en banc court specifically asked for review of the damages award as related to the willfulness determination. Such review gets short shrift from my colleagues, who simply ignore the en banc court's admonition that the premises and consequences of "willful" action receive objective, nationally consistent, implementation.

"Precedent holds that a finding of willfulness authorizes, but does not require, enhanced damages." *Laitram Corp. v. NEC Corp*, 115 F.3d 947, 955 (Fed. Cir. 1997)); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1582 (Fed. Cir. 1992) (refusal to enhance damages despite the jury's verdict of willful infringement); *Modine Mfg. Co. v. Allen Group, Inc.,* 917 F.2d 538, 543 (Fed. Cir. 1990) (same); *Delta–X v. Baker Hughes Prod. Tools, Inc.,* 410, 413 (Fed. Cir. 1993) (considering whether the defendant made a substantial challenge to infringement).

Extensive precedent supports judicial refusal to enhance damages when the case is close and the equities counsel moderation, not punishment. The award of punitive damages depends on both the infringer's degree of culpability, and the injury that the infringement imposed on the patentee. Bard was awarded full recovery for its loss of business to the Gore product. The district court stated that "the Court is satisfied that a fair and full amount of compensatory money damages, when combined with a progressive compulsory license, will adequately compensate Plaintiffs' injuries, such that the harsh and

extraordinary remedy of injunction–with its potentially devastating public health consequences—can be avoided." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 03-CV-0597, 2009 WL 920300, at *5 (D. Ariz. Mar. 31, 2009).

The district court's recognition of the public's interest and medical benefits imparted by Gore's product, and the court's refusal to enjoin its provision, cannot be reconciled with the punitive doubling of damages. There was no showing, or even a charge, of intentional harm, as required for severe punishment as here meted out. *See Restatement (Second) of Torts* §500 (1965).

Thus, regardless of whether willfulness was a supportable ruling, the doubling of the damages award is untenable. From my colleagues' contrary ruling, I respectfully dissent.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

No. CV 03-0597-PHX MHM

[Filed October 30, 2013]

Bard Peripheral Vascular, Inc. and David Goldfarb, M.D.,	)
Plaintiffs,	)
v.	)
W. L. Gore & Associates, Inc.,	)
Defendant.	)

ORDER GRANTING PLAINTIFFS' MOTION FOR LEAVE TO EXECUTE ON JUDGMENT

Pursuant to the Court's Order filed October 17, 2013 (D.I. 1145), it is **HEREBY ORDERED** that:

1. Plaintiffs are entitled to execute immediately on the Amended Clerk's Judgment filed August 24, 2010 (D.I. 1047) as follows:

a. Lost profits damages in the amount of $102,081,578.82 and reasonable royalty damages in the amount of $83,508,292.20, for a total of $185,589,871.02, to which Plaintiffs are entitled for the

time period ending June 30, 2007, are due pursuant to the Amended Clerk's Judgment dated August 24, 2010, and are immediately payable to Plaintiffs;

b. Taxable costs in the amount of $165,554.54 are due pursuant to the Amended Clerk's Judgment dated August 24, 2010, and are immediately payable to Plaintiffs;

c. Prejudgment interest on the damages specified above in paragraph 1.a., in the amount of $18,558,987.10, are due pursuant to the Amended Clerk's Judgment dated August 24, 2010, and are immediately payable to Plaintiffs; and

d. Supplemental lost profits damages in the amount of $ 44,556,381.24 and supplemental reasonable royalty damages in the amount of $64,440,740.00, for a total of $108,997,121.24, to which Plaintiffs are entitled for the time period beginning July 1, 2007 and ending March 31, 2009, are due pursuant to the Amended Clerk's Judgment dated August 24, 2010, and are immediately payable to Plaintiffs.

2. Plaintiffs are entitled to post-judgment interest pursuant to 28 U.S.C. § 1961 on the amounts specified above, calculated daily at a rate of 0.25%, compounded annually, for the period beginning August 24, 2010 and ending on the date of payment ($2,505,570.23 as of October 31, 2013).

3. Subject to paragraph 6.a below, all royalty payments held in the CRIS, as well as all interest accumulated on those accounts, are immediately due and payable to Bard. As of October 25, 2013, the principal of the compulsory royalty payments total

$541,607,871.75 (D.I. 1046, 1062, 1065, 1066, 1069, 1071, 1073, 1075, 1077, 1096, 1123, 1129, and 1139). Gore's October 31, 2013 compulsory royalty payment shall be deposited with the CRIS and thereafter be immediately due and payable to Bard. Only Gore's deposit of $195,000,000 deposited as Registry Case No. DAZX203CV000597001, and an additional $13,000,000 as explained in paragraph 6.a, will remain in the CRIS.

4. All future royalty payments beginning after October 31, 2013, shall be made by Gore directly to Bard in accordance with the terms in the Amended Clerk's Judgment filed August 24, 2010 (D.I. 1047).

5. Any stay previously issued by the Court concerning the enforcement of the money judgments listed above in paragraphs 1-4 is hereby lifted effective immediately.

6. In accordance with the foregoing, Bard shall collect the amounts payable above on November 1, 2013, in the manner set forth below:

a. All amounts in the Court's registry system, except $195,000,000 deposited as Registry Case No. DAZX203CV000597001 and $13,000,000 from Registry Case No. DAZX203CV000597014, should be released by the Clerk to Bard on November 1, 2013. The Clerk will retain all remaining amounts in the CRIS, in satisfaction of Gore's obligations under paragraph 10 below.

b. On November 1, 2013, Fidelity and Deposit Company of Maryland and Zurich American Insurance Company shall pay (or cause to be paid) to Bard the full face amount of $115,000,000 of supersedeas bond No. CGB 8936325. Gore is liable for

the payment of this $115,000,000 to Bard until payment is actually made to Bard by Fidelity and Deposit Company of Maryland and Zurich American Insurance Company.

c. On November 1, 2013 Liberty Mutual Insurance Company shall pay (or cause to be paid) to Bard the amount of $213,817,104.13 from supersedeas bond No. 019025260. Gore is liable for the payment of this $213,817,104.13 to Bard until payment is actually made to Bard by Liberty Mutual Insurance Company.

Payment of these amounts to Bard shall satisfy all Plaintiffs' interests in the money judgments listed above in paragraphs 1-3 of this order.

7. Upon Fidelity and Deposit Company of Maryland and Zurich American Insurance Company's payment to Bard as set forth in 6.b above, it is ordered that the bond posted by Fidelity and Deposit Company of Maryland and Zurich American Insurance Company shall be cancelled, be of no further effect, and Fidelity and Deposit Company of Maryland and Zurich American Insurance Company shall be fully and finally released from any and all liability under the bond. Once this Order is issued by the Court and the payment has been remitted by Fidelity and Deposit Company of Maryland and Zurich American Insurance Company, Plaintiffs shall have no right to make any further claim under the bond.

8. Upon Liberty Mutual Insurance Company's payment to Bard as set forth in 6.c above, it is ordered that the bond posted by Liberty Mutual Insurance Company shall be cancelled, be of no further effect, and Liberty Mutual Insurance Company shall be fully and

finally released from any and all liability under the bond. Once this Order is issued by the Court and the payment has been remitted by Liberty Mutual, Plaintiffs shall have no right to make any further claim under the bond.

9. The only portions of the Amended Clerk's Judgment filed August 24, 2010 (D.I. 1047) that remain subject to any stay previously issued by the Court are:

a. Enhanced damages in the amount of $185,589,871.02.

b. Attorneys' fees and nontaxable costs in the amount of $19,000,000.00.

c. Prejudgment interest on the fees and costs specified above in paragraph 9.b., in the amount of $1,900,000.00.

d. The total amount of the money judgment that remains subject to a stay is therefore $206,489,871.02, subject to post-judgment interest.

10. As a condition of maintaining a stay of execution on those parts of the money judgment described in paragraph 9, Gore is required to maintain a bond sufficient to satisfy the amounts reflected in paragraph 9 and post-judgment interest thereon.

11. Following receipt of the funds listed in paragraphs 1-3 of this order, Plaintiffs shall file with the Court a partial accord and satisfaction of judgment for the portions of the Amended Clerk's Judgment reflected in paragraphs 1-3 above, which will not extend to the amounts in paragraphs 4 and 9 above.

IT IS SO ORDERED.

Dated this 30th day of October, 2013.

/s/_____
Mary H. Murguia
United States Circuit Judge
designated as United States District Judge

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

No. CV 03-0597-PHX-MHM

[Filed October 17, 2013]

Bard Peripheral Vascular, Inc., and David Goldfarb, M.D.,	)
Plaintiffs,	)
v.	)
W. L. Gore & Associates, Inc.,	)
Defendant.	)

ORDER

Before the Court are Defendant's Request for Judicial Notice of Decision on Request for Reexamination of United States Patent No. 6,436,135 ("'135 patent") ("Def.'s Req.") (Doc. 1122); Defendant's Motion for a New Trial or in the Alternative to Amend the Judgment and Memorandum in Support ("Def.'s Mem.") (Doc. 1113); and Plaintiffs' Motion for Leave to Execute on the Judgment ("Pls.' Mot.") (Doc. 1109). Counsel for the parties presented oral argument on June 12, 2013.

I. Defendant's Request for Judicial Notice

Defendant asks the Court to take judicial notice of the "Decision On Request For Reexamination" issued by the Central Reexamination Unit ("CRU") of the United States Patent and Trademark Office on January 23, 2013, submitted as Exhibit A to Defendant's Request. (Def.'s Req. at 2, Ex. A). The CRU granted an ex parte reexamination of claims 20-27 of the '135 patent based on the Matsumoto reference. (Doc. 1122, Ex. A). However, on July 11, 2013, Plaintiffs filed a Notice of Supplemental Authority that on July 10, 2013, the U.S. Patent and Trademark Office terminated the reexamination. (Doc. 1138, Bard's Notice of Supplemental Authority - Notice of Termination of Reexamination). Defendant's Request for Judicial Notice is denied as moot.

II. Defendant's Motion for a New Trial

Defendant has moved for a new trial based on the assumption that the Court has granted judgment as a matter of law in its favor and against Plaintiffs based on the issue of willful infringement. (Def.'s Mem. at 1). Defendant alternatively moves for an amendment to the Amended Clerk's Judgment based on the premise that the Court has found that Defendant did not willfully infringe the '135 patent. *(Id.* at 24). Defendant seeks a ruling lowering the ongoing royalty rates assessed against it as found by the Court.

The Court has issued an Order finding against Defendant on the issue of willful infringement and in favor of Plaintiffs. Defendant's motion for new trial or, in the alternative, for an amendment to the judgment, is denied.

III. Plaintiffs' Motion for Leave to Execute on the Judgment

Plaintiffs move for leave to execute on the August 24, 2010 Amended Clerk's Judgment to the extent it is final and non-appealable following the Federal Circuit's decisions in *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.,* 670 F.3d 1171 (Fed. Cir. 2012) *("Bard I"),* and *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.,* 682 F.3d 1003 (Fed. Cir. 2012) *("Bard II").* (Pls.' Mot.). Plaintiffs contend that the final and non-appealable portions of the Amended Judgment are appropriate for execution, equitable considerations favor execution on those portions of the Amended Judgment, and Plaintiffs are entitled to post-judgment interest on the final and non-appealable portions of the Amended Judgment other than the quarterly payments. (Doc. 1110, Mem. in Support of Pls.' Mot. for Leave to Execute on J.). Defendant responds in opposition that the Court stayed enforcement of the Amended Judgment with respect to money judgments and ordered the escrow of Defendant's royalty payments until entry of a final and non-appealable judgment. (Doc. 1116, Def.'s Opp'n to Pls.' Mot. for Leave to Execute on J. ("Def.'s Opp'n") at 2). Defendant argues that execution on the judgment is not appropriate because a final and non-appealable judgment has not been entered.

The Court has considered the parties' arguments. The Court also has considered Defendant's supplemental authority which it does not find persuasive. (Doc. 1136). The Court of Appeals for the Federal Circuit affirmed the judgment that the '135 patent is valid. The Federal Circuit remanded the issue

of willfulness so that this Court could reconsider its denial of JMOL. The Court has now ruled that Defendant is not entitled to JMOL on the issue of willful infringement. The Court's reconsideration of its rulings on enhanced damages and attorneys' fees is not necessary. The Court finds no compelling reason to further stay execution of the Amended Clerk's Judgment regarding the portions that are final and non-appealable based on *Bard I* and *Bard II*.

Accordingly,

IT IS ORDERED that Defendant's Request for Judicial Notice of Decision on Request for Reexamination of United States Patent No. 6,436,135 (Doc. 1122) is **denied as moot.**

IT IS FURTHER ORDERED that Defendant's Motion for a New Trial or in the Alternative to Amend the Judgment (Doc. 1113) is **denied.**

IT IS FURTHER ORDERED that Plaintiffs' Motion for Leave to Execute on the Judgment (Doc. 1109) is **granted regarding the final and non-appealable issues.** Any stay previously issued by the Court concerning the final and non-appealable issues in the Amended Clerk's Judgment is lifted. Plaintiffs shall submit a proposed Order.

Dated this 16th day of October, 2013

/s/_____
Mary H. Murguia
United States Circuit Judge
designated as United States District Judge

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

No. CV-03-597-PHX-MHM

[Filed August 24, 2010]

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

Plaintiffs,

vs.

W.L. Gore & Associates, Inc.,

Defendant.

W.L. Gore & Associates, Inc.,

Counterclaimant,

vs.

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

Counterdefendants.

AMENDED CLERK'S JUDGMENT

Pursuant to the Court's Orders filed July 27, 2010 (Doc. Nos. 1040 and 1039); July 21, 2010 (Doc. No. 1036); July 9, 2010 (Doc. No. 1034); March 31, 2009 (Doc. Nos. 941 and 942); and July 29, 2008 (Doc. Nos. 833, 834, and 835); and the Jury's Verdict, entered on December 11, 2007 (Doc. No. 771), the following Amended Judgment is entered:

1. This action was tried to a jury with Judge Murguia presiding, and the jury rendered a verdict, (Doc. No. 771), reflected below:

   a. Plaintiffs David Goldfarb, M.D. ("Goldfarb") and Bard Peripheral Vascular, Inc. ("BPV") (collectively, "Plaintiffs") proved that the subject W.L. Gore & Associates, Inc.'s ("Gore") surgical graft and stent graft products infringe the asserted claims of U.S. Patent No. 6,436,135 (the "'135 Patent");

   b. Plaintiffs proved that Gore's infringement was willful; and,

   c. Gore failed to prove by clear and convincing evidence that the '135 Patent is invalid.

2. The Court denied post-trial motions to set-aside the verdict or for a new trial. (Doc. Nos. 833 and 834.)

3. Gore's claims of inequitable conduct were tried to the Court, and the Court found that Gore did not prove by clear and convincing evidence that Dr. Goldfarb and/or his attorneys committed

inequitable conduct during the prosecution of the '135 Patent.

4. For the time period ending June 30, 2007, Plaintiffs are entitled to lost profits damages in the amount of $102,081,578.82 and reasonable royalty damages in the amount of $83,508,292.20, for a total of $185,589,871.02. For the reasons set forth in its Order dated March 31, 2009 (Doc. No. 941), these damages are doubled from $185,589,871.02 to the sum of $371,179,742.04 pursuant to 35 U.S.C. § 284.

5. For the time period beginning July 1, 2007 and ending March 31, 2009, Plaintiffs are entitled to lost profits damages in the amount of $44,556,381.24 and reasonable royalty damages in the amount of $64,440,740, for a total of $108,897,121.24. For the reasons set forth in its Order dated July 9, 2010 (Doc. No. 1034), the Court declines to enhance these damages pursuant to 35 U.S.C. § 284.

6. For the reasons set forth in its Order dated March 31, 2009 (Doc. No. 941), Plaintiffs are entitled to an award of their reasonable attorneys' fees and nontaxable costs in the sum of $19,000,000 pursuant to 35 U.S.C. § 285.

7. For the reasons set forth in its Order dated March 31, 2009 (Doc. No. 942), Plaintiffs are entitled to an award of prejudgment interest on the damages specified in Paragraph 4 above (damages before enhancement) in the sum of $18,558,987.10. Plaintiffs are entitled to an award of prejudgment interest on the attorneys'

fees award specified in Paragraph 6 above in the sum of $1,900,000. The Court declines to award prejudgment interest on the damages specified in Paragraph 3 above.

8. Plaintiffs are awarded post-judgment interest pursuant to 28 U.S.C. § 1961.

ORDER CONCERNING COMPULSORY LICENSE

WHEREAS, this Court has denied Plaintiff Bard Peripheral Vascular, Inc.'s motion for a permanent injunction prohibiting prospective infringement by W.L. Gore & Associates, Inc. ("Gore") of U.S. Patent No. 6,436,135;

IT IS HEREBY ORDERED granting a compulsory license to Bard Peripheral Vascular, Inc. and David Goldfarb, M.D. in the form of 20% on surgical grafts, 15% on stent-grafts, 15% on the PROPATEN® surgical grafts, and 12.5% on VIABAHN® stent-grafts with heparin against W.L. Gore & Associates, Inc.

IT IS FURTHER ORDERED that Gore be permitted to practice, and Bard Peripheral Vascular, Inc. ("Bard"), a subsidiary of C.R. Bard, Inc., be compelled to permit Gore to practice, the '135 patent subject to the following terms:

1. **TERM:** Gore's obligation to pay a royalty associated with this ORDER is effective as of April 1, 2009, and expires upon the expiration of the '135 patent, on August 20, 2019, unless earlier terminated as provided herein.

2. TERMINATION:

(a) The provisions of this ORDER permitting Gore to practice the '135 patent shall terminate if Gore violates this ORDER, including without limitation if Gore violates its obligation to timely pay royalties, and fails to cure any such breach within thirty (30) days after receipt of written notice thereof from Bard or the Court. Upon any such termination, Gore shall no longer be permitted to practice the '135 patent.

(b) Should all the asserted claims (20-27) of the '135 patent be held invalid, not infringed, and/or unenforceable in a final and nonappealable judgment in this case, then this ORDER shall be void and all payments made by Gore hereunder and escrowed, plus interest accrued thereon, shall be returned to Gore.

(c) If there is a final and non-appealable judgment in another case that all the asserted claims (20-27) of the '135 patent are held invalid or unenforceable, then the Parties' obligations under this ORDER will immediately terminate.

3. SCOPE OF ORDER: This ORDER permitting Gore to practice the '135 patent under the terms specified herein is: (i) non-

transferable and does not inure to the benefit of any Gore joint venturers, affiliates, successors, or any other legal person beyond Gore; (ii) non-exclusive to Gore in so much as the ORDER does not limit in any way whatsoever Bard's ability to license, sublicense or assign any or all of its rights in the '135 patent, including rights granted under this ORDER; and (iii) limited to permitting Gore to make, use, sell and/or import the following products in the United States:

(a) Standard Grafts (Standard Walled Ringed; Standard Walled Removable Ringed; Thin Walled Ringed; Thin Walled Removable Ringed; Standard Walled; Thin Walled);

(b) Stretch Grafts (Standard Walled Stretch; Standard Walled Large Diameter Stretch; Standard Walled Removable Ringed Stretch; Standard Walled Bifurcated Stretch; Thin Walled Bifurcated Stretch; Standard Walled Ringed Stretch; Standard Walled Ringed Dialysis; Standard Walled Removable Ringed Stretch; Thin Walled Removable Ringed Stretch; Thin Walled Ringed Stretch; Thin Walled Stretch);

(c) PROPATEN® Grafts;

(d) INTERING® Grafts;

(e) INTERING® Stretch Grafts;

(f) ACUSEAL® Patch;

(g) Cardiovascular Patchs;

(h) VIABAHN® Stent-Grafts;

(i) EXCLUDER® Stent-Grafts;

(j) TAG® Stent-Grafts;

(k) VIATORR® Stent-Grafts;

(l) Gore products not more than colorably different from those onthe market as of December 11, 2007, and falling within any of 3(a) through 3(k) hereof.

(m) Gore products falling within any of 3(a) through 3(l) that are approved by the FDA for new vascular indications.

This ORDER shall not confer any right to Gore to enforce the '135 patent nor any right to seek to have Bard enforce the' 135 patent. All rights to prosecute, maintain, enforce, license, sublicense or assign the '135 patent are reserved solely and exclusively to Bard.

4. ROYALTY PAYMENT

(a) SURGICAL GRAFT PRODUCTS: "Surgical Graft Products" are those products identified in 3(a), (b), (d), (e), (f), (g) and (l), to the extent applicable. The royalty rate on such products is 20% of Gore's net selling price from Gore's sale of Surgical Graft Products.

(b) STENT GRAFT PRODUCTS: "Stent Graft Products" are those products

identified in 3(i), (j), (k) and (1), to the extent applicable. The royalty rate on such products is 15% of Gore's net selling price from Gore's sale of Stent Graft Products.

(c) PROPATEN® Grafts: "PROPATEN® Grafts" are those products identified in 3(c), and (1), to the extent applicable. The royalty rate on such products is 15% of Gore's net selling price from Gore's sale of PROPATEN® Grafts.

(d) VIABAHN® Stent-Grafts: "VIABAHN® Stent-Grafts" are those products identified in 3(h), and (l), to the extent applicable. The royalty rate on such products that include heparin is 12.5% of Gore's net selling price from Gore's sale of VIABAHN® Stent-Grafts. The royalty rate on such products that do not include heparin is 15% of Gore's net selling price from Gore's sale of VIABAHN® Stent-Grafts.

(e) Gore shall have no obligation to pay any royalties for products identified in Section 3 covered by 35 U.S.C. § 271(e)(1).

(f) As used herein, "net selling price" shall be the invoiced selling price (or imputed price, based on the average net selling price for the applicable

products for the preceding two fiscal quarters, if non-monetary consideration is provided or services are bundled with such sales) of a product identified in Section 3 sold by or on behalf of Gore to a third party in an arms-length transaction less the following deductions to the extent recognized in accordance with applicable generally accepted accounting principles consistently applied to all Gore products and services: excise and sales taxes, quantity and cash discounts granted and taken by customers and not already reflected in the invoiced selling price, freight and handling charges to the extent included in the invoiced selling price, and allowances for returns due to warranty claims.

6. **PAYMENT TIMING:** Payments by Gore to Bard shall be wired in same day funds quarterly no later than the 30th day following the close of the calendar quarter. For clarity, payment for the first quarter shall be made within 30 days after March 31, payment for the second quarter shall be made within 30 days after June 30, payment for the third quarter shall be made within 30 days after September 30, and payment for the fourth quarter shall be made within 30 days after December 31. Payment for any quarters ending before the entry date of this Order shall be made within 30 days of the

entry of this Order. Thereafter, payments shall be made within 30 days of the end of the subsequent quarters. If the 30th day following the end of the quarter is a Saturday, Sunday or holiday, then the payment is due on the next business day, thereafter.

7. **ESCROW:** Payments made under this ORDER shall be escrowed with this Court until there is a final and non-appealable judgment in this case. During the time when escrowed payments are deposited with the Court, to the extent that the Clerk of the Court is unable to process a wire transfer, Gore shall deposit a cashier's check with the Clerk of the Court on or before the day payment is due.

8. **AUDIT RIGHTS**

(a) Gore is ORDERED to keep complete, true and accurate books of account and records, including but not limited to, unit sales, dollar sales and average selling price for infringing products, for the purpose of determining the royalty amounts payable. Gore shall certify its compliance with the ORDER annually 60 days after the close of its financial year and ensure that the quarterly payments for the preceding financial year are in accordance with the ORDER. Such certification shall be accompanied with any underpayments for the preceding four

quarters. If Gore's certification process reveals an underpayment in excess of five percent (5%) of the amount owed, Gore is ORDERED to pay interest on the unpaid royalties at the prime interest rate calculated quarterly, at the same time. An underpayment discovered pursuant to this section will not terminate this ORDER pursuant to Section 2 unless Gore fails to pay the underpayment within 60 days of the end of its financial year.

(b) Bard shall have the right, upon reasonable notice and at its expense, to direct an independent certified accounting firm to inspect and audit the relevant accounting and sales books and records, including but not limited to, the unit sales, dollar revenue and average selling price for each infringing product. The audit may be made once per year and may cover any period within the previous four completed fiscal years prior to the audit, provided that such period has not been previously audited. The determination of the independent certified accounting firm shall be final. In the event an audit reveals an underpayment, Gore shall remit payment of such amount to Bard within thirty (30) days of receiving written notice of such underpayment from the independent certified

accounting firm. In addition, if any such audit reveals an underpayment in excess of five percent (5%) of the amount owed for the period audited, Gore is ORDERED to pay the reasonable fees and expenses actually incurred relating to the audit as well as interest on the unpaid royalties at the prime interest rate calculated quarterly, which Gore is ORDERED to pay to Bard within thirty (30) days of notice from Bard to Gore. An underpayment discovered pursuant to this Section 8(b) will not terminate this ORDER pursuant to Section 2 unless Gore fails to pay the underpayment within thirty (30) days of notice.

If the audit discloses an overpayment, Bard is ORDERED to credit Gore the overpayment amount for future payments. If the overpayment exceeds the royalty amount owed by Gore at the expiration of this ORDER, Bard is ORDERED to refund Gore the amount of overpayment in excess of Gore's owed royalties within thirty (30) days.

9. **MARKING**: Gore shall mark all products covered by this ORDER in accordance with 35 U.S.C. § 287.

10. **NOTICE OF NEW PRODUCTS:** Gore shall provide Bard notice no less than 180 days before the first anticipated commercial sale of any new vascular product utilizing ePTFE that it contends constitutes to be a Gore

product covered by Section 3(1) or Section 3(m) of this ORDER.

11. **DISPUTE RESOLUTION:** Bard and Gore shall meet and confer in good faith in an attempt to resolve all disputes that may arise under the ORDER. The Court specifically retains jurisdiction to enforce, modify, or terminate this ORDER as the equities may require, and to adopt procedures for resolution of any dispute under the ORDER.

12. **FORM OF NOTICES:** All notices of any asserted breach or any other asserted dispute under this compulsory license shall be in writing and shall be deemed given when sent by (a) prepaid, registered or certified mail, addressed to the party at the below address, or (b) by private courier service signature for delivery required, addressed to the party at the address below. Each party may change such address from time to time by notice so given.

To Bard: C.R. Bard, Inc.

730 Central Avenue

Murray Hill, NJ USA

Attn: General Counsel

(800) 367-2273

App. 58

To Gore: W. L. Gore & Associates, Inc.

551 Paper Mill Road

Newark, Delaware 19711

Attn: General Counsel

August 24, 2010

RICHARD H. WEARE
District Court Executive/Clerk

s/L. Dixon
By: Deputy Clerk

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

No. CV-03-0597-PHX-MHM

[Filed March 31, 2009]

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

Plaintiff,

vs.

W.L. Gore & Associates, Inc.,

Defendant.

ORDER

Currently pending before the Court are Defendant's Motion Pursuant to Fed.R.Civ.P. 12(b)(1) and 12(h)(3) to Dismiss Plaintiffs' Complaint for Lack of Standing or in the Alternative Renewed Motion for Judgment as a Matter of Law (Dkt.#849.), Motion for New Trial or Remittitur for Excessive Damages (Dkt.#840.), Motion for Judgment as a Matter of Law Regarding Invalidity Because Cooper and Goldfarb are Joint Inventors (Dkt.#841.), Renewed Motion for Judgment as a Matter of Law Regarding Willful Infringement (Dkt.#842.), Renewed Motion for Judgment as a Matter of Law

Regarding Invalidity of the '135 Patent' for Failure to Disclose Best Mode (Dkt.#843.), Renewed Motion for Judgment as a Matter of Law that Claims 20-27are Invalid for Failure to Satisfy the Written Description Requirement of 35 U.S.C. § 112, ¶1 (Dkt.#844.), Renewed Motion for Judgment as a Matter of Law that Claims 20-27 are Invalid Under 35 U.S.C. § 102(B) for Lack of Novelty in View of the 1973 Matsumoto *Surgery* Article (Dkt.#845.), Renewed Motion for Judgment as a Matter of Law Regarding Plaintiffs' Failure to Prove that Gore's Accused Products Meet the Typicality Element of Claims 20-27 (Dkt.#846.), Renewed Motion for Judgment as a Matter of Law Regarding Plaintiffs' Claim that Propaten Infringes the '135 Patent.' (Dkt.#847.) After reviewing the pleadings and holding oral argument on Defendant's remittitur motion, the Court issues the following Order.

I. STANDING

In the instant Motion, Gore reiterates arguments it set forth in its previous standing briefing. See Doc. 652. Although standing may be challenged at any time, the Federal Rules do not grant the right to assert the same standing arguments repeatedly.

> It makes sense that, at some point, even jurisdictional rulings achieve a reasonable level of finality. Surely a court that has decided that it has jurisdiction is not duty-bound to entertain thereafter a series of repetitive motions to dismiss for lack of jurisdiction. Jurisdictional reconsiderations can be as wasteful as any other kind.

Ferreira v. Borja, 93 F.3d 671, 674 (9th Cir. 1996). Gore's latest standing motion ignores the factual findings the Court has previously made based on the record evidence. For example:

- Gore again argues that Dr. Goldfarb lacked standing because the 1980 License transferred "all substantial rights" in the Goldfarb application to C.R. Bard. (Gore's Motion at 8-11). Yet the Court expressly found that Dr. Goldfarb did not transfer all substantial rights to C.R. Bard under the 1980 License. See Order, July 29, 2008, at 16 ("Dr. Goldfarb retains substantial rights in the 1980 agreement. . . ."); and 17 ("Dr. Goldfarb retained substantial rights to his patent application.").

- Gore again argues that there was no implied-in-fact license of the 1980 License in conjunction with Bard's acquisition of Impra/BPV. Id. at 11-13. Yet the Court expressly found, consistent with the Federal Circuit's holding in Waymark Corp. v. Porta Sys. Corp., 334 F.3d 1358, 1364 (Fed. Cir. 2003), that the record evidence established that the "1996 transfer to Impra/BPV of the 1980 license, created at least an implied-in-fact license … ." Order, July 29, 2008, at 16.

- Gore again argues that the 1997 Amendment did not transfer the exclusive license to Impra/BPV because Mr. McDermott's signature was allegedly insufficient to bind C.R. Bard. Doc. No. 849 at 14-16. Yet the Court expressly found that Mr. McDermott entered into the agreement on behalf of C.R. Bard and thus no additional signature was required. Order, July 29, 2008, at 18.

In addition, the Court also found that "by at least 1997, there is a writing transferring the exclusive license from C.R. Bard to BPV." Id. at 17, 19. Thus, BPV had constitutional standing to sue with Dr. Goldfarb, the then patent holder. Waymark Corp. v. Porta Sys. Corp., 334 F.3d 1358, 1364 (Fed. Cir. 2003) ("Under such circumstances, the partnership had standing to bring the action, and it was permissible to join Waymark as a plaintiff under the alleged oral exclusive license."). Gore's argument that all assignments of exclusive licenses are required to be in writing is both wrong as a matter of law and irrelevant in light of the Court's express factual findings. Nevertheless, the Court will again entertain Gore's arguments regarding Plaintiffs' standing.

Interestingly, Gore bases its current Motion on documents and deposition testimony that, although being listed in the Pre-Trial Order, are not in evidence and were not presented during trial. Gore offers no explanation for not introducing such information into the evidentiary record. However, the record is now closed and Gore points to no authority permitting a party to base a Rule 12(h)(3) motion on evidence a party failed to submit following a full evidentiary hearing.[1] Indeed, consideration of evidence outside the

[1] Essentially, it appears that Gore is asking the Court to reopen the record. But Gore has failed to make any proffer in support of such reopening and the case law does not support Gore's belated attempt to do so. See, e.g., Locklin v. Switzer Bros., Inc., 299 F.2d 160, 169 (9th Cir. 1961) ("The time for testing of proof is the time of trial. Our judicial system does not contemplate that the rights of litigants shall be held in abeyance for months or years in order that hindsight may provide a more accurate appraisal of

record is improper under Fed.R.Civ.P. 50(b) because such motions challenge the sufficiency of the evidence based on the record "as it existed when the trial was closed." Elbert v. Howmedica Inc., 143 F.3d 1208, 1209 (9th Cir. 1998). Further, where there has been a full evidentiary hearing on the merits, as there has been here, the Court must "evaluate standing from all materials of record." Pandrol USA,LP v. Airboss Ry. Prods., 320 F.3d 1354, 1367 (Fed. Cir. 2003) (citation omitted).

Moreover, even if supplementation of the record were permissible under Rule 12(h)(3), Gore's reliance on inadmissible testimony[2] is not because "any evidence submitted outside the pleadings [must] be 'competent.'" Kamen v. Am. Tel. & Tel. Co., 791 F.2d 1006, 1011 (2d Cir. 1986) (rejecting "conclusory and hearsay statements contained in the affidavits submitted by defendants"); accord Sapp v. FDIC, 876 F. Supp. 249, 251 (D. Kan. 1995) ("[A]ffidavits in support of or opposing motions to dismiss for lack of jurisdiction must comply with the requirements of Fed. R. Civ. P. 56(e) … [and must] set forth such facts as would be admissible into evidence[.]"). Gore's improper and

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evidence."); Romeo v. Sherry, 308 F. Supp. 2d 128, 140 (E.D.N.Y. 2004) (refusing to consider new evidence contained in post-trial briefing where "[t]he lack of diligence by [movant's] counsel in pursuing this evidence and bringing it to the court's attention in a timely fashion was the result of his own actions (or inaction)."); see also Fed. R. Evid. 403 (relevant evidence may be excluded on grounds of "unfair prejudice" and "undue delay").

[2] For example, Gore cites the deposition testimony of Mr. Krueger, a witness within the Court's subpoena power, who did not testify during trial.

inadmissible evidentiary supplementation, therefore, cannot support its Motion.

Nor can Gore's effort to manufacture alleged legal error salvage its Motion. Gore disingenuously argues that the Court applied the wrong standard of proof when it denied Gore's last standing motion by mischaracterizing the import of a single line at the end of the Court's Order – a line that does not purport to set forth the applicable legal standard. Gore's Motion at 1. Gore has cherry-picked one line at the end of the Court's Order and misrepresents that it reflects a misallocation of the burden of proof. However, a review of the entirety of the Court's judgment (instead of a single line out of context) establishes that the Court correctly reviewed and credited the standing evidence adduced by Plaintiffs, and concluded that Gore failed to adduce sufficient credible evidence to rebut Plaintiffs' showing.[3]

A. Background

The Court reiterates the relevant background, which was similarly provided in its pre-judgment JMOL Order addressing standing. On or about October 24, 1974, Dr. Goldfarb filed a patent application involving the subject matter of the '135 patent. The '135 patent issued in Dr. Goldfarb's name on August 20, 2002. At the time this suit was filed, Dr. Goldfarb was the owner of the '135 patent.

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[3] Courts "review judgments, not the rhetoric in opinions." Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984).

On or about September 23, 1980, Dr. Goldfarb and USCI entered into a written license agreement pursuant to which Dr. Goldfarb granted USCI a "worldwide, exclusive license[], with the right to sublicense, to make, use, and sell products covered by [the Goldfarb Application]." PX4; Trial. Tr., 11/7/07, at 462:10-463:4 (Goldfarb). The 1980 license did not transfer all of Dr. Goldfarb's rights to USCI. For example, Dr. Goldfarb retained the right to share in any damages recovered from enforcement or licensing of the '135 patent. PX4 § 5.3. Dr. Goldfarb also retained significant reversionary rights if C.R. Bard did not prosecute its rights. Id. at §§ 3.1-3.2. In addition, the exclusive license excluded a category of products ("heart valves") from its "subject matter." Id. at 1.1.

In September 1996, C.R. Bard acquired Impra. Trial Tr., 11/16/07, at 1635:20-22 (McDermott). At that time, USCI was no longer involved in the vascular graft business and it subsequently was sold. Id. at 1644:9-19 (McDermott). Responsibility for C.R. Bard's vascular graft business had passed to Bard Vascular Systems Division, which manufactured non-ePTFE grafts, and that business was merged into Impra. Id. at 1635:23-1636:9, 1639:24-1640:17 (McDermott).

Though a wholly-owned subsidiary, Impra was a separate corporate entity from C.R. Bard. Id. at 1680:17-1681:6 (McDermott). Thus, as Mr. McDermott testified, because Impra was the sole C.R. Bard entity manufacturing ePTFE grafts, all rights and obligations under the 1980 License were transferred to it. Id. at 1644:2-1645:10 (McDermott); see also 11/07/07 Tr. at 489:6-490:18 (Goldfarb). This testimony was confirmed by the extensive evidence of the parties' subsequent

conduct, including the following: (i) the payment to, and acceptance by Dr. Goldfarb, of all royalty payments from Impra, (Trial Tr., 11/16/07, at 1644:20-1645:10, 1647:14-23 (McDermott); PX564 (showing Impra royalty payments).); (ii) the entry into the written amendment of the 1980 License by Dr. Goldfarb, C.R. Bard and Impra in 1997 making Impra the exclusive licensee, (PX191); (iii) Impra's granting of a sublicense to Endorsed as the holder of "certain license rights under United States Patent No. 6,436,135, including the right to grant sublicenses," (PX785 at 785.1), and (iv) Dr. Goldfarb's 2007 assignment of the '135 patent to BPV (Impra's successor) confirming that Dr. Goldfarb had "granted [BPV] an exclusive, worldwide license under the Patent." PX1475 at 1475.2. The 1997 Amendment (PX191) is particularly significant. Not only did this agreement confirm the understanding of all three contracting parties – Dr. Goldfarb, C.R. Bard and Impra – that C.R. Bard had "assigned and transferred the License Agreement to Impra along with responsibility for management of Bard's vascular graft business," (id. at 191.1), but it also amended and substantially altered the terms of the 1980 License by replacing USCI with Impra as the exclusive licensee, (id. at § 3), removing the subject matter exclusion of heart valves under the license, (id. at §§ 5 and 6), and granting Impra the ability to freely assign the license to any affiliate or division of C.R. Bard (id. at § 14). Thus, as the Court found, the 1997 Amendment enlarged and enhanced the rights granted to Impra by transferring several of Dr. Goldfarb's previously retained rights. Doc. No. 833 at 19-20; see also DX3181 (referring to "a new agreement"). The preamble to the 1997 Amendment expressly states that it is made "by and among" Dr. Goldfarb, C.R. Bard, and Impra. PX191

at 191.1. As the Court has already found, Mr. McDermott's unrebutted testimony established that he signed the agreement both as President of Impra and on behalf of C.R. Bard with its full knowledge and consent. Trial Tr., 11/16/07, at 1647:2-5 (McDermott). The authority of Mr. McDermott to enter into this agreement on behalf of C.R. Bard was confirmed by the decade-long course of conduct during which C.R. Bard has never repudiated the agreement. The Court explicitly found that these facts established standing. Doc. No. 833 at 13-20.

In support of its Motion, Gore presents document and deposition testimony from the previous New Jersey litigation between C.R. Bard and Gore. Not a single one of the documents attached to Gore's Motion were presented or admitted at trial or are "materials of record." Pandrol USA, L.P. v. Airboss Ry. Products, Inc., 320 F.3d 1354, 1367 (Fed. Cir. 2003). Gore presents no justification for its failure to timely present this alleged evidence, and cites no authority establishing that it is legally permissible for the Court to consider such non-evidence at this late stage. Indeed, Gore does not even explain why it waited until its most recent standing motion to cite to this non-record evidence.

B. Legal Standard

Standing is a judicially created doctrine that is an essential part of the case-or-controversy requirement of Article III. Pritikin v. Dept. of Energy, 254 F.3d 791, 796 (9th Cir. 2001). "To satisfy the Article III case or controversy requirement, a litigant must have suffered some actual injury that can be redressed by a favorable judicial decision." Iron Arrow Honor Soc. v. Heckler,

464 U.S. 67, 70 (1984). "In essence the question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues." Warth v. Seldin, 422 U.S. 490, 498 (1975).

The doctrine of standing "requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted." Allen v. Wright, 468 U.S. 737, 752 (1984). The court is powerless to create its own jurisdiction by embellishing otherwise deficient allegations of standing. Whitmore v. Arkansas, 495 U.S. 149, 155-56 (1990).

C. Discussion

The Plaintiffs have met their burden of establishing standing. Standing in a patent infringement case is derived from the Patent Act: "A patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281. The term "patentee" includes "not only the patentee to whom the patent was issued but also the successors in title to the patentee." 35 U.S.C. § 100(d). The Federal Circuit recognizes three categories of potential plaintiffs in patent cases: "[1] those that can sue in their own name alone; [2] those that can sue as long as the patent owner is joined in the suit; and [3] those that cannot even participate as a party to an infringement suit." Morrow v. Microsoft Corp., 499 F.3d 1332, 1339 (Fed. Cir. 2007). The first two categories of plaintiffs have constitutional standing to sue for patent infringement. Id. After considering the evidentiary record here, the Court previously determined that Dr. Goldfarb was "the owner of the patent title" and that Bard Peripheral Vascular ("BPV") was the exclusive licensee when the

suit was filed. Order, July 29, 2008, at 19-20. Based on these two findings, the Court determined that Plaintiffs had standing. Id. at 20.

1. Transfer of Rights

Gore argues that Dr. Goldfarb's complaint must be dismissed because Goldfarb granted all substantial rights to C.R. Bard and C.R. Bard is not a plaintiff." Gore's Motion at 8. In an attempt to support this claim, Gore ascribes legal error to the Court's July 29 Order asserting that the Court "used the wrong legal test" in finding that Dr. Goldfarb did not transfer "all rights," as opposed to "all substantial rights," to C.R. Bard. Gore's Motion at 8 (citing Order at 15), see also id. at 1, 9. Gore mischaracterizes the Court's holding and ignores the Court's express finding, which stated that: "[c]ontrary to Gore's argument, Dr. Goldfarb retained substantial rights in the 1980 agreement including, *inter alia*, the right to share in any patent damages or license fees. Thus, the 1980 agreement granted an exclusive license, not title, to USCI/C.R. Bard." Order, July 29, 2008, at 16; see also id. at 17 ("In addition, Dr. Goldfarb retained substantial rights to his patent application."). However, Gore's mischaracterization of, and refusal to acknowledge, the Court's factual findings is not well taken. The Court's July 29 Order makes plain that the Court applied the correct legal test: "To determine whether an agreement conveys all substantial rights in the patent, '[the court] must ascertain the intention of the parties and examine the substance of what was granted by the agreement.'" Fieldturf, Inc. v. Sw. Rec. Indus., 357 F.3d 1266, 1269 (Fed. Cir. 2004). "In making such a determination, it is helpful to consider rights retained by the grantor in

addition to rights transferred to the grantee." Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc., 248 F.3d 1333, 1342 (Fed. Cir. 2001). This is precisely the analysis conducted by the Court in finding that Dr. Goldfarb retained "substantial rights" under the 1980 License. July 29,2008 Order at 15-16.

Gore nonetheless challenges the Court' factual findings claiming that "[a]s a matter of law, none of these retained rights are substantial rights and do not affect the conclusion that C.R. Bard received substantially all the rights." Gore's Motion at 9. However, Gore appears to be rearguing its point based on the same legal authority it previously relied on, which the Court previously considered and disregarded. See Gore's Response to Plaintiffs' Objection to Gore's Notice [re:] Standing, Doc. 829, at 5 (citing Vaupel Texilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 874-75 (Fed. Cir. 1991).

The instant case is distinguishable from Vaupel for a number of reasons. First, unlike the agreement in Vaupel (which had no subject matter limitation), the 1980 License expressly excluded a category of products ("heart valves") from its "subject matter." See Order, July 29, 2008, at 15 (citing PX4 at § 1.1). Licenses with "subject matter" exclusions are "field of use" licenses and cannot confer "all substantial rights." See, e.g., Int'l Gamco, Inc. v. Multimedia Games, Inc., 504 F.3d 1273, 1278 (Fed. Cir. 2007) ("exclusive field of use licensee does not have standing to sue in its own name" because license "divide[s] the scope of a patent right by its subject matter"). At a minimum, this exclusion is strong evidence that Dr. Goldfarb and C.R. Bard intended the 1980 agreement to be a license not an

assignment.[4] Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1132 (Fed. Cir. 1995) (license was exclusive where patentee reserved "a limited right to make, use and sell products embodying the patented inventions").

Second, Dr. Goldfarb retained an ownership interest in any patent that C.R. Bard elected to abandon, with "any patent so obtained [] not [] subject this LICENSE," (PX4 at § 3.2), and received royalties irrespective of the prosecution or maintenance of any patents (Id. § 2.2). Dr. Goldfarb's reversionary interest was, thus, materially different from the termination provision in Vaupel, which applied only in instances of bankruptcy or cessation of manufacture. See Order, July 29, 2008, at 15 (citing PX4 at §§ 3.1-3.2).

Third, the right to sue granted under the 1980 License is different from the right to sue in Vaupel and is limited to the right to "file, control, defend and settle, by granting a sublicense or otherwise, all actions and claims against third parties for infringement of any PATENTS brought against Dr. GOLDFARB or USCI

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[4] Gore's argument declaring that the exclusion of heart valves was "not a substantial right under the patent" is baseless. The 1980 License defines "VASCULAR PROSTHESES" as "prostheses for replacing, repairing or bypassing blood vessels of the human body except HEART VALVES." PX4 AT § 1.1. Thus, as of the time of the 1980 License, the parties clearly understood heart valves to be within the scope of the licensed patents (otherwise they would not have needed to expressly exclude them), and clearly thought that this right was substantial enough to expressly carve it out of their license. In addition, Gore's claim that heart valves fall outside of the Court's claim construction is unsubstantiated and lacks evidentiary foundation. The issue of whether ePTFE heart valves constitute a vascular prosthesis has yet to be decided and was not put before the Court.

seeking to declare a PATENT invalid." PX4 at § 5.3. By its terms, therefore, this right is limited to third party challenges to validity and does not grant C.R. Bard the exclusive right to sue for all infringement as Gore contends. Sicom Sys. Ltd. v. Agilent Techs., Inc., 427 F.3d 971, 979 (Fed. Cir. 2005) (no virtual assignment where licensee was granted exclusive right to sue for "commercial" infringement only.) In addition, Dr. Goldfarb's right to share in any litigation damages was contingent on him bearing a portion of the litigation costs. PX4 at § 5.3. The 1980 License thus contemplated Dr. Goldfarb's participation in any lawsuit, which is contrary to an assignment. See e.g., Abbott Labs., 47 F.3d at 1132 (no virtual assignment where "the parties appear to have contemplated that [patentee] could participate in a suit" filed by licensee).

Fourth, the 1980 License was not assignable by C.R. Bard except in limited circumstances to "any successor to or purchaser of all or substantially all of its VASCULAR PROSTHESIS business." PX4 at § 6.4. This precludes any assignment because "limits on the assignment of rights are a factor weighing in favor of finding a transfer of fewer than all substantial rights." Intellectual Prop. Dev., 248 F.3d at 1345; see also Abbott Labs., 47 F.3d at 1132 (finding "the right to prevent Abbott from assigning its rights under the license to any party other than a successor in business" a substantial retained right).

In sum, Plaintiffs presented substantial evidence – confirmed by the issuance of the patent to Dr. Goldfarb and the January 2007 Assignment of Patent Rights (PX1475) – demonstrating that the parties intended

that the 1980 License to be a transfer of less than "all substantial rights."

2. Implied-In-Fact License

Because the Court determined, based on the evidence, that the 1980 License is not a virtual assignment, it found that, as in Waymark, the "1996 transfer to Impra/BPV of the 1980 license, created at least an implied-in-fact transfer of the license to Impra/BPV thereby conferring standing to sue in conjunction with Dr. Goldfarb." Order, July 29, 2008, at 16. Gore raises a new argument asserting that the terms of the 1980 License require an express written assignment. Gore's Motion at 12. However, Gore's argument is wrong. First, New Jersey law (which governs the 1980 License) expressly permits the oral assignment of contracts. See, e.g., Paxson v. Comm'r, 144 F.2d 772, 775 (3d Cir. 1944) ("New Jersey follows the Restatement view that contracts may be assigned orally."). Second, there is no requirement in the 1980 License for a written assignment, because the only restriction on assignment is that the transferee be a "successor or purchaser of all or substantially all of [C.R. Bard's] VASCULAR PROSTHESIS business." PX4 at § 6.4. Mr. McDermott's unrebutted trial testimony established that Impra/BPV was the successor to that vascular prosthesis business, (Trial Tr., 11/16/07, at 1636:2-9 (McDermott) and 1639:24-1640:17 (McDermott), as confirmed by the 1997 Amendment, (PX191 at 191.1.), and Impra/BPV's assumption of all rights and obligations under the 1980 License for over a decade. Trial Tr., 11/16/07, at 1644:20-1645:10 (McDermott), 1647:14-23 (McDermott); PX564. The evidence adduced at trial,

thus, strongly supports the Court's finding that there was "at least" an implied-in-fact assignment of the 1980 License. See, e.g., Weiner v. Rollform, Inc., 744 F.2d 797 (Fed. Cir. 1984) (finding standing based on oral exclusive distribution agreement as fact-finder "was at liberty to believe the testimony that an oral contract existed"). Moreover, even if the 1980 License required a written assignment, it is well-settled under New Jersey law that the terms of a contract (including a requirement for written consent to any transfer) may be waived by the parties. Goldstein v. Barclay Amusement Corp., 123 N.J.L. 166, 169 (N.J. 1939). Such waiver may be "by a written instrument, a course of dealing, or even passive conduct, *i.e.*, taking no action to invalidate the assignment *vis-à-vis* the assignee." Garden State, L.P. v. First Fidelity Bank, N.A., 305 N.J. Super. 510, 523, 702 A.2d 1315 (1997). Plaintiffs presented substantial evidence demonstrating that Dr. Goldfarb – the only party who could have objected – consented to the assignment of the 1980 License, including: Dr. Goldfarb's agreement to amend the 1980 License to make Impra the exclusive licensee; Impra/BPV's assumption of all rights and obligations under the 1980 License, including the payment of royalties to Dr. Goldfarb; and Dr. Goldfarb's 2007 assignment of the '135 patent to BPV expressly acknowledging that "Dr. Goldfarb granted [BPV] an exclusive, worldwide license under the Patent." See Trial Tr., 11/07/08, at 489-90 (Goldfarb); Trial Tr., 11/16/08, at 1646-47 (McDermott); Trial Tr., 11/16/08, at 1644-45 (McDermott); PX191; PX564; PX1475 at 1475.2.

Thus, the only evidence presented is that all relevant parties – Dr. Goldfarb, Impra/BPV, and C.R.

Bard – treated BPV as the exclusive licensee, which is sufficient to establish standing. See, e.g., Kalman v. Berlyn Corp., 914 F.2d 1473, 1482 (Fed. Cir. 1990) (granting standing to *de facto* licensee as the "real party in interest"). Moreover, to the extent that Gore is correct that a written transfer of the license is required, the Court found that "by at least 1997, there is a writing transferring the exclusive license from C.R. Bard to BPV." Order, July 29, 2008, at 17, 19.

3. Transferring a License by Way of a Writing

Gore asserts that all transfers of exclusive licenses are required to be in writing. Gore's Motion, Doc. 849, at 12 ("[U]nder 35 U.S.C. § 261, a transfer of an existing exclusive written license is required to be in writing"). As the Court has previously ruled, Gore's argument is wrong as a matter of law. However, if a written transfer of C.R. Bard's exclusive license were somehow required, the evidence underlying the Court's findings shows that there is such a writing, the 1997 Agreement Amending License Agreement. Order, July 29, 2008 at 17 (finding that the record supports finding that "by at least 1997, there is a writing transferring the exclusive license from C.R. Bard to BPV").

Gore now argues that the Court's finding cannot stand because "[a]ny assignment of C.R. Bard's license to BPV, under 35 U.S.C. § 261 and the case law, had to be in writing signed by C.R. Bard as the assignor." Gore's Motion at 2. Again, Gore misstates the law and the facts.

Section 261, to the extent it applies, only states that patents "shall be assignable in law by an instrument in

writing," and imposes no limitations as to the form or content of such writing. See generally Morrow, 499 F.3d at 1337 n.3 ("The type of written instrument [under 35 U.S.C. § 261] (*e.g.*, license or assignment agreement, dissolution agreement, or merger agreement) and the factual context in which the instrument is created is irrelevant.") The lack of C.R. Bard's signature on the 1997 Amendment is thus irrelevant under 35 U.S.C. § 261.

4. Prudential Standing

The record evidence that Plaintiffs introduced at trial further confirms that a C.R. Bard's signature was not required. For example, the preamble to PX191 expressly states that the 1997 Agreement is "made … by and among David Goldfarb, M.D., … C.R. Bard, Inc., and IMPRA, Inc." Another example is that the evidence showed that although the 1997 Amendment was drafted by C.R. Bard, and identified C.R. Bard as a party, the only signature block C.R. Bard included for itself was through Mr. McDermott in his capacity as president of C.R. Bard's wholly-owned subsidiary Impra. PX191 at 191.1 and .3; Trial Tr., 11/16/07, at 1646:4-7 (McDermott). A third example is that Mr. McDermott confirmed C.R. Bard's intent to be bound by the Agreement, testifying that he signed it on C.R. Bard's behalf and with Bard's express authorization.[5] Trial Tr., 11/16/07, at 1647:2-5 (McDermott). This evidence overwhelmingly establishes Mr. McDermott's

[5] The Court has already found that this testimony is not negated by Mr. McDermott's testimony on cross-examination that he signed the 1997 Amendment as President of Impra. Order,July 29, 2008, at 18 n.1.

authority to enter into the 1997 Amendment for C.R. Bard. Alfano v. BDO Seidman, LLP, 393 N.J. Super. 560, 569 (N.J. Super. Ct. App. Div. 2007) ("When one corporation acts as the agent of a disclosed principal corporation, the latter corporation may be liable on contracts made by the agent.") In addition, C.R. Bard's failure to repudiate Mr. McDermott's actions during the decade-long assumption of all rights and obligations under the 1980 License by Impra/BPV confirms Mr. McDermott's authority, and constitutes a ratification of the 1997 Amendment. Thermo Contractor Corp. v. Bank of N.J., 69 N.J. 352 (1976) ("Ratification may be express or implied, and intent may be inferred from the failure to repudiate an unauthorized act, … or from conduct on the part of the principal which is inconsistent with any other position than intent to adopt the act."). The admitted evidence thus proves that the 1997 Amendment was a written assignment.

The record evidence indisputably established that BPV was an exclusive licensee, therefore, BPV unquestionably has constitutional standing. Intellectual Prop. Dev., 248 F.3d at 1346 (exclusive licensees are "constitutionally injured by another entity that makes, uses or sells the invention.") All that is required for prudential standing, therefore, is for the "patentee" to be joined. Id. at 1348. Because both Dr. Goldfarb and C.R. Bard are parties, and have participated throughout its duration, there are no prudential standing concerns.[6] Evident Corp. v. Church

[6] If it appeared to the Court that standing was an issue here and that to have standing C.R. Bard is a necessary plaintiff, the Court would grant Plaintiffs leave to amend the Complaint under

& Dwight Co., 399 F.3d 1310, 1314 (Fed. Cir. 2005) ("[R]egardless of whether [the patent owner] was brought into the suit by the accused or the licensee, there is no standing problem.").

II. MOTION FOR NEW TRIAL OR REMITTITUR

Pursuant to Fed. R. Civ. P. 59 Defendant requests that the Court grant a new trial, or in the alternative, a remittitur, based on claim that the jury awarded Plaintiffs excessive "reasonable royalty" damages.

A. Legal Standard

The decision of whether to grant a new trial rests with the sound discretion of the trial court. See Allied Chem. Corp. v. Daifon, Inc., 449 U.S. 33, 36 (1980). Traditionally, trial courts grant new trial motions "only if the verdict is contrary to the clear weight of the evidence, is based upon false or pernicious evidence or to prevent a miscarriage of justice." Molski v. M.J. Cable, Inc., 481 F.3d 724, 729 (9th Cir. 2007). In the context of damages, a new trial is generally granted when the trial court finds that the damages awarded by the jury are "grossly excessive or monstrous, clearly not supported by the evidence or based only on speculation or guesswork." See Monsanto Co. V. Ralph,

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Fed.R.Civ.P. 15 and 21. Intellectual Prop. Dev., 248 F.3d at 1348 n.5 ("[E]ven appellate-level amendments to correct jurisdictional defects may be appropriate to allow an exclusive license to join the patent owner." (citing Mentor H/S, Inc. v. Med. Device Alliance, Inc., 240 F.3d 1016, 1019 (Fed. Cir. 2001)). However, the Court finds standing exists with the current Plaintiffs and does not find amendment necessary.

382 F.3d 1374, 1383 (Fed. Cir. 2004). When an award of damages justifies a new trial, the trial court may, within its discretion, "grant defendant's motion for a new trial or deny the motion conditional upon the prevailing party accepting a remittitur." Fenner v. Dependable Trucking Co., 716 F.2d 598, 603 (9th Cir. 1983). If the prevailing party accepts remittitur, judgment must be entered in the lesser amount. Fenner v. Dependable Trucking Co., 716 F.2d 598, 603 (9th Cir. 1983). This allows the party to avoid the delay and expense of a new trial when the jury's verdict is excessive in relation to the evidence found in the record. Unisplay S.A. v. Am. Elect. Sign Co., 69 F.3d 512, 519 (Fed. Cir. 1995).

B. Analysis

Defendant makes two central arguments in its motion for a new trial/remittitur. Defendant first claims that the verdict returned by the jury was "grossly excessive" and cannot stand. Next, Defendant argues that the jury's verdict of a 10% reasonable royalty was not supported by the evidence and was contradictory. Because of the alleged excessiveness and inconsistent nature of the verdict, Defendant asks the Court to either grant a new trial or reduce Plaintiffs' reasonable royalty damages award to $41.8 Million.

With respect to whether the jury's verdict was grossly excessive, the Court notes that this argument was not substantively or adequately addressed by Defendants in their briefing. In any event, the Court is unmoved by Defendants's bare bones assertion that the jury's determination of damages could in any sense be considered grossly excessive or monstrous. Although neither party specifically argued for a 10% reasonable

royalty, that does not render the jury's verdict erroneous for "the factual determination of a reasonable royalty . . . need not be supported, and indeed, frequently is not supported by the specific figures advanced by either party." Smithkline Diagnostics, Inc. v. Helena Labs. Corp., 926 F.2d 1161, 1167 (Fed. Cir. 1991). "Rather, a jury's choice simply must be within the range encompassed by the record as a whole." Unisplay, 69 F.3d at 519. Here, consistent with the Court's instructions, Plaintiffs presented evidence establishing not only that a reasonable royalty was greater than 5%, but Plaintiffs attempted to argue at trial that a royalty of 15% or higher was supportable. As Plaintiffs note, the evidence presented at trial established that Defendant has sold billions of dollars of ePTFE grafts embodying Dr. Goldfarb's invention, and have reaped substantial profits as a result. Indeed, the Goldfarb patent was an important industry achievement, which, some 30 years later, still remains the gold standard for vascular grafts, and both Bard and Gore have enjoyed substantial commercial success from Dr. Goldfarb's invention, each selling millions of ePTFE grafts. Under circumstances such as these, the jury's award cannot be fairly characterized as grossly excessive or monstrous.

The Court will now turn to the merits of whether damages amount was inconsistent or otherwise not supported by the clear weight of the evidence adduced at trial. The point of departure for an analysis of damages in the instant case is found in the language of the Patent Act, which states that damages for infringement shall be "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the

infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284. To achieve adequate compensation, an award of damages must provide "full compensation." General Motors Corp. V. Devex Corp., 461 U.S. 648, 654-55 (1983). The award must also not be less than a reasonable royalty, the purpose of which "is not to direct the form of the compensation, but to set a floor below which damage awards may not fall." Rite-Hite Corp. V. Kelley Co., 56 F.3d 1538, 1544 (Fed. Cir. 1995). The Patent Act's position on damages is "expansive rather than limiting. It affirmatively states that damages must be adequate, while providing only a lower limit and other limitation." Id.

In the instant case, Defendant argues that the jury determined that Gore's 5% option to sublicense the '135 patent lapsed on February 9, 2004 was available to it during the August 2002 hypothetical negotiation. As such, Defendant contends that the option constituted a binding contract. Thus, when the jury calculated a reasonable royalty award of 10%, without accounting for the 5% royalty rate of the option, it rendered the verdict internally inconsistent, meriting either a new trial or remittitur. Plaintiffs counter by arguing that there are several ways to reconcile the 10% royalty with the jury's finding that the option lapsed on February 9, 2004. First, Plaintiffs suggest that based on the evidence, the jury could determine that the 5% rate negotiated in 1984 was not a reasonable royalty and was incapable of adequately compensating Plaintiff for the infringement. Second, Plaintiff writes that the jury could have determined that the 1984 agreement was merely an "agreement to agree," and thus not available to Defendant in the hypothetical negotiation. Third, Plaintiffs claim that the jury was entitled to

treat the option as lapsed in both the real world and in the hypothetical negotiation.

Without addressing all of the arguments raised by the parties in their moving papers, the Court notes that Defendant has not convincingly argued that the 5% option constitutes a ceiling on the amount of damages that Plaintiffs could recover as a reasonable royalty rate under 35 U.S.C. § 284. For that reason, the jury's verdict cannot be classified as inconsistent or irreconcilable. For similar reasons the imposition of a 10% reasonable royalty rate was not against the clear weight of the evidentiary record.

As Plaintiffs contend, the record is replete with evidence suggesting that a 5% royalty rate—negotiated in 1984, 18 years before the hypothetical negotiation—could not reflect what a reasonable royalty would be in 2002 in view of the vastly changed circumstances of the parties. In addition, the 5% royalty was negotiated as part of the settlement of litigation with Gore, and as such, is only of limited relevance to the hypothetical negotiation. See Rite-Hite Corp. v. Kelley Co., 774 F. Supp. 1514, 1535 (E.D. Wis. 1991) ("settlement-induced royalty agreements are determined largely by factors not considered in the 'hypothetical royalty negotiation' . . . ."). Importantly, the 5% royalty rate of the lapsed option was negotiated at a time when the Goldfarb application was still being processed and was in the midst of a contentious challenge by Defendant. There were numerous uncertainties at that time, including: (1) whether Dr. Goldfarb would prevail in the interference; (2) if Dr. Goldfarb did prevail, whether a patent would issue; (3) if a patent issued, whether its claims would cover Gore's products; and (4) if a patent

issued, whether its claims would be upheld as valid. Because none of the uncertainties that existed in 1984 are present during the hypothetical negotiation, the evidence presented tended to show that the 5% rate negotiated in 1984 did not set the ceiling on the amount of damages that would be adequate to compensate Plaintiffs for the infringement. Furthermore, as Plaintiffs note, the fact that the 5% royalty was confirmed by the real world evidence establishing that the lapsed option might have been a below market deal because of the uncertainties that existed at the time. As fact witness, Mr. McDermott, testified, based on his extensive industry experience, that the 5% royalty was "phenomenally low" and "below market rate."

> Q: And based on that experience, and being president of the company, what was your view on a royalty rate of five percent in your industry?
>
> A: Well, it was phenomenally low. To license a competitor at that level just— I was surprised. I wasn't involved when that got done originally. But when I learned about it, I was certainly surprised.
>
> Q: What was your view when the option was not exercised?
>
> A: Well, because I felt it was such below market rate and they didn't take it, I was just surprised. It didn't make sense to me.

(11/16/07 tr. at 1667:6-16.) The jury was entitled to rely on such evidence and conclude that the 5% rate negotiated in 1984 was significantly less than a

reasonable royalty resulting from a hypothetical negotiation in 2002 based on materially different circumstances.

The Court is further unmoved by Defendant's argument that the 10% royalty cannot stand because Gore "would never have agreed to pay more than five percent rate of the option during the hypothetical negotiation." (Dkt.#840, p. 1.) Notwithstanding Defendant's contention, it should be noted that Gore did not try to exercise the option and did not take a license to the Goldfarb patent. Instead, Defendant elected to take their chances with litigation; now that the jury has found Defendant's conduct to be objectively reckless, the fact that Gore would prefer to now pay the 5% royalty that it earlier rejected rather than the 10% royalty assessed by the jury is irrelevant. "[W]hat an infringer would prefer to pay is not the test the damages." Rite-Hite, 56 F.3d at 1555 (citing TWM Mfg. Co. v. Dura Corp., 789 F.2d 895, 900 (Fed. Cir. 1986)). In fact, as Plaintiffs point out, the Federal Circuit has specifically rejected the claim that Defendant has made, holding that the law does not preclude reasonable royalty from "be[ing] set so high that no rational self-interested wealth maximizing infringer acting *ex ante* would ever have agreed to it." Monsanto Co. v. Ralph, 382 F.3d 1374, 1383 (Fed. Cir. 2004).

Lastly, Defendants incorrectly assert that the jury determined that the lapsed option was in effect on August 20, 2002, and therefore was an available non-infringing alternative in the hypothetical negotiation. To the contrary, the jury was only asked to determine the reasonable period of time for exercise of the lapsed

option, and was not asked to determine whether it was "in effect." Moreover, this Court previously determined that "the unexercised Option is nothing more than an agreement to agree at some point in the future, rather an enforceable contract" and held that "whether Gore is entitled to limit Bard's royalty damages claim . . . to five percent" was a question for the jury. (Dkt.# 559, p. 29.)

Defendant's claim that it can simply exercise the lapsed option in the hypothetical negotiation ignores the fact that the hypothetical negotiation does not mirror real business conditions. Rather, the "willing licensee/licensor approach must be flexibly applied as a 'devise in the aid of justice.'" TWM, 789 F.2d at 900 (internal citations omitted). Accordingly, the hypothetical negotiation differs from the real world at the time of the hypothetical negotiation in two significant respects. First, the court must "assume, for purposes of the hypothetical negotiation, that all parties would have known all relevant information." Mobil Oil Corp. v. Amoco Chems. Corp., 915 F. Supp. 1333, 1353 (D. Del. 1994). Second, and most importantly, the hypothetical negotiation requires the trial court to take into account facts that occur after the date of the first infringement. See Fromson v. Western Lito Plate and Supply Co., 853 F.2d 1568, 1575 (Fed. Cir. 1988). Here, among the subsequent information that the jury was permitted to take into account in the hypothetical negotiation was the fact that the parties could not agree on any of the material terms of a sublicense. It was undisputed that the lapsed option did not contain the negotiated terms of any sublicense agreement. It was also undisputed that following the issuance of the Goldfarb patent, Bard

sent Gore a partial list of suggested license terms "to be discussed" including provisions on the royalty base on which royalties would be due; details as to the exclusivity of the sublicense; assignability or transfer provisions; provisions relating to payment and audit; provisions describing termination; covenants by Gore not to attack the validity or enforceability of the Goldfarb patent. As Plaintiffs note, not one of these terms was ever agreed on by the Parties. (11/16/07 Tr. At 1657:4-1668:21, 1727:7-12; 11/29/07 Tr. At 2493:8-2498:18; 12/04/07 Tr. At 3043:1-3047:20.) Instead the only evidence at trial was that in the event that Gore did decide to exercise the lapsed option, all of the material license terms needed to be negotiated.

In fact, Defendant's expert on the damages issue, Professor Teece, stated that he did not know what terms the Parties would agree to because he had not "done an analysis of what would be needed to finish off the actual world this—or to convert the option, to exercise the option and convert it into a license agreement." (11/29/07 Tr. At 2496:16-19.) This lack of any agreement as to the material terms was also confirmed by Plaintiffs' licensing expert, Dr. Berneman, who testified that "many significant aspects" still required negotiation, and that reasonable parties frequently never reach agreement over such terms. (12/05/07 Tr. At 3237:1-22.)

The jury was therefore free to credit Plaintiffs' evidence and find that the lapsed option was merely an agreement to agree, though not an enforceable contract, and that Gore could not simply exercise it without first working out the terms. Just as in the real world, the jury was free to conclude that the Parties

could not work out the material terms of any agreement before the option lapsed and thus the lapsed option was not available to Gore to exercise in the hypothetical negotiations. Thus, the jury's 10% reasonable royalty award is supported by record evidence and fully consistent with the jury's finding that Gore's 5% option lapsed on February 9, 2004.

In sum, Defendant has not met the requirements for a new trial or remittitur on the issue of damages.

III. REMAINING RENEWED MOTIONS FOR JUDGMENT AS A MATTER OF LAW

The Court will now address Defendant's remaining Motions. These Motions are all Renewed Motions for Judgment as a Matter of Law: Motion for Judgment as a Matter of Law Regarding Invalidity Because Cooper and Goldfarb are Joint Inventors (Dkt.#841.), Renewed Motion for Judgment as a Matter of Law Regarding Willful Infringement (Dkt.#842.), Renewed Motion for Judgment as a Matter of Law Regarding Invalidity of the '135 Patent' for Failure to Disclose Best Mode (Dkt.#843.), Renewed Motion for Judgment as a Matter of Law that Claims 20-27are Invalid for Failure to Satisfy the Written Description Requirement of 35 U.S.C. § 112, ¶1 (Dkt.#844.), Renewed Motion for Judgment as a Matter of Law that Claims 20-27 are Invalid Under 35 U.S.C. § 102(B) for Lack of Novelty in View of the 1973 Matsumoto *Surgery* Article (Dkt.#845.), Renewed Motion for Judgment as a Matter of Law Regarding Plaintiffs' Failure to Prove that Gore's Accused Products Meet the Typicality Element of Claims 20-27 (Dkt.#846.), Renewed Motion for Judgment as a Matter of Law Regarding Plaintiffs'

Claim that Propaten Infringes the '135 Patent.' (Dkt.#847.)

A renewed motion for judgment as a matter of law is properly granted "if the evidence, construed in the light most favorable to the nonmoving party, permits only one reasonable conclusion, and that conclusion is contrary to the jury's verdict." Pavao v. Pagay, 307 F.3d 915, 918 (9th Cir. 2002). The "jury's verdict must be upheld if its is supported by substantial evidence, which is evidence adequate to support the jury's conclusion, even if it is also possible to draw a contrary conclusion." Id. Accordingly, a court "can overturn the jury's verdict and grant such a motion only if there is no legally sufficient basis for a reasonable jury to find for that party on that issue." Costa v. Desert Palace, Inc., 299 F.3d 858, 859 (9th Cir. 2002) (internal citations omitted). If there is "sufficient evidence before the jury on a particular issue, and if the jury instructions on the issue were correct, then the jury's verdict must stand." Transgo, Inc. v. Ajac Transmission Parts Corp., 768 F.2d 1001, 1014 (9th Cir. 1985).

In ruling on a motion for judgment as a matter of law, the trial court must view all evidence in the light most favorable to the nonmoving party, draw all reasonable inferences in the favor of the nonmover, and disregard all evidence favorable to the moving party that the jury is not required to believe. Costa, 299 F.3d at 859. The court "may not substitute [its] view of the evidence for that of the jury," nor can the court "make credibility determinations nor weigh the evidence." Id. The "high hurdle" of the 50(b) standard thus "recognizes that credibility, inferences, and factfinding are the province of the jury, not [the] court." Id.

The Court is intimately familiar with the all of the invalidity defenses and other issues that Defendant has raised in its renewed motions and finds little need to revisit each one individually. Suffice it to say that the Court is firmly convinced that the jury's decisions were supported by substantial evidence. The Court therefore denies Gore's remaining Renewed Motions for Judgment as a Matter of Law.

Accordingly,

IT IS HEREBY ORDERED denying Defendant's Motion Pursuant to Fed.R.Civ.P. 12(b)(1) and 12(h)(3) to Dismiss Plaintiffs' Complaint for Lack of Standing or in the Alternative Renewed Motion for Judgment as a Matter of Law. (Dkt.#849.)

IT IS FURTHER ORDERED denying Defendant's Motion for New Trial or Remittitur for Excessive Damages. (Dkt.#840.)

IT IS FURTHER ORDERED denying Defendant's Motion for Judgment as a Matter of Law Regarding Invalidity Because Cooper and Goldfarb are Joint Inventors. (Dkt.#841.)

IT IS FURTHER ORDERED denying Defendant's Renewed Motion for Judgment as a Matter of Law Regarding Willful Infringement. (Dkt.#842.)

IT IS FURTHER ORDERED denying Defendant's Renewed Motion for Judgment as a Matter of Law Regarding Invalidity of the '135 Patent' for Failure to Disclose Best Mode. (Dkt.#843.)

IT IS FURTHER ORDERED denying Defendant's Renewed Motion for Judgment as a Matter of Law that

Claims 20-27are Invalid for Failure to Satisfy the Written Description Requirement of 35 U.S.C. § 112, ¶1. (Dkt.#844.)

IT IS FURTHER ORDERED denying Defendant's Renewed Motion for Judgment as a Matter of Law that Claims 20-27 are Invalid Under 35 U.S.C. § 102(B) for Lack of Novelty in View of the 1973 Matsumoto *Surgery* Article. (Dkt.#845.)

IT IS FURTHER ORDERED denying Defendant's Renewed Motion for Judgment as a Matter of Law Regarding Plaintiffs' Failure to Prove that Gore's Accused Products Meet the Typicality Element of Claims 20-27. (Dkt.#846.)

IT IS FURTHER ORDERED denying Defendant's Renewed Motion for Judgment as a Matter of Law Regarding Plaintiffs' Claim that Propaten Infringes the '135 Patent.' (Dkt.#847.)

DATED this 31st day of March, 2009.

/s/_____
Mary H. Murguia
United States District Judge

APPENDIX F

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ARIZONA

No. CV 03-0597–PHX-MHM

[Filed July 29, 2008]

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

Plaintiffs,

vs.

W.L. Gore & Associates, Inc.,

Defendant.

W.L. Gore & Associates, Inc.,

Counterclaimant,

vs.

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

Counterdefendants.

ORDER

Presently, Gore has ten outstanding Motions for Judgment as a Matter of Law ("JMOL"). Gore's ten motions include the following: (1) Gore's Motion for JMOL Regarding Plaintiffs' Claim of Willful Infringement; (2) Gore's Motion for JMOL Regarding Invalidity of the '135 Patent for Failure to Disclose Best Mode; (3) Gore's Motion for JMOL that Claims 20-27 are Invalid for Failure to Satisfy the Written Description Requirement of 35 U.S.C. § 112, ¶ 1; (4) Gore's Motion for JMOL Regarding Plaintiffs' Failure to Prove that Gore's Accused Products Meet the Typicality Element of Claims 20-27; (5) Gore's Motion for JMOL that Claims 20-27 are Invalid under 35 U.S.C. § 102(B) for Lack of Novelty in View of the 1973 Matsumoto Surgery Article; (6) Gore's Motion for JMOL Regarding Plaintiffs' Claim that Propaten Infringes the '135 Patent; (7) Gore's Motion for JMOL Regarding Invalidity for Anticipation by Dr. Norton's December 1971 Use in "Mrs. B"; (8) Gore's Motion for JMOL Regarding Invalidity for Improper Inventorship Because Cooper and Goldfarb are Joint Inventors; (9) Gore's Motion for JMOL Regarding Plaintiffs' Lack of Standing; and (10) Gore's Motion for JMOL that Claim 20 is Obvious in Light of the Volder Publication. This Order addresses the first nine of Gore's JMOL Motions. The Court will issue a separate Order addressing Gore's tenth Motion for JMOL relating to obviousness.

LEGAL STANDARD

Rule 50, Fed.R.Civ.P., states in relevant part as follows:

> If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may:
>
> (A) resolve the issue against the party; and
>
> (B) grant a motion for judgment as a matter of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.

"Judgment as a matter of law is proper if the evidence, construed in the light most favorable to the non-moving party, allows only one reasonable conclusion . . . ." Acosta v. City and County of San Francisco, 83 F.3d 1143, 1145 (9th Cir. 1996); see also Pavao v. Pagay, 307 F.3d 915, 918 (9th Cir. 2002) (a motion for judgment as a matter of law should be granted only "if the evidence . . . permits only one conclusion, and that conclusion is contrary to the jury's verdict."). "If reasonable minds could differ as to the import of the evidence, however, a verdict should not be directed." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250-51 (1986). In other words, to grant JMOL, there most be "no scenario by which a jury could have concluded" in the nonmoving party's favor. City Solutions, Inc. v. Clear Channel Commc'ns, 365 F.3d 835, 841 (9th Cir. 2004) (reversing grant of motion for JMOL).

DISCUSSION

I. GORE'S MOTION FOR JMOL REGARDING PLAINTIFFS' CLAIM OF WILLFUL INFRINGEMENT

Gore has moved for JMOL regarding Plaintiffs' claim of willful infringement, claiming Plaintiffs did not proffer sufficient evidence to meet their burden of proving willful infringement by clear and convincing evidence.

"[T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." In re Seagate Tech., LLC, 497 F.3d 1360, 1368 (Fed. Cir. 2007). Stated another way, "proof of willfulness . . . requires at least a showing of objective recklessness." Id. If this objective standard is satisfied, then the plaintiffs must establish the existence of a separate, subjective element – the risk that the defendant's conduct was objectively reckless "was either known or so obvious that it should have been known to the accused infringer." Id.

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

are of record." ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1472, 1574-75 (Fed. Cir. 1984).

Where the matter alleged to be invalidating was expressly considered by the PTO, the party challenging validity has the "added burden . . . of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar with their work with the level of skill in the art and whose duty it is to issue only valid patents." Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984).

The trial record in this case provides sufficient evidence for the jury to have found willful infringement by clear and convincing evidence. Such evidence includes the extensive litigation history before the PTO – all of which has found Dr. Goldfarb to be the rightful inventor and patent holder – and that Gore relied on the same references (the Soyer, Volder, and Matsumoto articles) to support its invalidity defense that the PTO previously found not to invalidate Dr. Goldfarb's invention. The Court finds sufficient evidence upon which a reasonable jury could have found willful infringement. Accordingly, Gore's Motion for JMOL Regarding Plaintiffs' Claim of Willful Infringement is denied.

II. GORE'S MOTION FOR JMOL REGARDING INVALIDITY OF THE '135 PATENT FOR FAILURE TO DISCLOSE BEST MODE

Gore alleges that the '135 patent is invalid for violating the best mode requirement of 35 U.S.C. § 112.

A best mode analysis involves two steps. "First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963 (Fed. Cir. 2001). "Second, if the inventor possessed a best mode, the fact finder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it." Id. "The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time of filing," whereas "the second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art." Id. Both steps must be proven by clear and convincing evidence for each asserted claim. Liquid Dynamics Corp. v. Vaughan Co. Inc., 449 F.3d 1209, 1223 (Fed. Cir. 2006).

"There is no requirement in 35 U.S.C. § 112 that an applicant point out which of his embodiments he considers his best mode; that the disclosure includes the best mode contemplated by the applicant is enough to satisfy the statute." Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 589 (Fed. Cir. 1988) (internal citations omitted). Thus, contrary to Gore's assertion, the best mode requirement is satisfied when an inventor discloses a range that includes his best mode. See e.g., Ernsthausen v. Nakayama, 1 U.S.P.Q. 1539, 1549 (Bd. Pat. App. & Inter. 1985) ("There is no concealment of best mode here since one of ordinary skill in the art could readily determine the best operating mode . . . by producing and testing display samples . . . within the rage of thicknesses disclosed by [the patent applicant]").

This Motion bears a striking resemblance to the arguments Gore set forth in its February 2004 Motion for Partial Summary Judgment (Doc. 68 at 5-13). The Court denied that Motion. Now, three years later, following the trial of this matter, Gore asserts the argument again.

In support of its position, Gore cites a number of statements Dr. Goldfarb made in a number of different scholarly publications. However, Gore has not presented sufficient evidence to meet its high burden that the papers were prepared prior to the filing of the Goldfarb application. Nor has Gore provided sufficient evidence to demonstrate that Dr. Goldfarb actually had a "best mode" for carrying out the invention at the time the '135 patent application was filed, let alone sufficient evidence to establish a violation of the best mode requirement. Gore has failed to establish that a reasonable jury would not have a legally sufficient evidentiary basis to find for the Plaintiffs on this issue. Accordingly, Gore's Motion for JMOL regarding invalidity of the '135 patent for failure to disclose best mode is denied.

III. GORE'S MOTION FOR JMOL THAT CLAIMS 20-27 ARE INVALID FOR FAILURE TO SATISFY THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. § 112, ¶ 1

Gore asserts that Claims 20-27 of the '135 patent are invalid for violating the written description requirement of 35 U.S.C. § 112. The written description requirement of 35 U.S.C. § 112 requires that the patent applicant "recount his invention in such detail that his future claims can be determined to be encompassed

within his original creation." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991). "The adequacy of the written (*i.e.*, the disclosure) is measured from the face of the application . . . ." New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1295 (Fed. Cir. 2002). In determining whether the written description requirement has been satisfied, the "application considered as a whole must convey to one of ordinary skill in the art, either explicitly or inherently, that [the inventor] invented the subject matter claimed . . . ." Reiffin v. Microsoft Corp., 214 F.3d 1342, 1346-45 (Fed. Cir. 2000). "Although [the] applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

Gore specifically asserts that claims 20-27 of the '135 patent are invalid for lack of written description because they "encompass grafts having any wall thickness" and thus are not limited to a wall thickness of 0.2 and 0.8 mm, which Gore alleges is "critical" to Dr. Goldfarb's invention. Gore's argument appears to ignore the fact that these same issues were rejected by the Patent Office.

Gore also asserts that claims 20-27 are invalid for failure to satisfy the written description requirements because the claims do not require "through the wall [*i.e.*, transmural] cellular ingrowth" resulting in a neointima. However, this Court has previously considered and rejected this argument after Gore asserted it during claim construction. The Court is not persuaded by the latest assertion of this argument.

In view of the substantial evidence demonstrating that wall thickness is not an essential element of Dr. Goldfarb's invention, and because Gore has not established that one of ordinary skill would understand that the '135 patent required complete transmural ingrowth, Gore has not met its burden. Gore has not demonstrated that no reasonable jury could find that the asserted claims of the '135 patent comply with the written description requirement. Accordingly, Gore's motion for JMOL is denied.

IV. GORE'S MOTION FOR JMOL REGARDING PLAINTIFFS' FAILURE TO PROVE THAT GORE'S ACCUSED PRODUCTS MEET THE TYPICALITY ELEMENT OF CLAIMS 20-27

Gore contends that it is entitled to JMOL on infringement because Plaintiffs purportedly have failed to demonstrate that the accused products satisfy the "average distance between nodes" requirement in each of the asserted claims. Gore's motion for JMOL is based on the assertion that the claim limitation of an "average distance between nodes" is required to be applied "to all of the ePTFE portions of the prosthetic device." This is contrary to the Court's express construction of the asserted claims as requiring ePTFE including but not limited to the microstructure recited in the claims.

The evidence established during trial establishes that a reasonable jury could find that each of Gore's accused products "includes" an ePTFE component that satisfies each of the claim limitations. For example, Gore's employee/expert witness on the accused stent-grafts, Dr. Vonesh, testified that each of the accused Gore stent-grafts includes an ePTFE component having

an average internodal distance within the claimed range. On the other hand, the only evidence Gore offered to rebut infringement of the "average distance between nodes" limitation at trial (and as evidence to support its JMOL now) is the testimony and measurements of Gore's expert Dr. McMillian. However, Dr. McMillin offered no testimony to contradict that the ePTFE base graft included in each of the accused products has a "typical" distance between nodes that fits within the claims.

Gore has failed to establish that a reasonable jury would not have a legally sufficient evidentiary basis to find for the Plaintiffs on this issue. Accordingly, Gore's Motion for JMOL as to Plaintiffs' failure to prove that Gore's accused products meet the typicality elements of claims 20-27 is denied.

V. GORE'S MOTION FOR JMOL THAT CLAIMS 20-27 ARE INVALID UNDER 35 U.S.C. § 102(B) FOR LACK OF NOVELTY IN VIEW OF THE 1973 MATSUMOTO SURGERY ARTICLE

Gore seeks JMOL regarding claims 20-27 of the '135 patent, claiming they lack novelty in view of the 1973 Matsumoto Surgery article.

If a single item of prior art discloses every element of a patent claim, that claim is "anticipated" and, hence, invalid under 35 U.S.C. § 102 for lack of novelty. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383 (Fed. Cir. 2001). The prior art reference must also "be sufficient to enable those skilled in the art or science to understand the nature and operation of the invention, and carry it into practice use." In re

Omeprazole Patent Lit., 483 F.3d 1364, 1379-80 (Fed. Cir. 2007) (internal citations omitted). Where the allegedly anticipatory prior art was expressly considered by the PTO, as is true here, the party challenging validity faces the "added burden . . . of overcoming the deference that is due to a qualified government agency presumed to have properly done its job." Am. Hoist, 725 F.2d at 1359.

The evidence establishes that the 1973 Matsumoto article was not enabling, as neither Gore nor any of the other doctors with whom Gore was working, could determine the structure disclosed in the Matsumoto article or replicate Matsumoto's results. In fact, at trial, Gore's fact witness, Mr. Detton, stated that "you couldn't figure anything" from the Matsumoto article "because the article itself did not define anything." Trial Tr., 11/27/08 at 1959:17 - 161:3 (Detton).

Gore has failed to establish that a reasonable jury would not have a legally sufficient evidentiary basis to find for the Plaintiffs on this issue. Accordingly, Gore's Motion for JMOL regarding lack of novelty in view of the 1973 Matsumoto Surgery article is denied.

VI. GORE'S MOTION FOR JMOL REGARDING PLAINTIFFS' CLAIM THAT PROPATEN INFRINGES THE '135 PATENT

Gore argues for JMOL with respect to its Propaten Vascular Grafts. Gore bases its Motion on the assertion that Plaintiffs' chief infringement expert witnesses, Dr. Anderson and Mr. Calcote, did not mention Propaten during their testimony and that Dr. Becker's testimony regarding Propaten was based on Gore's 510(k) notification. Thus, Gore contends that Plaintiffs

presented no proof of infringement regarding Gore's Propaten graft.

Though it is true that Dr. Becker testified about Gore's 510(k) notification, she also testified that Gore told the FDA that Propaten Vascular Grafts had the same physical structure and tissue ingrowth characteristics as the predicate Gore-Tex Vascular Graft (K830806), Gore-Tex Stretch Vascular Graft (K903931) and FEP Ringed Gore-Tex Stretch Vascular Graft with Removable Rings (K933943) already on the market. Dr. Becker's testimony is further confirmed by the evidence demonstrating (1) that the Propaten Vascular Grafts have an "average fibril length" that is within the claimed ranges of the '135 patent (see, e.g., PX1397.30; PX480.31; PX493.19); and (2) that the tissue ingrowth in the Propaten Vascular Grafts is the same as that observed in the underlying Gore-Tex Stretch Vascular Graft (see, e.g., PX1397.41).

In addition, there is sufficient factual evidence to support a finding that Gore's Propaten Vascular Grafts consists of an underlying Gore-Tex Stretch Vascular Graft (a product whose structure was discussed at length during the trial) with an added layer of bonded heparin molecules (see, e.g., PX1397.13). There is also evidence to show that the addition of heparin molecules has no effect on the underlying microstructure of the ePTFE graft (see, e.g., PX305.7). One cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device. Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1482 (Fed. Cir. 1984).

Gore has not established that a reasonable jury could not have found for Plaintiffs as to their claim that

Gore's Propaten Vascular Grafts infringe the '135 patent. Accordingly, Gore's Motion for JMOL on this issue is denied.

VII. GORE'S MOTION FOR JMOL REGARDING INVALIDITY FOR ANTICIPATION BY DR. NORTON'S DECEMBER 1971 USE IN "MRS. B"

Gore asserts that it is entitled to JMOL that claims 20-25 and 27 of the '135 patent are invalid for anticipation due to the implantation of a Gore-Tex vascular graft in a human patient, "Mrs. B" in December 1971. Gore bases its Motion on slides allegedly obtained from Dr. Lawrence Norton, that Gore argues show the graft after explantation.

To show invalidity by anticipation, "[e]very element of the claimed invention must be literally present, arranged as in the claim. The identical invention must be shown in as complete detail as is contained in the patent claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236 (Fed. Cir. 1989). Furthermore, when the anticipatory prior art being relied on is a "public use," such as here, the party asserting invalidity must prove both (1) a public use, and (2) that the "invention" in the public was "ready for patenting." Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1379 (Fed. Cir. 2005). The "ready for patenting" requirement "can be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." Pfaff v. Wells, 525 U.S. 55, 67-68 (1998). Again, where

the allegedly anticipatory prior art was expressly considered by the PTO, as is true here, the party challenging validity faces the "added burden . . . of overcoming the deference that is due to a qualified government agency presumed to have properly done its job." Am. Hoist, 725 F.2d at 1359.

Gore has not provided sufficient evidence to show that the Norton slides were actually implanted in Mrs. B. In fact, the evidence demonstrates significant questions about the origin of slides C196X and C196Y, including Dr. Norton's testimony during the interference, Mr. Lawrence Green's testimony, and considerable evidence that suggests that the slides may actually have been from animal testing. Gore has not overcome this evidence and, instead, seems to assume that the slides represent the graft implanted in Mrs. B.

Nor has Gore met its burden to show that Dr. Norton's work was anticipatory. In its Motion, Gore has not established, nor even discussed, the "ready for patenting" requirement to prove anticipation. In contrast, the evidence shows that Dr. Norton lacked appreciation of the critical elements of (i) fibril length and (ii) "a microstructure that permits tissue ingrowth," as claimed in the '135 patent. Thus, Dr. Norton's work was not "ready for patenting" and cannot constitute anticipatory prior use as a matter of law. Pfaff, 525 U.S. at 66.

Finally, a reasonable jury could find that Dr. Norton's work was experimental and, thus, not a public use. See TP Labs., Inc. v. Professional Positioners, Inc., 724 F.2d 965, 970 (Fed. Cir. 1984) (holding that "if a use is experimental, even though not secret, 'public use' is negated"). Dr. Norton testified that he "wasn't a

hundred percent sure that [the graft] would work" for Mrs. B but contemplated trying the Gore-Tex tube in Mrs. B based on his "experience in the laboratory" using the same material "as replacement for veins in animals." Trial Tr., 11/27/07, at 2074:20-2075:13. Plus, the Soyer et al., "A New Venous Prosthesis" article in Surgery in 1972, which discusses Dr. Norton's work and his implantation of an ePTFE graft in Mrs. B, describes the implantation in Mrs. B as having been conducted on an "experimental basis." DX3334.

The Court does not find that a reasonable jury would not have a legally sufficient evidentiary basis to find in favor of the Plaintiffs on this issue. Accordingly, Gore's Motion for JMOL is denied.

VIII. GORE'S MOTION FOR JMOL REGARDING INVALIDITY FOR IMPROPER INVENTORSHIP BECAUSE COOPER AND GOLDFARB ARE JOINT INVENTORS

Gore argues that it is entitled to JMOL for improper inventorship contending that Peter Cooper and Dr. Goldfarb were co-inventors. Gore previously argued to the PTO and the Federal Circuit that Dr. Goldfarb's work should "inure" to Peter Cooper's credit. However, both the PTO and the Federal Circuit found that Dr. Goldfarb's work did not inure to Mr. Cooper or Gore's credit. Further, the Federal Circuit found that Mr. Cooper: (1) had not conceived of the invention at the time he sent ePTFE tubes to Dr. Goldfarb, and (2) never communicated a conception or any information regarding fibril lengths to Dr. Goldfarb.

To establish its claim of joint inventorship, Gore must prove by clear and convincing evidence that Mr.

Cooper "contribute[d] in some significant manner to the conception or reduction to practice of the invention." 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 applied in practice." Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Joint inventorship can only arise when "collaboration or concerted effort occurs, that is, 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).

Thus, the test for joint inventorship requires more of a showing of concerted effort between co-inventors than is required to meet the test for inurement. However, despite this standard, Gore failed to present sufficient evidence to show that a reasonable jury could not have found the patent valid notwithstanding Gore's claims of improper inventorship. Gore has not established that a reasonable jury could have found that Mr. Cooper was not a co-inventor of the '135 patent. Accordingly, Gore's Motion for JMOL on this issue is denied.

IX. GORE'S JMOL MOTION REGARDING PLAINTIFFS' LACK OF STANDING

Gore's JMOL Motion Regarding Standing alleges that the Plaintiffs, Dr. David Goldfarb, and Bard Peripheral Vascular, Inc., ("BPV"), lack standing to sue for infringement of the '135 Patent. Gore contends that there is a document in evidence from 1980 in which Dr. Goldfarb granted an exclusive license of the '135 patent application to USCI Surgical Products Division, C.R.

Bard, Inc. ("USCI"), a division of C.R. Bard. There also is a 1997 amendment that refers to a written assignment and transfer of the 1980 exclusive license from USCI or C.R. Bard to Impra, which later became BPV. However, the written assignment referred to in the 1997 amendment is not in evidence, nor did Plaintiffs produce such a document during discovery. Gore asserts that without such a written instrument in evidence transferring the 1980 exclusive license from USCI/C.R. Bard to Impra/BPV, the transfer is invalid and Plaintiffs lack standing in this lawsuit.

A. BACKGROUND

The evidence demonstrates that on October 24, 1974, Dr. Goldfarb filed a patent application involving the subject matter of the '135 patent. The '135 patent issued in Dr. Goldfarb's name on August 20, 2002. At the time this suit was filed, Dr. Goldfarb was the owner of the '135 patent.

On September 23, 1980, Dr. Goldfarb and USCI entered into a written license agreement pursuant to which Dr. Goldfarb granted USCI a "worldwide, exclusive license[], with the right to sublicense, to make, use, and sell products covered by [the Goldfarb Application]." PX4; Trial. Tr., 11/7/07, at 462:10-463:4 (Goldfarb). The 1980 license did not transfer all of Dr. Goldfarb's rights to USCI. For example, Dr. Goldfarb retained the right to share in any damages recovered from enforcement or licensing of the Goldfarb patent. PX4 § 5.3. Dr. Goldfarb also retained significant reversionary rights if C.R. Bard did not prosecute its rights. Id. at §§ 3.1-3.2. In addition, the exclusive license excluded a category of products ("heart valves") from its "subject matter." Id. at 1.1.

In September 1996, C.R. Bard acquired Impra. Trial Tr., 11/16/07, at 1635:20-22 (McDermott). At that time, USCI was no longer involved in the vascular graft business and it subsequently was sold. Id. at 1644:9-19 (McDermott). Following C.R. Bard's purchase of Impra, C.R. Bard's existing non-ePTFE vascular graft business (the Bard Vascular Systems Division) was merged into Impra. Id. at 1635:23-1636:9, 1639:24-1640:17 (McDermott).

Impra was the sole C.R. Bard division making and selling ePTFE grafts and, because of this, C.R. Bard transferred responsibility for the 1980 license to Impra. Id. at 1644:9-19 (McDermott.) Dr. Goldfarb, C.R. Bard, and Impra confirmed the transfer of the license to Impra in the written February 2, 1997 "Agreement Amending License Agreement." PX191. Pursuant to the 1997 amendment, Impra assumed all of USCI's rights and obligations under the 1980 license agreement including the payment of all royalties to Dr. Goldfarb. Trial Tr., 11/16/07, at 1644:20-1645:7 (McDermott). In addition, the 1997 amendment also added new terms to the agreement including replacing "[a]ll references" to Bard's division (USCI) in the 1980 License with Impra/BPV, removing the subject matter exclusion regarding heart valves, and changing the assignment clause to expressly provide Impra the right to "assign . . . to any affiliate or division of C.R. Bard, Inc. . . ." PX191.

The '135 patent issued on August 20, 2002. Dr. Goldfarb, as the patentee, and BPV ("Impra" at that time), filed suit as co-plaintiffs in 2003. On January 30, 2007, BPV (Impra's successor) and Dr. Goldfarb entered into an Assignment of Patent Rights

Agreement. Pursuant to this agreement, BPV acquired "all rights, title and interest in and to the [Goldfarb patent]" including the right to "sue and collect damages for violations of the [Goldfarb patent]," regardless of whether the violations occurred prior to or after the execution date of this Agreement." PX1476.

B. DISCUSSION

Gore contends that Dr. Goldfarb lacked standing to bring the instant lawsuit because, Gore asserts, Dr. Goldfarb assigned the right to enforce the '135 patent to C.R. Bard as part of the exclusive license given to C.R. Bard. Gore argues that Dr. Goldfarb retained only naked title to the '135 patent, and "cannot maintain suit in his own name." Thus, Gore asserts, Dr. Goldfarb acting without C.R. Bard, who Gore contends remained the exclusive licensee at the time of filing suit, lacked standing to sue. However, the 1980 license did not transfer all of Dr. Goldfarb's rights to the '135 patent. For example, Dr. Goldfarb retained the right to share in any damages recovered from enforcement or licensing of the Goldfarb patent. PX4 § 5.3. Dr. Goldfarb also retained significant reversionary rights if C.R. Bard did not prosecute its rights. Id. at §§ 3.1-3.2. In addition, the exclusive license excluded a category of products (heart valves) from its subject matter. Id. at 1.1. Moreover, as discussed below, C.R. Bard transferred its exclusive license to Impra/BPV. Therefore, Dr. Goldfarb, in conjunction with Impra/BPV, had standing to enforce the patent.

The Patent Act provides that a patentee has a remedy for patent infringement by civil action. 35 U.S.C. § 281. "This has been interpreted to require that a suit for infringement must ordinarily be brought by

a party holding legal title to the patent." Enzo APA & Son, Inc. v. Geapag A.G., 134 F.3d 1091, 1093 (Fed. Cir. 1998). Yet, in Rite-Hite Corp. v. Kelly Co., Inc., 56 F.3d 1538, 1552 (Fed. Cir.1995), the Federal Circuit held as follows:

> Under certain circumstances, a licensee may possess sufficient interest in the patent to have standing to sue as a co-plaintiff with the patentee. Such a licensee is usually an 'exclusive licensee.' To be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory as well. If the party has not received an express or implied promise of exclusivity under the patent, *i.e.*, the right to exclude others from making, using, or selling the patented invention, the party has a 'bare license,' and has received only the patentee's promise that party will not be sued for infringement.

An exclusive license need not be in writing. A license may be written, oral, or implied-in-fact. Waymark Corp. v. Porta Sys. Corp., 334 F.3d 1358, 1364 (Fed. Cir. 2003) (stating as follows:

> Only assignments need be in writing under 35 U.S.C. § 261. Licenses may be oral. Waymark allegedly had an oral license from [a member of the partnership]. It is true that only in extremely limited circumstances can the holder of an oral transfer of patent rights sue for infringement in its own name. However, the

> partnership claimed a written assignment of the patent. *Under such circumstances, the partnership had standing to bring the action, and it was permissible to join Waymark as a plaintiff under the alleged oral exclusive license.*

(emphasis added) (citations omitted)).

Here, as in Waymark, the alleged 1996 transfer to Impra/BPV of the 1980 license, created at least an implied-in-fact transfer of the license to Impra/BPV thereby conferring standing to sue in conjunction with Dr. Goldfarb. This implied-in-fact transfer was done in conjunction with Bard's acquisition of Impra/BPV, whereby Impra/BPV assumed all rights and responsibilities for the license including the right to sue to enforce the patent, provided it joined Dr. Goldfarb, the patent title holder at the time. In further support of an implied-in-fact transfer of the exclusive agreement is the testimony of then-president of Impra, John McDermott, that pursuant to the transfer, Impra assumed the obligation to pay Dr. Goldfarb royalties as his licensee. Trial Tr., 11/16/07, at 1644:20-1645:10 (McDermott).

Gore argues that any oral or implied-in-fact license to BPV is, at most, a non-exclusive license that does not confer standing. Gore theorizes that C.R. Bard had a written exclusive license that amounted to a transfer of title because of the limited rights that Dr. Goldfarb retained. Therefore, Gore contends, any transfer of C.R. Bard's rights would be an assignment of title, which requires a writing.

Contrary to Gore's argument, Dr. Goldfarb retained substantial rights in the 1980 agreement including,

inter alia, the right to share in any patent damages or license fees. Thus, the 1980 agreement granted an exclusive license, not title, to USCI/C.R. Bard. C.R. Bard was free to orally transfer its exclusive license to BPV, thereby conveying standing to enforce the patent with Dr. Goldfarb. See Waymark, 334 F.3d at 1364 (an oral licensee could properly join patent suit by partnering with holder of written assignment of patent); Kalman v. The Berlyn Corp, 914 F.2d 1473, 1482 (Fed. Cir. 1991) (a licensee had standing to sue along with the patentee because the parties had stipulated to the existence of a license); Weinar v. Rollform, Inc., 744 F.2d 797, 807 (Fed. Cir. 1984) (an oral exclusive distribution agreement was sufficient to create standing to sue for patent infringement).

In its Motion, Gore relies on Enzo APA & Son v. Geapag A.G., 134 F.3d at 1093, to assert that "[a]n oral assignment of the exclusive license is ineffective." (Gore Mot. at 2.) Enzo, however, addressed the more narrow question of whether an oral exclusive licensee had standing to enforce a patent in its own name where it failed to join the patentee and subsequently received a *nunc pro tunc* assignment. Id. at 1092. The Federal Circuit rejected this claim and, reiterating well-established precedent, held that an exclusive licensee may only file suit in its own name where it is the actual or "virtual assignee" of the patent, which requires written evidence of such an assignment. Id. at 1093. The instant case is distinguishable from Enzo for a number of reasons. Here, Dr. Goldfarb, the patent holder, is a party to the lawsuit. In addition, Dr. Goldfarb retained substantial rights to his patent application. Finally, by at least 1997, there is a writing

transferring the exclusive license from C.R. Bard to BPV.

Plaintiffs claim that the 1997 amendment, which is in evidence, not only confirms the earlier agreement but serves as a new agreement because it added additional terms. Gore, on the other hand, asserts that the 1997 amendment is insufficient to create standing because (1) it was not executed by C.R. Bard or USCI (the 1980 exclusive licensee) and (2) because it did not assign the 1980 exclusive license, but merely conformed the alleged 1996 assignment for which there is nothing in the record to support.

Gore's argument that the 1997 amendment was not executed by C.R. Bard focuses on Mr. McDermott's testimony in which he acknowledged that he had signed the 1997 agreement "on behalf of" Impra/BPV. However, Mr. McDermott also testified that he signed on behalf of C.R. Bard with its express consent.

> Q. Now, did you get approval from your management at C.R. Bard, the owners of Impra, to enter into this agreement [PX191] on their behalf?
>
> A. Yes, yeah.

Trial Tr., 11/16/2007, at 1647:2-5 (McDermott).[1]

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[1] The Court recognizes that Mr. McDermott testified on direct examination that he had express consent from C.R. Bard to enter into the 1997 agreement and then later on cross-examination stated that he signed the agreement as the president of Impra. See Trial Tr., 11/16/2007, at 1647:2-5, 1690:19-20 (McDermott). However, the Court does not find that Mr. McDermott's statement that he signed the agreement as the President of Impra negates

In support of Gore's second argument that the 1997 assignment merely confirmed the alleged 1996 assignment, Gore filed a Notice of New Authority Relating to Plaintiffs' Lack of Standing (Doc. 825). In Gore's Notice, Gore asserts that the recent Federal Circuit decision in Mars, Inc. v. Coin Acceptors, Inc., 527 F.3d 1359 (Fed. Cir. 2008), "reaffirms Gore's position that the Amendment to the license does not give BPV standing to sue" because in Mars the Federal Circuit held that a later amendment to a license "confirming" an alleged prior transfer is merely a "confirmation" and does not serve to transfer the license. Plaintiffs filed an "Objection to Gore's . . . [Allegedly] New Authority Related to Plaintiffs' Lack of Standing" (Doc. 827). Gore filed a Response to Plaintiffs' Objection to Gore's Notice (Doc. 829) and Plaintiffs filed a Reply (Doc. 832).

In Mars, Mars owned the patent-in-suit when the complaint was filed in 1990 and undisputedly had standing. Mars, 527 F.3d at 1363. Mars entered into an agreement transferring "its entire interest in the Covered Intellectual Property that relates to the business of the parties" to a wholly-owned subsidiary, Mars Electronics Inc., ("MEI"), in a 1996 agreement. Id. The Federal Circuit ruled that the 1996 agreement operated to transfer title in the patent-in-suit from Mars to MEI such that "Mars lacked standing as of 1996." Id. at 1370. In 2006, Mars entered into a purchase agreement with its subsidiary in which Mars purported to reacquire title to the patent-in-suit to correct the jurisdiction defect created in 1996. Id. The

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his statement that he had C.R. Bard's consent to enter into the agreement.

purchase agreement was not made part of the record. Id. at 1364. Instead, Mars relied on a later dated "Confirmation Agreement" to establish the transfer of title. Id. The Confirmation Agreement stated as follows:

> Mars and the Buyer [MEI] do hereby acknowledge that Mars owns and retains the right to sue for past infringement of the Litigation Patents. To the extent that MEI may have or claim any rights in or to any past infringement of the Litigation Patents or any recovery therefor, upon the terms and subject to the conditions of the Purchase Agreement, MEI hereby does irrevocably assign all such rights to Mars.

Id. at 1371. The Federal Circuit found this language insufficient to transfer title back to Mars and correct the jurisdictional defect. Id. at 1369. It held that the first sentence of the above paragraph was not "a transfer itself." Id. at 1371. It also determined that although the second sentence did constitute a transfer, the language was insufficient to confer standing because it was "an assignment of the right to sue for past infringement, not an assignment of title." Id. at 1371-72. ("We see no provision in the Confirmation Agreement that transfers title to the [patent-in-suit] back to Mars.").

Mars is distinguishable from the instant case. Here, the 1997 written Agreement Amending License Agreement was not merely "confirmatory" as Gore contends. Rather, the 1997 Agreement created a new license agreement between Dr. Goldfarb and

Impra/BPV. The terms of the 1980 License that were amended by the 1997 Agreement include the following:

- Replacing "[a]ll references" to Bard's division (USCI) in the 1980 License with Impra/BPV;
- Removing the subject matter exclusion regarding heart valves;
- Changing the assignment clause to expressly provide Impra the right to "assign . . . to any affiliate or division of C.R. Bard, Inc. . . ."

Thus, unlike Mars where the Confirmation Agreement merely "acknowledged" that Mars owned the patents, here, the 1997 Agreement expressly transferred in writing the rights from C.R. Bard to Impra/BPV and actually enhanced those rights by granting additional rights to Impra/BPV that Dr. Goldfarb had previously retained. Moreover, also distinguishable from Mars, here, the owner of the patent title – Dr. Goldfarb – was a plaintiff at the commencement of the lawsuit and has remained a plaintiff throughout the entire litigation.

Gore has not established that Plaintiffs lack standing. Accordingly, Gore's Motion for JMOL Regarding Plaintiffs' Lack of Standing is denied.

CONCLUSION

For the foregoing reasons,

IT IS ORDERED denying Gore's Motion for JMOL Regarding Plaintiffs' Claim of Willful Infringement (Doc. 651).

IT IS FURTHER ORDERED denying Gore's Motion for JMOL Regarding Invalidity of the '135 Patent for Failure to Disclose Best Mode (Doc. 731).

IT IS FURTHER ORDERED denying Gore's Motion for JMOL that Claims 20-27 are Invalid for Failure to Satisfy the Written Description Requirement of 35 U.S.C. § 112, ¶ 1 (Doc. 732).

IT IS FURTHER ORDERED denying Gore's Motion for JMOL Regarding Plaintiffs' Failure to Prove that Gore's Accused Products Meet the Typicality Element of Claims 20-27 (Doc. 734).

IT IS FURTHER ORDERED denying Gore's Motion for JMOL that Claims 20-27 are Invalid under 35 U.S.C. § 102(B) for Lack of Novelty in View of the 1973 Matsumoto Surgery Article (Doc. 736).

IT IS FURTHER ORDERED denying Gore's Motion for JMOL Regarding Plaintiffs' Claim that Propaten Infringes the '135 Patent (Doc. 737).

IT IS FURTHER ORDERED denying Gore's Motion for JMOL Regarding Invalidity for Anticipation by Dr. Norton's December 1971 Use in "Mrs. B" (Doc. 740).

IT IS FURTHER ORDERED denying Gore's Motion for JMOL Regarding Invalidity for Improper Inventorship Because Cooper and Goldfarb are Joint Inventors (Doc. 741).

IT IS FURTHER ORDERED denying Gore Motion for JMOL Regarding Plaintiffs' Lack of Standing (Doc. 652).

DATED this 29th day of July, 2008.

/s/
Mary H. Murguia
United States District Judge

APPENDIX G

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2014-1114

[Filed April 8, 2015]

BARD PERIPHERAL VASCULAR, INC., DAVID GOLDFARB, M.D.,
Plaintiffs-Appellees,

C.R. BARD, INC.,
Counterclaim Defendant-Appellee,

v.

W.L. GORE & ASSOCIATES, INC.,
Defendant-Appellant.

Appeal from the United States District Court for the District of Arizona in No. 2:03-cv-00597-MHM, Judge Mary H. Murguia.

ON PETITION FOR REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, CHEN, and HUGHES, *Circuit Judges*.[*]

PER CURIAM.

O R D E R

Appellant W. L. Gore & Associates, Inc. filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by appellees Bard Peripheral Vascular, Inc., C.R. Bard, Inc., and David Goldfarb, M.D. The petition was first referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on April 15, 2015.

FOR THE COURT

April 8, 2015
Date

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

[*] Circuit Judge Taranto did not participate.

APPENDIX H

35 U.S.C. § 100

§ 100 Definitions

When used in this title unless the context otherwise indicates--

(a) The term "invention" means invention or discovery.

(b) The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

(c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.

(d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.

(e) The term "third-party requester" means a person requesting ex parte reexamination under section 302 who is not the patent owner.

(f) The term "inventor" means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.

(g) The terms "joint inventor" and "coinventor" mean any 1 of the individuals who invented or discovered the subject matter of a joint invention.

(h) The term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by 2 or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

(i)(1) The term "effective filing date" for a claimed invention in a patent or application for patent means--

(A) if subparagraph (B) does not apply, the actual filing date of the patent or the application for the patent containing a claim to the invention; or

(B) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority under section 119, 365(a), 365(b), 386(a), or 386(b) or to the benefit of an earlier filing date under section 120, 121, 365(c), or 386(c).

(2) The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought.

(j) The term "claimed invention" means the subject matter defined by a claim in a patent or an application for a patent.

35 U.S.C. § 261

§ 261. Ownership; assignment

Subject to the provisions of this title, patents shall have the attributes of personal property. The Patent and Trademark Office shall maintain a register of interests in patents and applications for patents and shall record any document related thereto upon request, and may require a fee therefor.

Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.

A certificate of acknowledgment under the hand and official seal of a person authorized to administer oaths within the United States, or, in a foreign country, of a diplomatic or consular officer of the United States or an officer authorized to administer oaths whose authority is proved by a certificate of a diplomatic or consular officer of the United States, or apostille of an official designated by a foreign country which, by treaty or convention, accords like effect to apostilles of designated officials in the United States, shall be prima facie evidence of the execution of an assignment, grant or conveyance of a patent or application for patent.

An interest that constitutes an assignment, grant or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or

prior to the date of such subsequent purchase or mortgage.

35 U.S.C. § 281

§ 281. Remedy for infringement of patent

A patentee shall have remedy by civil action for infringement of his patent.

APPENDIX I

LICENSE

This Agreement made this 23rd day of September, 1980 ("EFFECTIVE DATE") by and between David Goldfarb, M.D. 421 18th St., Suite 115, Phoenix, AZ 85006 ("DR. GOLDFARB") and USCI Surgical Products Division, C. R. Bard, Inc. a corporation of New Jersey, having offices at Concord Road, Box 566, Billerica, Massachusetts 01821 ("USCI").

WITNESSETH

WHEREAS, DR. GOLDFARB represents to USCI that he is the inventor of certain inventions relating to vascular prostheses made from polytetrafluorethylene ("PTFE") that has been expanded; and

WHEREAS, DR. GOLDFARB wishes to have such inventions commercialized and has offered to grant USCI exclusive, worldwide licenses under any patents that issue based on such inventions as now exist or as he may make or own, except heart valves derived from cooperative research with Shiley Scientific, Inc. (HEART VALVES); and

WHEREAS, USCI has for many years made and sold vascular prostheses other than those made from PTFE and wishes to become licensed under such patents on the terms and subject to the conditions provided below.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the Parties hereto hereby agree as follows:

SECTION ONE

LICENSE

1.1 Subject Matter. This Agreement relates to prostheses for replacing, repairing or bypassing blood vessels of the human body except HEART VALVES ("VASCULAR PROSTHESES"). DR. GOLDFARB's inventions relate to VASCULAR PROSTHESES made from PTFE that has been pasteformed and stretched into a strong, porous shape ("EXPANDED PTFE"). The term "EXPANDED PTFE" will be understood to include use of PTFE alone or with other materials. VASCULAR PROSTHESES made from EXPANDED PTFE are referred to herein as "PTFE GRAFTS".

1.2 Inventions and IMPROVEMENTS. DR. GOLDFARB reresents that he is the owner of the entire, right, title and interest in and to the inventions that are disclosed and claimed in the patent applications listed in Exhibit A, which is a part of this Agreement, and to those inventions that are identified in Exhibit A but that are not the subject of a patent application listed therein ("INVENTIONS"). DR. GOLDFARB contemplates performing additional research such that after the EFFECTIVE DATE he may make or own inventions that are betterments to or improvements upon PTFE GRAFTS ("IMPROVEMENTS").

1.3 PATENTS. Letters Patent issued by any country of the world based on INVENTIONS or IMPROVEMENTS are subject to this Agreement and are referred to as "PATENTS".

1.4 Grant. DR. GOLDFARB hereby grants to USCI worldwide, exclusive licenses, with the right to sublicense, to make, use and sell products covered by PATENTS except HEART VALVES. USCI shall promptly furnish DR. GOLDFARB with a true copy of any sublicense made by USCI.

SECTION TWO

ROYALTIES

2.1 5% Rate. A product sold to a customer in a country where a PATENT has been granted will be referred to herein as "LICENSED PRODUCT" if that product is covered by at least one claim of that PATENT. When USCI or its sublicensee sells LICENSED PRODUCT in that country, running royalty will accrue in DR. GOLDFARB's favor at the rate of 5% of the "NET SELLING PRICE" (as defined below) of the LICENSED PRODUCT. However, if a court of competent jurisdiction has rendered decision (from which no appeal has or can be taken) that some claims of the PATENT are invalid and if no other valid claims of the PATENT cover the LICENSED PRODUCT, then from the date of the decision the running royalty at the above rate will no longer accrue when the LICENSED PRODUCT is sold in that country.

2.2 2.5% Rate. PTFE GRAFT sold to a customer in a country where a PATENT has not issued or where an issued PATENT has been declared invalid will be

referred to herein as a "ROYALTY BEARING PRODUCT". When USCI or its sublicensee sells a "ROYALTY BEARING PRODUCT" in that country before or during the "PERIOD" defined below, a running royalty will accrue in DR. GOLDPARB's favor at the rate of 2.5% of the NET SELLING PRICE (as defined below) of the ROYALTY BEARING PRODUCT. The "PERIOD" extends for a term of 5 years from the date on which the Federal Food and Drug Administration ("FDA") notifies USCI that it may sell PTFE GRAFTS commercially.

2.3 NET SELLING PRICE. The term "NET SELLING PRICE" means the invoiced selling price of a product sold to a third party customer, less the following deductions: excise and sales taxes, quantity and cash discounts, freight and handling charges and allowances for returns. In the event that a LICENSED PRODUCT or a ROYALTY BEARING PRODUCT is sold in a kit or in combination with other products that are not LICENSED PRODUCTS or ROYALTY BEARING PRODUCTS and the kit or combination has a composite invoiced selling price, then for royalty purposes the NET SELLING PRICE shall be the NET SELLING PRICE of products similar to said LICENSED PRODUCT or ROYALTY-BEARING PRODUCT that are sold individually at generally the same time as the kit or combination. USCI warrants that it will have no affiliates that will be an end user of LICENSED PRODUCTS or ROYALTY BEARING PRODUCTS.

2.4 Minimum Royalties. Subject to the following conditions, USCI shall have the following minimum royalty obligations:

a) Obligations. When the PERIOD starts, minimum royalty will become payable on a calendar year basis. The minimum royalty will be payable during the entire PERIOD, except as provided in b) below. If a U.S. PATENT exists and has not been held invalid, the minimum royalty will be 12,000 U.S. Dollars for any such full calendar year or a pro rata portion thereof for a partial calendar year. Before the U.S. PATENT issues, or after same has been held invalid, the minimum royalty will 6,000 U.S. Dollars for any such full calendar year or a prorata portion thereof for a partial calendar year.

b) Conditions. If at any time during the PERIOD USCI is prevented from making or selling PTFE GRAFTS, whether by a court order from which no appeal has or can be taken or by government regulation, no minimum royalty shall be payable unless and until USCI again has the right to make and sell PTFE GRAFTS, and in that event the appropriate minimum royalty shall be payable for the remainder of a full five years.

2.5 Records and Royalties. Settlement of the accrued running royalties is to be made on a calendar quarter basis, with payments to be made to DR. GOLDFARB within two (2) months following each quarter. Each payment is to be accompanied by a report for the quarter. Before any PATENTS issue, the report shall state the price, type and number of ROYALTY BEARING PRODUCTS sold by USCI or its sublicensees,

> the total NET SELLING PRICE of same and a computation of the accrued running royalties. After a PATENT issues, the report shall also state the number and NET SELLING PRICE of LICENSED PRODUCTS sold by USCI and its sublicensees in the country of sale that corresponds to the country that granted the PATENT and a computation of the accrued running royalties.

Each report for a fourth calendar quarter shall indicate whether the PERIOD existed during the prior calendar year. If so, the report shall state the applicable minimum royalty pro rated over the calendar year according to when the PERIOD started and when any U.S. PATENT was effective. If the running royalties that accrued for the prior calendar year equal or exceed the computed minimum royalty, then USCI shall pay to DR. GOLDFARB the balance of the accrued royalties less any applicable deductions.

If the computed minimum royalty exceeds the accrued running royalty for the calendar year, then the excess, less any applicable deductions, shall be paid to DR. GOLDFARB.

USCI will keep complete records concerning its sale of LICENSED PRODUCTS and ROYALTY BEARING PRODUCTS and shall require same to be kept by its sublicensees. During the one (1) year period following the date of any given report and payment, DR. GOLDFARB may initiate inspection and audit of such records through a qualified representative of its own selection. Such representative shall promptly complete such inspection and audit, shall keep information concerning such records in confidence, except to the

extent necessary to enforce rights under this Agreement, and shall report to DR. GOLDFARB only whether a given royalty report is correct and if not, the corrected information.

SECTION THREE

OBTAINING PATENTS

3.1 IMPROVEMENTS. DR. GOLDFARB shall disclose to USCI all IMPROVEMENTS except HEART VALVES promptly after he invents or owns same and shall take all such steps as USCI reasonably requests in respect to assisting USCI to obtain PATENTS based thereon.

USCI shall at its own cost and expense have counsel of its own selection prepare and file applications to obtain PATENTS based on IMPROVEMENTS in such countries as USCI in its sole discretion elects. In the event that USCI elects not to file such an application in any of the countries listed in Exhibit B, which is part of this Agreement, based on a patentable IMPROVEMENT, then it shall notify DR. GOLDFARB thereof at least 3 months before the date of any statutory bar (under U.S. law) known to USCI at the time it makes such election. DR. GOLDFARB shall have the right to request USCI to file such application in any such country, provided that he shall reimburse USCI for its actual costs incurred to prepare and prosecute same and to maintain the resulting PATENT.

3.2 Prosecuting Patent Applications. USCI shall in its sole discretion but in good faith and at its own cost and expense:

(a) control the prosecution of all patent applications that may result in PATENTS and

(b) maintain PATENTS.

In performing such obligations USCI shall have the right in its sole discretion to select counsel and to elect to abandon any patent application, provided however, that USCI gives DR. GOLDFARB reasonable prior notice of its intention to effect such abandonment. In the event that USCI makes such election, DR. GOLDFARB shall have the right at his sole cost and expense to elect to continue the prosecution or to allow the application to become abandoned. If Dr. GOLDFARB continues the prosecution, any patent so obtained shall not be subject to this LICENSE.

USCI shall keep DR. GOLDFARB informed of all communications received from and sent to the various patent offices in respect to the prosecution of such applications. DR. GOLDFARB acknowledges that his assistance is essential to the successful prosecution of such applications. DR. GOLDFARB agrees that at USCI's request made upon prior notice that does not unreasonably interfere with DR. GOLDFARB's medical schedule, he shall conduct or direct such studies and research as is reasonably necessary to advise USCI's counsel in respect to prosecution of the applications, including identifying the critical aspects of INVENTIONS and IMPROVEMENTS, provided however, that USCI reimburses DR. GOLDFARB for the reasonable and actual out-of-pocket expenses that he incurs in performing such studies and research upon submission of appropriate vouchers evidencing such expeditures, to include without limitation thereto,

necessary personnel, consumable supplies, animal care and transport, laboratory studies, photography, manuscript and publication costs, capital equipment and facility usage costs and usual overhead items. The protocol and costs for such studies and research shall have prior joint approval of USCI and DR. GOLDFARB.

SECTION FOUR

MEDICAL SUPPORT

4.1 General. DR. GOLDFARB agrees that at USCI's request made by reasonable advance notice and according to schedules that do not conflict with his medical practice he will assist USCI in providing the following professional presentations concerning ROYALTY BEARING PRODUCTS and LICENSED PRODUCTS:

(a) to USCI's sales force,

(b) for medical journals and

(c) to the medical community,

USCI will reimburse DR. GOLDFARB for such reasonable out-of-pocket expenses as DR. GOLDFARB incurs in the performance of same for travel, lodging and meals. Upon presentation of receipts for the payment of such expenses USCI shall reimburse DR. GOLDFARB.

4.2 Review of USCI's Activities. At times convenient to DR. GOLDFARB and not fewer than two times per year, USCI shall review with DR. GOLDFARB at USCI's manufacturing facility or at such other location as designated by USCI,

the following of its activities relating to ROYALTY BEARING PRODUCTS and LICENSED PRODUCTS:

(a) design of products under development,

(b) manufacturing of products,

(c) control of product quality, and

(d) users' comments.

USCI shall at that time afford DR. GOLDFARB an opportunity to observe, comment on and make suggestion as to such activities.

SECTION FIVE

COVENANTS

5.1 Liability. It is understood that USCI shall be responsible for commercializing ROYALTY BEARING PRODUCTS and LICENSED PRODUCTS, including design, manufacture, and quality control.

USCI agrees to indemnify and hold harmless DR. GOLDFARB from and against any third party claim for alleged product liability with respect to LICENSED PRODUCTS or ROYALTY BEARING PRODUCTS sold by USCI, it being understood that such indemnity obligation shall not extend to any third party claim based upon any alleged medical malpractice.

To make a claim based on the provisions of this Paragraph 5.1, DR. GOLDFARB shall give prompt written notice to USCI of any claim which might give rise to said claim against USCI, stating the nature and basis of said claim and the amount thereof.

In the event that any action, suit or proceeding is brought against DR. GOLDFARB with respect to which USCI may have liability hereunder, then USCI, at its election, shall have the right to compromise or defend such asserted liability through counsel of its own choosing and expense, or may request that at USCI's expense the action, suit or proceeding be defended by DR. GOLDFARB, including all proceedings on appeal or for review which counsel for defendant shall deem appropriate. If USCI elects to have DR. GOLDFARB defend such action, suit or proceeding through counsel of DR. GOLDFARB's choice, USCI shall have the right to be represented by an advisory counsel and accountants, at its own expense, and USCI shall be kept fully informed of such action, suit or proceeding at all stages thereof whether or not it is so represented. The Parties hereto agree to render to each other such assistance as they may reasonably require of each other in order to ensure the proper and adequate defense of any such action, suit or proceeding. DR. GOLDFARB shall not make any settlement of any claims which might give rise to liability of USCI under this Paragraph 5.1 without the written consent of USCI, provided that such consent shall not be unreasonably withheld, unless USCI shall have failed or refused to defend such claim.

In the event that USCI shall pay to DR. GOLDFARB any sum by virtue of this indemnification proceeding, DR. GOLDFARB shall assign to USCI his claim, if any, against any third party whose claim gives rise to such indemnification.

5.2 Dominant Patent. In the event of a claim or action by a third party against USCI based on alleged

infringement of a patent ("DOMINANT PATENT") of the third party, arising out of USCI's manufacture or sale of LICENSED PRODUCTS, then USCI shall have the right to agree in good faith to accept a license under the DOMINANT PATENT from such third party, whether before or after an action for infringement is brought against USCI. USCI shall notify DR. GOLDFARB of the terms of such license. Except as limited below, any royalties paid or payable to such third party under such license may be deducted by USCI from the royalties payable to DR. GOLDFARB under this Agreement based on the sale of LICENSED PRODUCTS.

If such an action is commenced against USCI in respect to LICENSED PRODUCTS, USCI shall have the right to deduct up to one-half of the royalties that would otherwise be payable to DR. GOLDFARB based on LICENSED PRODUCTS and to use the deducted royalties to pay up to one-half of USCI's costs, and fees incurred in defending, and any damages awarded as a result of, such action. The royalty reduction shall continue to until same equals one-half of USCI's said costs, expenses and damages.

In no event shall USCI's deductions of royalties for those paid to a third party or for such infringement action under this paragraph 5.2 or for events under paragraph 5.3 or a combination of deductions authorized by paragraphs 5.2 and 5.3 result in a royalty rate of less than 2.5% payable to DR. GOLDFARB based on LICENSED PRODUCTS. Further, the minimum royalty shall be reduced from $12,000 by the same overall percentage as the 5%

royalty rate was so reduced by the deductions, but shall not be less than $6,000 per calendar year.

At USCI's request, DR. GOLDFARB shall render to USCI such assistance as is reasonably necessary to USCI's defense of any such infringement claim or suit, provided that USCI gives reasonable notice thereof and that such assistance does not unreasonably interfere with DR. GOLDFARB's medical practice.

5.3 Enforcement and Licensing of PATENTS. Subject to the following, USCI shall have the right in its sole discretion to file, control, defend and settle, by granting a sublicense or otherwise, all actions and claims against third parties for infringement of any PATENTS brought against DR. GOLDFARB or USCI seeking to declare a PATENT invalid. At USCI's request, DR. GOLDFARB shall render to USCI such assistance as is reasonably necessary to USCI's prosecution or defense of such action and claims. USCI shall pay all costs, expenses and fees incurred as result of said claim or action (hereinafter referred to as "LITIGATION COSTS"). However, USCI shall have the right to deduct up to one-half of the royalties that would otherwise be payable to DR. GOLDFARB based on LICENSED PRODUCTS and to use the deducted royalties to pay up to one half of USCI's costs, expenses, and fees incurred in defending, and any damages awarded against DR. GOLDFARB or USCI as a result of, such action. The royalty reduction shall continue until same equals one-half of USCI's said costs, expenses and damages.

In the event that such action or claim by USCI is successful and USCI recovers damages or royalties based on past infringement, USCI and DR.

GOLDFARB shall share said damages and royalties according to the proportion of USCI's LITIGATION COSTS that were borne by each Party.

In the event that USCI grants to the third party a sublicense, then USCI shall pay to DR. GOLDFARB royalty of 5% of the NET SELLING PRICE of such products as are sold by the third party and as are LICENSED PRODUCTS under the sublicensed PATENT. However, if USCI makes good faith, but unsuccessful, effort to grant a sublicense at a royalty rate in excess of 5%, but is successful in granting the sublicense at a rate of 5% or less, then USCI shall pay to DR. GOLDFARB a royalty of one-half of the rate agreed to by USCI and the third party.

As a further exception to the above 5% sublicense royalty rate obligation, in the event that USCI grants a sublicense as a part of a settlement of a claim or suit brought by a third party based on USCI's alleged infringement of a DOMINANT PATENT, then any royalties paid by the third party to USCI under a PATENT shall be divided equally by USCI and DR. GOLDFARB.

5.4 Right of First Refusal. It is understood that DR. GOLDFARB hereafter may make or own inventions that are or can be embodied in products or processes and that relate to the diagnosis, treatment, surgical repair or mitigation of conditions or diseases of the heart or vasculature except HEART VALVES. Such products and processes, other than INVENTIONS and IMPROVEMENTS, will be referred to as "CARDIOVASCULAR PRODUCTS".

DR. GOLDFARB hereby grants to USCI the following right of first refusal with respect to CARDIOVASCULAR PRODUCTS. If DR. GOLDFARB makes, owns or controls any CARDIOVASCULAR PRODUCTS during the term of this Agreement and desires to sell or license the rights to same or to otherwise commercialize same, he shall disclose the CARDIOVASCULAR PRODUCTS to USCI subject to the terms of Exhibit C. He shall also advise USCI of the terms under which he is willing to sell, license or commercialize the CARDIOVASCULAR PRODUCTS. USCI shall have ninety days from the date of its receipt of the disclosure and terms in which to advise DR. GOLDFARB of its interest or lack of interest in the CARDIOVASCULAR PRODUCTS. In the event that USCI is interested then during the next sixty days the Parties' shall negotiate in good faith to reach agreement on the terms of sale, license or commercialization. In the event that no agreement is reached in the sixty day period or USCI is initially not interested in the CARDIOVASCULAR PRODUCTS, then DR. GOLDFARB shall have the right to offer the given CARDIOVASCULAR PRODUCTS to any third party and shall have no further obligation to USCI in respect thereto.

5.5 Confidential Relationship. USCI agrees to receive from DR. GOLDFARB and to keep disclosures of NEW PRODUCTS according to the requirements of Exhibit C, which is part of this Agreement.

DR. GOLDFARB agrees that all such information as he receives from or on behalf of USCI and as relates to the development, manufacture, patenting, sale or marketing of USCI's PTFE GRAFTS shall be received

and kept subject to the terms of Exhibit C. Without limiting the generality of the above, such information shall include USCI's royalty reports, patent applications relating to INVENTIONS or IMPROVEMENTS, disclosures of IMPROVEMENTS and USCI's activities disclosed under Pagraph 4.2.

SECTION SIX

GENERAL TERMS

6.1 Term. This Agreement shall commence on the EFFECTIVE DATE and shall extend thereafter until the expiration of the last PATENT to expire, or termination as herein provided, whereupon this Agreement shall automatically terminate except as follows. In the event that upon said expiration there exists pending patent application covering an INVENTION or an IMPROVEMENT that should be or has been disclosed to USCI by DR. GOLDFARB under this Agreement, then this Agreement shall continue until there is no longer in existence any such patent application or live PATENT or IMPROVEMENT that USCI has elected to make the subject of patent application whereupon this Agreement shall automatically terminate.

6.2 Notices. All notices of a material nature and payments required or permitted to be given hereunder shall be in writing and shall be deemed to be properly given and served when delivered in person to the receiving Party or sent by certified or registered air mail, postage and certification or registration prepaid, and properly addressed to the appropriate Party at the following address, unless such address is changed by prior notice in writing:

TO USCI	TO DR. GOLDFARB
C. R. BARD, INC. 731 Central Avenue Murray Hill, NJ 07974 Attn: General Counsel	Dr. David Goldfarb 421 N. 18th St., Suite 115 Phoenix, AZ 85006

6.3 Force Majeure. Any delays in, or failure by any Party hereto in the performance of any obligations hereunder shall be excused if and to the extent that the delay or failure is caused by unavailability of materials, material lead times, riot, strike, lockout, fire or other causes, whether similar or dissimilar to those hereinabove specified, which cannot reasonably be controlled by said Party; provided, however, that said Party gives to the other Party hereto prompt written notice of said act and the reasonably full particulars concerning such act. In the event that said delay or failure is excused under the provisions of this Paragraph 6.3, the said Party's obligations hereunder that were so excused shall remain excused during, but no longer than, the continuance of the act on which said excuse was based. The said excused Party shall use all possible diligence to remove the said act, but in the case of strikes or other labor disturbances shall not be required to settle same on terms contrary to its wishes.

6.4 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and shall not be assignable by either Party, except that USCI may assign same to any successor to or purchaser of all or substantially all of its VASCULAR PROSTHESIS business.

6.5 Controlling Law. This Agreement and the performance, rights and obligations of the Parties thereunder shall be governed and interpreted in accordance with the laws of the State of New Jersey and of the United States of America and any disputes between the Parties in respect to this License Agreement shall be decided by the competent courts in the State of New Jersey.

6.6 Amendment. This Agreement may be amended, modified, superceded or cancelled, and any of the terms, covenants, representations, warranties or conditions hereof may be waived, only by a written instrument executed by DR. GOLDFARB and BARD, or, in the case of a waiver, by the Party waiving compliance. The failure of any Party at any time or times to request the performance of any provision hereof shall in no manner affect the right at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term, covenant, representation or warranty contained in this Agreement whether by conduct or otherwise in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such condition or breach or waiver of any other condition or of the breach of any other term, covenant, representation or warranty of this Agreement.

6.7 Headings. The preceding Paragraph headings herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

6.8(a) Right of Either Party to Terminate on Breach by Other Party. If one party shall at any time commit any breach of any covenant, warranty or agreement herein

contained, and shall fail to remedy any such breach within thirty days after written notice hereof by the other party, such other party may at its option, and in addition to any other remedies that it may be entitled to, cancel this Agreement by notice in writing to such effect.

6.8(b) Right of licensor to Terminate on Breach by Licensee. If USCI shall at any time make default in the payment of any royalty, or the making of any report hereunder, or shall commit any breach of any covenant or agreements herein contained, or shall make any false report, and shall fail to remedy any such default or breach within thirty (30) days after written notice thereof by DR. GOLDFARB, DR. GOLDFARB may, at his option, cancel this Agreement and revoke the license herein granted, by notice in writing to such effect, but such act shall not prejudice the right of DR. GOLDFARB to recover any royalty or other sums due to him at the time of such cancellation, and shall not prejudice any cause of action or claim of DR. GOLDFARB accrued or to accrue on account of any breach or default by USCI.

IN WITNESS WHEREOF, the Parties have signed and caused this Agreement to be executed on their behalf on the day and year first written above.

/s/
Witness

/s/
David Goldfarb, M.D.

C. R. Bard, Inc.

/s/
Secretary

/s/
Daniel M. Mulvena
General Manager
USCI Surgical Division

EXHIBIT A

Goldfarb David PROSTHETIC VASCULAR GRAFT	517,415 10/24/74
FRANCE	75.04000 2/7/75
GREAT BRITAIN	1505591 2/14/75
CANADA	218,025 1/16/75
MEXICO	156,099 1/20/75
NETHERLANDS	75.03089 3/14/75
ITALY	47813-A/75 1/23/75
JAPAN	23802/75 2/26/75
SPAIN	433,725 1/10/75
SWITZERLAND	587,652 2/3/75
SWEDEN	7415996-3 12/19/74
WEST GERMANY	P2514231.8 4/1/75

BELGIUM	824,943 2/14/75
AUSTRALIA	76868/74 12/24/74

Goldfarb, David
GRAPHITE
IMPREGNATED
PROSTHETIC
VASCULAR
GRAFT MATERIALS

United States	862,816 12/21/77
Canada	313,611 10/17/78
EPC	78300871.7 12/20/78 ABANDONED
Japan	158126/78 12/21/78
Australia	42509/78 12/14/78

INVENTIONS NOT THE SUBJECT OF PATENT APPLICATION

Vascular graft coated with composite urethane/ graphite mixture

EXHIBIT B

FRANCE

GREAT BRITAIN

CANADA

MEXICO

NETHERLANDS

ITALY

JAPAN

SPAIN

SWITZERLAND

SWEDEN

WEST GERMANY

BELGIUM

AUSTRALIA

EXHIBIT C

In the event that one party (SUBMITTER) submits to the other party (RECEIVER) certain information in tangible form and identifies same as "Confidential – Use and disclosure of contents is subject to the terms and conditions of Agreement of _____ between DR. GOLDFARB and USCI," then RECEIVER shall accept and maintain said certain information subject to the following provisions, which said certain information is referred to below as "CONFIDENTIAL DISCLOSURE." The RECEIVER shall have no obligations under the provisions of this Agreement in respect to any information disclosed by the SUBMITTER to the RECEIVER that is not in tangible form and so identified, or if oral if same is not promptly reduced to tangible form, so identified and a copy thereof signed by each Party.

1. Each CONFIDENTIAL DISCLOSURE will be maintained in confidence by RECEIVER, will not be disclosed by RECEIVER to a third party and RECEIVER will make no use thereof except as provided hereinbelow.

2. The following information shall be exempt from this confidential relationship:

(a) Information documented by written correspondence between SUBMITTER and RECEIVER or representatives thereof prior to the date on which SUBMITTER submits and identifies said certain information to RECEIVER ("said DATE");

(b) Information that is publicly known prior to said DATE;

(c) Information that, on or after said DATE, becomes part of the public domain by publication or otherwise, other than by breach of this Agreement by RECEIVER;

(d) Information in tangible form that RECEIVER can show was in its possession on or prior to said DATE; and

(e) Information in tangible form that RECEIVER receives from a third party who did not acquire it, directly or indirectly, from SUBMITTER under an obligation of confidence.

3. RECEIVER agrees to return to SUBMITTER, upon request, each CONFIDENTIAL DISCLOSURE furnished to RECEIVER by SUBMITTER, provided that RECEIVER shall have the right to retain one copy thereof in its Law Department files (in the case of USCI) or in its counsel's files (in the case of DR. GOLDFARB) for reference only by counsel in the event that questions arise as to the extent of RECEIVER'S obligations under the provisions of this Exhibit C.

4. RECEIVER shall use CONFIDENTIAL DISCLOSURES only in the performance of the attached Agreement between DR. GOLDFARB and USCI.

APPENDIX J

AGREEMENT AMENDING
LICENSE AGREEMENT

Agreement made this 21st day of February, 1997 by and among David Goldfarb, M.D., 4480 Cottonwood Drive, HC Box 3682, Wilson, Wyoming 83014 ("DR. GOLDFARB"), C. R. Bard, Inc., a New Jersey corporation with its principal place of business at 730 Central Avenue, Murray Hill, New Jersey 07974 ("BARD") and IMPRA, Inc., an Arizona corporation with its principal place of business at 1625 West 3rd Street, Post Office Box 1740, Tempe, Arizona 85280 ("IMPRA").

WHEREAS, on September 23, 1980, DR. GOLDFARB and BARD, through its USCI Surgical Products Division entered into a license agreement (the "License Agreement") with respect to Vascular Prostheses made from expanded PTFE, pursuant to which DR. GOLDFARB granted to BARD, exclusive worldwide licenses, with the right to sublicense, to make, use and sell products covered by Patents; and

WHEREAS, due to several causes, including without limitation, the status and patentability of the patent which was the subject of the Cooper/Goldfarb interference proceeding commenced on September 19, 1983, before the Board of Patent Appeals and Interferences in the United States Patent and Trademark Office, (the "Interference") BARD discontinued sales of Royalty Bearing Products and the

parties suspended performance of their respective obligations under the License Agreement; and

WHEREAS, on September 16, 1996, BARD acquired IMPRA and thereafter assigned and transferred the License Agreement to IMPRA along with responsibility for management of BARD's vascular graft business; and as a result of the acquisition of IMPRA, Bard has commenced the sale of Royalty Bearing Products; and

WHEREAS, a decision on the Interference was rendered on October 18, 1996 awarding priority of inventorship to DR. GOLDFARB and a subsequent Request for Reconsideration by Cooper was denied on December 19, 1996; and

WHEREAS, DR. GOLDFARB and IMPRA have agreed to amend the License Agreement in certain respects.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, DR. GOLDFARB and IMPRA agree as follows:

1. All defined terms utilized therein shall have the same meanings as set forth in the License Agreement and except as specifically amended by this Agreement, the License Agreement and all terms and provisions thereof remain and continue in full force and effect as set forth therein.

2. As of the date hereof, a list with copies of all the Patents is attached hereto as Exhibit I.

3. All references to "USCI" in the License Agreement are amended to read "IMPRA".

4. From the second WHEREAS clause, delete the phrase ", except heart valves derived from cooperative research with Shiley Scientific, Inc. (HEART VALVES);"

5. Amend Section 1.1 first sentence, by deleting the phrase "except HEART VALVES;"

6. Amend Section 1.4 first sentence, by deleting the phrase "except HEART VALVES;"

7. Section 2.2 of the License Agreement is amended to read in its entirety as follows:

> A PTFE Graft sold to a customer in a country where a Patent has not been issued or where an issued Patent has been declared invalid will be referred to herein as a "Royalty Bearing Product". When IMPRA or its Affiliate (as defined below) sells Royalty Bearing Product in that country before or during the "Period" defined below, a running royalty will accrue in Dr. Goldfarb's favor at the rate of 2.5% of the Net Selling Price (as defined below) of the Royalty Bearing Product. The "Period" extends for term of 34 months from September 15, 1996 through June 15, 1999. "Affiliate" includes any corporation or other business entity controlled by, controlling, or under common control with a party to this Agreement.

8. Section 2.1 of the License Agreement is amended as follows:

> In the second sentence replace the words ". . . or its sublicensee . . ." with ". . . or its Affiliate . . .".

9. Section 2.5 is amended by addition of the following clarification:

> The first royalty payment to Dr. Goldfarb will be made on or before February 28, 1997, representing royalties accrued for the initial period from September 15, 1996 to December 31, 1996.
>
> Also delete the following: ". . . or its sublicensee . . ." from the third sentence, and ". . . and its sublicensee . . ." from the fourth sentence.
>
> Revise the first sentence of the fourth paragraph by deleting ". . . and shall require same to be kept by its sublicensee".

10. Amend Section 3.1 first sentence, by deleting the phrase "except HEART VALVES;"

11. Notwithstanding anything to the contrary set forth in the License Agreement, royalties will not accrue or be payable to Dr. Goldfarb on sales of Royalty Bearing Products and License Products by any sublicensee of IMPRA. IMPRA agrees, however, that it will not utilize this provision by granting sublicenses to its affiliates or any purchasers of its vascular prosthesis business that would otherwise be royalty-bearing sales of IIMPRA.

12. Amend Section 5.3 by deleting the last two (2) paragraphs thereof.

13. Amend Section 5.4 first sentence, by deleting the phrase "except HEART VALVES;"

14. Amend Section 6.4 to read as follows:

Assignment: This Agreement shall be binding upon and inure to the benefit of The Parties, and their respective successors and shall not be assignable by either Party, except that IMPRA may assign same to any affiliate or division of C. R. Bard, Inc., or to any successor to or purchaser of all or substantially all of its Vascular Prosthesis business.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the dates first above written.

/s/ _____	/s/ _____
Witness	David Goldfarb, M.D.
	IMPRA, Inc.
/s/ _____	/s/ _____
Witness	John D. McDermott, President

EXHIBIT 1

Goldfarb David PROSTHETIC VASCULAR GRAFT	517,415 10/24/74
FRANCE	75.04000 2/7/75
GREAT BRITAIN	1505591 2/14/75
CANADA	218,025 1/16/75
MEXICO	156,099 1/20/75
NETHERLANDS	75.03089 3/14/75
ITALY	47813-A/75 1/23/75
JAPAN	23802/75 2/26/75
SPAIN	433,725 1/10/75
SWITZERLAND	587,652 2/3/75
SWEDEN	7415996-3 12/19/74
WEST GERMANY	P2514231.8 4/1/75

BELGIUM	824,943 2/14/75
AUSTRALIA	76868/74 12/24/74
Goldfarb, David GRAPHITE IMPREGNATED PROSTHETIC VASCULAR GRAFT MATERIALS	
UNITED STATES	862-816 12/21/77
CANADA	313,611 10/17/78
JAPAN	158126/78 12/21/78
AUSTRALIA	42509/78 12/14/78

APPENDIX K

ASSIGNMENT OF PATENT RIGHTS

THIS AGREEMENT, is made effective as of 30 day of January, 2007 (the "Effective Date"), by and between David Goldfarb, an individual, currently residing at 4480 Cottonwood Drive, Wilson, Wyoming 83014, ("Dr. Goldfarb") and Bard Peripheral Vascular, Inc., a division of C.R. Bard, Inc., an Arizona corporation that has offices located at 1625 West 3rd Street, Tempe, Arizona 85281 ("Bard"). Dr. Goldfarb and Bard are referred to herein collectively as the "Parties," and individually as a "Party."

WHEREAS, Dr. Goldfarb is the sole owner of all right and interest in and to U.S. Patent Number 6,436,135 granted and issued on August 20, 2002 (the "Patent");

WHEREAS, Bard and Dr. Goldfarb are Parties to the License Agreement (as defined below) pursuant to which Dr. Goldfarb granted to Bard an exclusive, worldwide license under the Patent;

WHEREAS, Bard desires to acquire all right, title and interest in the Patent, as well as any related foreign patent applications and related foreign patents (and, in each case where appropriate, the related resulting patents), and any continuation, continuation-in-part, reissuance, reexamination, renewal, extension or division thereof, or any patent applications from which any of the foregoing claim priority (collectively,

the "Patent Rights") from Dr. Goldfarb and Dr. Goldfarb desires to sell the Patent Rights to Bard; and,

WHEREAS, effective upon the acquisition by Bard of the Patent and assignment by Dr. Goldfarb of all right, title and interest in the Patent Rights, the Parties desire to terminate the License Agreement.

NOW, THEREFORE, in consideration of the above recitals and the mutual covenants herein, as well as good and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties covenant and agree to be legally bound as follows:

1. Representations and Warranties. Dr. Goldfarb represents and warrants that (i) there are no liens, restrictions, mortgages, security interests or other encumbrances that involve the Patent Rights, (ii) he is the sole owner and sole inventor of the Patent Rights and has not granted any licenses, covenants not to sue or other rights or interests in the Patent Rights other than those granted to Bard, and (iii) he is not party to any agreement and does not have any commitments or obligations, implied or explicit, that limit, encumber or conflict in any manner with his right to assign the Patent Rights or otherwise enter into this Agreement.

2. Termination of License Agreement. The Parties entered into a License Agreement dated September 23, 1980, as amended by that certain First Amendment to the License Agreement dated February 21, 1997 (collectively, the "License Agreement") with respect to the Patent Rights. Pursuant to the provisions of Section 6.6 of the License Agreement, the Parties may terminate the License Agreement by a written

instrument executed by the Parties. Therefore, the Parties acknowledge that effective upon consummation of the transactions contemplated by this Agreement, including execution by Dr. Goldfarb of the Bill of Sale, the License Agreement and any other contractual arrangements between the Parties related thereto, whether oral or written are terminated. Notwithstanding the foregoing provision, nothing set forth herein shall result in the expiration or limitation of any obligations of confidentiality and limited use of information contained in Section 5.5 of the License Agreement.

3. Assignment of Patent Rights. For good and valuable consideration, the receipt of which is acknowledged, Dr. Goldfarb agrees to and hereby sells, transfers, and irrevocably assigns to Bard, and Bard hereby accepts, any and all right, title and interest in and to the Patent Rights and the inventions disclosed therein. Dr. Goldfarb further grants and assigns to Bard any and all such right as he may have retained to sue and collect damages for violations of the Patent Rights, regardless of whether the violations occurred prior to or after the execution date of this Agreement. Dr. Goldfarb agrees that he shall execute such further documents and shall do such further acts as may be necessary to perfect the transfer of the entire right, title and interest of the Patent Rights to Bard.

4. Patent Litigation. In connection with any action involving the Patent Rights, including the pending matter captioned Bard Peripheral Vascular, Inc. and David Goldfarb, M.D. v. W.L. Gore & Associates, Inc., No. 03-0597-PHX-MHM, filed in United States District Court for the District of Arizona, Dr. Goldfarb shall

assist in such action at the request of Bard. Dr. Goldfarb shall reasonably cooperate with Bard and Bard's counsel in prosecuting such action, including the production of documents and records, providing declarations and depositions, testifying at trial, and identifying and working with other potential witnesses, and providing reasonable assistance to Bard's counsel at trial. Bard shall reimburse Dr. Goldfarb for all reasonable and customary out-pocket expenses incurred by him in connection therewith, provided that such expenses have been pre-approved by Bard in writing and are adequately substantiated by written vouchers and receipts to the reasonable satisfaction of Bard.

5. Survival. Sections 3 and 4 will survive any termination or expiration of this Agreement.

6. Governing Law and Choice of Venue. This Agreement shall be construed and interpreted in accordance with the Laws of New Jersey without regard to the conflict of law principles thereof. The Parties consent that any and all litigation commenced between them arising from this Agreement shall take place exclusively in the State of New Jersey and the Parties consent to the exclusive jurisdiction of the state and federal courts in New Jersey.

7. Execution of Counterparts. This Agreement may be executed in two or more duplicate counterparts, each of which will be considered an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, Dr. Goldfarb and Bard have executed and delivered this Agreement on the Effective Date.

BARD PERIPHERAL VASCULAR, INC.	DAVID GOLDFARB
By. /s/	/s/
Name: John McDermott	
Title: President	

BILL OF SALE

KNOW ALL MEN BY THESE PRESENTS, that for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, David Goldfarb, an individual, currently residing at 4480 Cottonwood Drive, Wilson, Wyoming 83014, ("Seller"), does hereby sell and assign to Bard Peripheral Vascular, Inc., a division of C.R. Bard, Inc., an Arizona corporation that has offices located at 1625 West 3rd Street, Tempe, Arizona 85281 ("Buyer"), good and freely transferable title in and to Seller's entire right, title and interest in and to U.S. Patent Number 6,436,135 granted and issued on August 20, 2002 (the "Patent"), as well as any related foreign patent applications and related foreign patents (and, in each case where appropriate, the related resulting patents), and any continuation, continuation-in-part, reissuance, reexamination, renewal, extension or division thereof, or any patent applications from which any of the foregoing claim priority (collectively, the "Patent Rights"). Seller and Buyer are referred to herein collectively as the "Parties," and individually as a "Party."

Nothing in this Bill of Sale is intended to alter any obligation assumed by Buyer or retained by Seller under the Assignment of Patent Rights dated January 30, 2007 by and between Seller and Buyer (the "Assignment of Patent Right").

As consideration for the Assignment of the Patent Rights, Buyer shall pay to Seller the amount of Seven Million Dollars ($7,000,000) USD (the "Purchase Price") via cashier's check or wire transfer to Seller's account within three (3) business days upon Buyer's

receipt of the Bill of Sale executed by Seller. Subject to and in consideration of the payment of the Purchase Price, Seller acknowledges that the Purchase Price constitutes satisfaction in full of all royalties, fees, costs, expenses and all other amounts accrued or accruable pursuant to the License Agreement (as defined in the Assignment of Patent Rights), including any royalties from Buyer for the fourth quarter of 2006. Except as provided below, and as provided in the License Agreement (as defined in the Assignment of Patent Rights), the Parties shall keep the terms and conditions of this paragraph strictly confidential and shall not disclose them to anyone, except their attorneys, parent or affiliated entities, accountants, financial institutions and advisors, auditors, or tax advisors ("Permitted Persons"), unless required to do so by process of law. As for the Permitted Persons, the Parties agree: (a) to advise them of the confidentiality of the information disclosed; and (b) to instruct them to maintain the same confidentiality that the Parties must maintain.

This Bill of Sale shall inure to the benefit of Buyer, its successors and assigns and shall be binding upon Seller, his heirs and representatives.

This Bill of Sale shall be governed by and construed under the substantive laws of the State of New Jersey (without regard to the conflict of law principles thereof).

IN WITNESS WHEREOF, Seller has executed and delivered this Bill of Sale on the 30 day of January, 2007.

/s/ _____ /s/ _____
David Goldfarb Witness

STATE OF Arizona
COUNTY OF Maricopa

On this 30 day of January, 2007 personally appeared before me, the said named Dr. David Goldfarb to me known and known to me to be the person described in and who executed the foregoing instrument and (s)he acknowledged that (s)he executed the same in the capacity indicated, that (s)he was duly authorized to do so, and being duly sworn by me, made oath that the statements in the foregoing instrument are true.

My Commission Expires: January 29, 2009.
/s/ _____ (Signature of Notary Public)

Notary Public (Official Seal)