

**United States Court of Appeals
for the Federal Circuit**

**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.

2014-1114

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 ePTFE 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.

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

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).

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

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.

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 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 decid-

ed 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 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 rec-

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.

ord, 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 non-joinder 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.

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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.”).

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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.

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

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

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.

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.

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.

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.

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.

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.