

No. 15-41

IN THE
Supreme Court of the United States

W.L. GORE & ASSOCIATES, INC.,

Petitioner,

v.

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

Respondents.

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

BRIEF IN OPPOSITION

JOHN C. O'QUINN
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
john.oquinn@kirkland.com

August 25, 2015

QUESTION PRESENTED

Although petitioner did not raise this issue in either its first or second appeal to the United States Court of Appeals for the Federal Circuit, nor in either of its petitions for rehearing *en banc*, and although the courts below found—based on the facts—that there was a written agreement between all the relevant parties conveying an exclusive patent license, petitioner now asks this Court to consider the following question:

Does 35 U.S.C. § 261 require that a grant or conveyance of an exclusive patent license be in writing.

CORPORATE DISCLOSURE

Respondent Bard Peripheral Vascular, Inc. is a wholly owned subsidiary of Respondent C.R. Bard, Inc., a publicly held company. No publicly held company owns 10% or more of C.R. Bard, Inc.'s shares.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
CORPORATE DISCLOSURE.....	ii
INTRODUCTION	1
COUNTERSTATEMENT OF THE CASE	3
I. Background.....	3
A. Dr. Goldfarb’s Invention	4
B. Patent Office Proceedings.....	5
C. Licensing The ’135 Patent	6
II. Proceedings Below.....	7
A. District Court Proceedings	7
B. Gore’s Prior Appeal.....	10
C. Remand and Subsequent Appeal	11
REASONS FOR DENYING THE PETITION	13
I. The Decision Below Does Not Implicate The Question Presented By The Petition	14
II. Gore Waived The Argument That 35 U.S.C. § 261 Requires All Exclusive Licenses Be In Writing.....	16
III. Gore’s Alleged Circuit Conflict Is Illusory	19
IV. The Federal Circuit’s Interpretation of § 261 Is Correct	23
CONCLUSION.....	29

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Almendarez-Torres v. United States</i> , 523 U.S. 224 (1998).....	26
<i>Aspex Eyewear, Inc. v. Altair Eyewear, Inc.</i> , 288 F. App'x 697 (Fed. Cir. 2008).....	23
<i>Bard Peripheral Vascular, Inc. v.</i> <i>W.L. Gore & Assocs., Inc.</i> , 670 F.3d 1171 (Fed. Cir. 2012) (<i>Bard I</i>).....	3, 4, 10
<i>Bard Peripheral Vascular, Inc. v.</i> <i>W.L. Gore & Assocs., Inc.</i> , 682 F.3d 1003 (Fed. Cir. 2012) (<i>Bard II</i>).....	3, 11
<i>California v. Rooney</i> , 483 U.S. 307 (1987) (<i>per curiam</i>).....	14
<i>Cooper v. Goldfarb</i> , 154 F.3d 1321 (Fed. Cir. 1998) (<i>Cooper I</i>).....	3, 6
<i>Cooper v. Goldfarb</i> , 240 F.3d 1378 (Fed. Cir. 2001) (<i>Cooper II</i>).....	3, 6
<i>Enzo APA & Son, Inc. v. Geapag A.G.</i> , 134 F.3d 1090 (Fed. Cir. 1998).....	24
<i>Exxon Co. v. Sofec, Inc.</i> , 517 U.S. 830 (1996).....	15

<i>FDA v. Brown & Williamson Tobacco Corp.</i> , 529 U.S. 120 (2000).....	27
<i>Graver Tank & Mfg. Co. v.</i> <i>Linde Air Prods. Co.</i> , 336 U.S. 271 (1949).....	15
<i>In re Cybernetic Servs., Inc.</i> , 252 F.3d 1039 (9th Cir. 2001).....	22, 23, 24
<i>Kimble v. Marvel Entertainment, LLC</i> , 135 S. Ct. 2401 (2015).....	28
<i>Littlefield v. Perry</i> , 88 U.S. (21 Wall.) 205 (1875).....	25
<i>Moore v. Marsh</i> , 74 U.S. (7 Wall.) 515 (1869).....	25
<i>Moraine Products. v. ICI America, Inc.</i> , 538 F.2d 134 (7th Cir. 1976).....	20, 21, 24
<i>Speedplay, Inc. v. Bebop, Inc.</i> , 211 F.3d 1245 (Fed. Cir. 2000)	17
<i>Tyler v. Tuel</i> , 10 U.S. (6 Cranch) 324 (1810)	26
<i>W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.</i> , 133 S. Ct. 932 (2013).....	11
<i>Waterman v. Mackenzie</i> , 138 U.S. 252 (1891).....	25, 26
<i>Youakim v. Miller</i> , 425 U.S. 231 (1976) (<i>per curiam</i>).....	18

<i>Zivotofsky ex rel. Zivotofsky v. Clinton</i> , 132 S. Ct. 1421 (2012)	18
---	----

Statutes & Rules

28 U.S.C. § 1295(a)(1)	10
28 U.S.C. § 1338	10
28 U.S.C. § 1338(a).....	10
35 U.S.C. § 135 (2006).....	5
35 U.S.C. § 261	<i>passim</i>
35 U.S.C. § 284	9
Act of Feb. 21, 1793, ch. 11, 1 Stat. 318	24, 26
Act of July 4, 1836, ch. 357, 5 Stat. 117	24
Act of July 8, 1870, ch. 230, 16 Stat. 198	24
Pub. L. No. 82-593, 6 Stat. 792 (1952).....	24
Pub. L. No. 112-99, 125 Stat. 284 (2011).....	5
S. Ct. R. 10.....	14

Other Authorities

2 William C. Robinson, <i>The Law of Patents</i> (1890).....	24
Harold Marquis, <i>Limitations on Patent License Restrictions: Some Observations</i> , 58 Iowa L. Rev 41, 55-57 (1972)	21, 22

Paris Convention for the Protection of Industrial Property of 1883, Art. IV, 25 Stat. 1372 (1887)	25
Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645	25

INTRODUCTION

This case involves a 40-year patent dispute between W.L. Gore & Associates (“Gore”) and Dr. David Goldfarb, the inventor of the ePTFE vascular graft. Over the course of this case, Gore has litigated virtually every conceivable issue at one time or another in what the district court called “shotgun” fashion, for which Gore was ultimately sanctioned. Among other things, Gore challenged inventorship, infringement, willfulness, and most recently standing. All of these were fact-intensive issues, and in each instance, Gore lost based on the facts.

The Petition for Certiorari raises none of the issues Gore actually litigated, but instead an issue it never pressed in the Federal Circuit—an issue that would not change the outcome of this case even if Gore were correct (which it is not). Specifically, Gore asks this Court to revisit the longstanding interpretation of 35 U.S.C. § 261: that the statutory requirement of a “writing” applies to patent *assignments* but not to patent *licenses*. This case simply does not present that question, because the transfer in this case *was* in writing. Not only is the question not presented, but Gore waived the issue multiple times; there is no division among the lower courts over the question; and the longstanding interpretation is correct. Moreover, Gore’s theory, if adopted, would pointlessly disturb the settled expectations of patentees and licensees across the nation. The petition should be denied.

First, in asking this Court to decide whether a writing is required for an exclusive patent license to be effective, Gore ignores the district court’s finding, affirmed by the Federal Circuit without dissent, that

there was in fact a *written* agreement between all the relevant parties—Dr. Goldfarb, C.R. Bard, and Bard Peripheral Vascular (“BPV”)—establishing that BPV was Dr. Goldfarb’s exclusive licensee. Although Gore quibbles with this finding, Gore does not assert that it is clearly erroneous—and this Court does not review such factual disagreements in any event. Because the question presented could have no effect on the outcome, given the finding that the license here was in writing, there is no basis for granting review.

Second, Gore did not raise the issue it now asks this Court to address in the court below. The premise of Gore’s standing challenge below was that Dr. Goldfarb had transferred all substantial rights in the patent to C.R. Bard, making the transfer a “virtual assignment,” which must be in writing to be valid. The Federal Circuit rejected the first step in that chain of reasoning—holding that Dr. Goldfarb retained significant rights in the patent, and thus that the transfer to C.R. Bard was a license, and not an assignment. Gore never argued that a writing was required for an exclusive *license*. Not in its first appeal. Not in its second appeal. And not in either of its two petitions for rehearing *en banc* or in its previous unsuccessful certiorari petition. This is not a Court of first resort, and it should not pass on a question that the Federal Circuit was never even asked to address.

Third, there is no division of authority warranting this Court’s review. As Gore ultimately concedes, there is neither any actual circuit split nor any division within the Federal Circuit. The Federal Circuit has consistently held for at least twenty

years, with no dissent, that patent licenses, unlike transfers of ownership (“assignments”), need not be in writing.

Fourth, this longstanding interpretation of the Patent Act is correct. Cases from this Court dating back nearly 150 years support that interpretation. Gore’s remaining arguments about “transparency” and workability are, tellingly, unsupported by any authority, and provide no basis to upset the settled expectations of patentees and licensees who have ordered their affairs in reliance on the law as it has been consistently articulated for decades.

In short, nothing about this case warrants further review. The Court should deny the petition.

COUNTERSTATEMENT OF THE CASE

I. Background

The relevant background is explained in the decision below and a prior decision of the Federal Circuit in this case. Pet. App. 2-4; *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, 1175-78 (Fed. Cir. 2012) (*Bard I*).

This dispute began in 1974, and includes (a) 28 years of examination and interference proceedings in the Patent Office, including two appeals to the Federal Circuit, *Cooper v. Goldfarb*, 154 F.3d 1321 (Fed. Cir. 1998) (*Cooper I*); *Cooper v. Goldfarb*, 240 F.3d 1378 (Fed. Cir. 2001) (*Cooper II*); (b) seven years of district court proceedings, including a lengthy trial in 2007 and a jury verdict; (c) a prior appeal and petition for writ of certiorari to this Court, *Bard I*, 670 F.3d 1171; *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003 (Fed. Cir. 2012) (*Bard II*), *cert. denied* 133 S.

Ct. 932 (2013); (d) a partial remand limited to reconsideration of willfulness; (e) yet another appeal, Pet. App. 1-18; and (f) the present petition. A summary follows.

A. Dr. Goldfarb's Invention

Dr. David Goldfarb revolutionized vascular medicine over four decades ago, in 1973, when he discovered the microstructure necessary for expanded polytetrafluoroethylene (“ePTFE”) to be used as a vascular graft. Dr. Goldfarb’s invention is described and claimed in U.S. Patent No. 6,436,135 (“the ’135 patent”).

Before 1973, Gore had tried for years to find medical uses for ePTFE. Fed. Cir. Joint Appendix (“JA”) 24988-89. Gore shipped boxes of ePTFE tubes to doctors and researchers around the world, and asked them to experiment. JA41135-36. ePTFE grafts in animal experiments sometimes succeeded but usually failed, and experimenters could not ascertain why. JA45455-60; Pet. App. 15. Independent of Gore’s unsuccessful attempts to develop an ePTFE graft, Dr. Goldfarb had long been interested in artificial implants. JA23593-608. Dr. Goldfarb took a different direction in his research than Gore and other doctors—focusing on *microscopic* rather than *macroscopic* properties—and his new direction succeeded. *See* JA37554-55.

Gore immediately recognized both the significance of Dr. Goldfarb’s invention, and that it was in fact Dr. Goldfarb’s. Gore referred to it as the “Goldfarb Structure” or “AHI Structure” (named for the Arizona Heart Institute where Dr. Goldfarb conducted his research). *Bard I*, 670 F.3d at 1182; JA3958; JA48098-100; JA28528; JA42880. Gore

wrote in January 1974 that “[a]ny success at this point in time is the direct result of the AHI efforts.” JA41408.

B. Patent Office Proceedings

Using what it learned from Dr. Goldfarb, Gore filed a patent application in 1974 solely in the name of its plant manager, Peter Cooper. Cooper’s application “plagiarized its working examples” and some of the language describing the invention “from a memorandum which described the work of a Dr. David Goldfarb.” JA51575 (1975 affidavit of Gore’s counsel). Indeed, after the application was filed, Cooper stole microscopic slides from Dr. Goldfarb’s laboratory, in hopes of understanding Dr. Goldfarb’s invention. Pet. App. 18. Dr. Goldfarb subsequently filed his own application.

From 1974 to 1983, Dr. Goldfarb’s and Cooper’s applications were prosecuted before the same examiner. JA47227-28; JA51490; JA108; JA47059-88. In 1983, the Patent Office declared an “interference” between the Goldfarb and Cooper applications,¹ which the parties then litigated for the next nineteen years. JA30198-200. In 1995, the

¹ In 2011, the Leahy-Smith America Invents Act, Pub. L. No. 112-99, 125 Stat. 284 (2011) replaced the United States patent system’s “first-to-invent” rule with a “first-inventor-to file” rule. Under the prior regime, when two inventors filed conflicting patent applications for the same invention, the Patent Office would hold an administrative “interference” proceeding to determine who was the first to invent the claimed subject matter and was entitled to the patent. *See generally* 35 U.S.C. § 135 (2006).

Patent Office found Dr. Goldfarb was the first to invent. JA35077-114.

Following two appeals by Gore to the Federal Circuit, *see Cooper I*, 154 F.3d at 1323; *Cooper II*, 240 F.3d at 1380-81, and further proceedings at the Patent Office, the Patent Office finally issued the '135 patent to Dr. Goldfarb on August 20, 2002.

C. Licensing The '135 Patent

In 1980, while Dr. Goldfarb's patent application was still pending, he entered into a license agreement with C.R. Bard, granting a "worldwide, exclusive license" to that application and to certain other patents and patent applications, Pet. App. 127, in exchange for royalties and other consideration, Pet. App. 5, 127-31. Dr. Goldfarb retained significant rights if various contingencies arose, Pet. App. 69-73, 107, 109, and the license excluded a category of products—heart valves—from its field of use. Pet. App. 127. By its terms, the license was just that: a license. Pet. App. 9, 65, 107, 111-12, 125. It was titled a "LICENSE," Pet. App. 125, included the defined term "LICENSED PRODUCT," Pet. App. 127, referred to the "license" throughout, and did not purport to assign the patent from Dr. Goldfarb to C.R. Bard.

Sixteen years later, in 1996, C.R. Bard acquired IMPRA, which later became Bard Peripheral Vascular, Inc. ("BPV"). Pet. App. 108. Because BPV is C.R. Bard's vascular graft subsidiary, with Dr. Goldfarb's consent, C.R. Bard transferred its interest in the 1980 license agreement to BPV. *Id.*; Pet. App. 5. BPV thereafter assumed C.R. Bard's rights and obligations under the license agreement. Pet. App. 111.

A year later, Dr. Goldfarb, C.R. Bard, and BPV entered into a *written* agreement updating and revising the terms of the 1980 agreement. Pet. App. 150-56. That 1997 updated license agreement, “by and among David Goldfarb ..., C.R. Bard ..., and IMPRA [now BPV],” acknowledges that C.R. Bard “assigned and transferred” its license to BPV in 1996. Pet. App. 150-51. And it makes clear BPV—not C.R. Bard—remains the licensee under the 1997 agreement. Other provisions of the 1997 agreement remove the heart-valve field-of-use restriction and revise the parties’ financial arrangements. Pet. App. 152-53. Dr. Goldfarb executed this updated agreement on February 21, 1997, and, as the district court found, John McDermott, BPV’s president and an officer of C.R. Bard, signed the agreement *on behalf of both BPV and C.R. Bard*. Pet. App. 61, 66-67, 113, 154.

In 2007, in a second *written* agreement, Dr. Goldfarb assigned all of his rights in the ’135 patent to BPV. Pet. App. 157-61.

II. Proceedings Below

Once Dr. Goldfarb’s patent issued, Gore refused to take a license and pay royalties. On March 28, 2003, Dr. Goldfarb and BPV sued Gore for infringement.

A. District Court Proceedings

Despite its 28-year campaign in the Patent Office for Dr. Goldfarb’s patent rights, Gore took the position in the district court that the patent was invalid in numerous ways and that none of Gore’s products were covered by the claims. As the district court said, Gore “adopted a ‘shotgun’ approach of litigating virtually every conceivable issue, thereby

burdening the Court with a number of meritless arguments.” JA4678.

Among its myriad defenses, Gore challenged Dr. Goldfarb’s and BPV’s standing. Gore asserted that Dr. Goldfarb lacked an ownership interest in the patent, on the theory that his 1980 license to C.R. Bard was a “virtual assignment,” transferring all substantial rights in the ’135 patent, and not just an exclusive license. Pet. App. 61, 109. Under Gore’s theory, that made C.R. Bard, not Dr. Goldfarb, the true owner of the ’135 patent. Pet. App. 61, 109, 111. According to Gore, BPV also lacked standing because the 1996 transfer, which Gore characterizes as transfer of ownership of the patent and not just a license, was not in writing; and (again, according to Gore) C.R. Bard was not a party to the written 1997 agreement. Pet. App. 61, 113.

The district court rejected Gore’s standing arguments *on the facts*—in two separate written opinions. Pet. App. 5. It held Goldfarb retained ownership of the ’135 patent, and thus standing to sue, because “the 1980 license did not transfer all of Dr. Goldfarb’s rights.” Pet. App. 109. The court specifically found “that the 1980 License is not a virtual assignment,” Pet. App. 73, making a writing unnecessary for its transfer. And it found that BPV had standing to sue under either the 1996 transfer of the exclusive license from C.R. Bard *or* the 1997 written agreement, which it found was between all three parties, BPV, C.R. Bard, and Dr. Goldfarb. Pet. App. 61-62, 75-78, 109-116. That 1997 agreement not only confirmed the earlier 1996 agreement but “created a new license agreement

between Dr. Goldfarb and Impira/BPV.” Pet. App. 115-16.

The district court rejected Gore’s assertion that C.R. Bard was not a party to the 1997 agreement on the facts. It found Gore’s position irreconcilable with the agreement itself, which “expressly states” it is “made ... by and among David Goldfarb, M.D., ... C.R. Bard, Inc., and IMPRA, Inc.” Pet. App. 76 (quoting Pet. App. 150). The district court relied on what it called “unrebutted” testimony that McDermott signed the agreement on behalf of BPV and C.R. Bard. *Id.*; Pet. App. 67, 113. If that factual finding is not overturned (and Gore does not claim it is clearly erroneous), it does not matter whether exclusive licenses must be in writing, because C.R. Bard transferred all its rights in the patent to BPV *in writing* in 1997.

After a 17-day trial, a jury found the ’135 patent valid and infringed, and awarded approximately \$185 million in damages. Pet. App. 47. The district court increased the damages award to approximately \$370 million pursuant to 35 U.S.C. § 284 because Gore’s infringement was willful. *Id.* Rather than enjoin Gore’s ongoing infringement, however, the district court ordered Gore to pay a 12.5% to 20% royalty on future infringing sales during the remaining term of the patent. Pet. App. 48. Although Gore could have stopped practicing Dr. Goldfarb’s patent after the verdict and ended its liability, Gore has chosen to continue infringing and therefore continues to incur and pay ongoing royalty obligations.

B. Gore’s Prior Appeal

Gore appealed the district court’s judgment to the Federal Circuit, raising anticipation, obviousness, inventorship, written description, and willfulness challenges, among others. *Bard I*, 670 F.3d at 1179. However, one issue it did not raise—and thus *waived*—was whether 35 U.S.C. § 261 requires that exclusive licenses be in writing (as opposed to assignments or even “virtual assignments,” which must be in writing). Indeed, Gore did not challenge Dr. Goldfarb’s or BPV’s standing or ownership of the patent at all, instead acknowledging that the district court had jurisdiction. Pet. App. 6; *see also* Brief of Appellant Gore at 1, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 10-1510 (Fed. Cir. Nov. 1, 2010), *available at* 2010 WL 4853331, (“Jurisdiction in the district court was based on 28 U.S.C. § 1338. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).”). Nor did Gore challenge the award of compensatory damages, including the right of the plaintiffs to recover lost profits.

The Federal Circuit determined that “[t]he district court had jurisdiction under 28 U.S.C. § 1338(a),” and proceeded to address the merits. *Bard I*, 670 F.3d at 1178. (In the second appeal, the Federal Circuit confirmed that this was a considered holding and not just an assumption of jurisdiction. Pet. App. 6.) It addressed each of Gore’s arguments and initially affirmed the judgment in full. *Bard I*, 670 F.3d at 1193. Gore petitioned for rehearing *en banc*, raising issues of inventorship and willful infringement—but again, did not raise whether exclusive licenses must be in writing. In an amended opinion, the panel remanded the issues of

willfulness, enhanced damages, and attorney's fees to ensure the district court applied the proper legal standard, but otherwise left the district court's judgment in place. *Bard II*, 683 F.3d at 1004-05. Gore sought certiorari on one of its inventorship defenses, which this Court denied. *See W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 133 S. Ct. 932 (2013).

C. Remand and Subsequent Appeal

On remand, Gore filed a renewed JMOL motion on willfulness, and—despite the limited remand—filed a motion for a new trial on liability and damages as well. Gore once again did not raise whether 35 U.S.C. § 261 requires a writing for all exclusive licenses or otherwise dispute standing or ownership of the patent. The district court denied Gore's motions and re-entered its original judgment. JA5-19; Pet. App. 41-45.

Gore again appealed to the Federal Circuit, this time asserting its infringement was not willful and questioning Dr. Goldfarb's and BPV's standing for the first time in nearly five years. It re-asserted its argument that Dr. Goldfarb lacked standing because he "virtually assigned" the '135 patent to C.R. Bard in 1980 by transferring all substantial rights in the patent. Pet. App. 5. And it argued that BPV lacked standing because no "written instrument" existed "transferring to BPV what [Gore] contends was the virtual assignment from Goldfarb to [C.R.] Bard Inc." Pet. App. 8. That argument "hinge[d]" on treating the 1980 agreement as a "virtual assignment." *Id.* Gore did not argue—even in the alternative—that exclusive patent licenses must be transferred in writing.

The Federal Circuit rejected Gore's arguments and affirmed the district court. It first held law of the case precluded Gore's attempt to re-litigate standing. Pet. App. 7. Although Gore argued to the contrary, the court saw "no reason to assume that the prior panel did not weigh standing." Pet. App. 6. To the contrary, the Federal Circuit held its prior opinion "confirmed" Goldfarb's and BPV's standing. *Id.*

The Federal Circuit nonetheless also considered and rejected Gore's standing challenge, finding it "an easy question" on the facts. Pet. App. 8. It found "no error in the district court's well-reasoned analysis" that the 1980 agreement is an exclusive license, not a "virtual assignment." Pet. App. 9. And it held "there is no question that in 1997, there *was* a written agreement between the parties affirming Bard's transfer of its rights to BPV" that "settles BPV's right to sue at the time of the complaint as Goldfarb's exclusive licensee." *Id.*; *see also* Pet. App. 8-9 ("[I]n 1997 there was a memorialized transfer of the exclusive license from Goldfarb and Bard Inc. to BPV's predecessor.").

Two members of the panel issued separate opinions on the unrelated issue of willfulness. Gore filed a rehearing petition raising issues of willfulness. It did not challenge the panel's unanimous standing decision, much less raise the issue of whether 35 U.S.C. § 261 requires a writing for all exclusive licenses. The Federal Circuit denied rehearing without comment, Pet. App. 120, and Gore now seeks this Court's review.

REASONS FOR DENYING THE PETITION

The petition does not warrant this Court's review for four independent reasons:

First, the “question presented” is not actually presented in this case. As a separate and independent ground for its standing decision, the district court found and the Federal Circuit affirmed that there *was*, in fact, a *written* exclusive license agreement between all the relevant parties. Gore's petition just assumes away this critical factual finding, burying its disagreement with it in footnotes without claiming it is clearly erroneous. This Court does not sit to resolve questions that do not affect the outcome of a case.

Second, Gore waived the issue it asks this Court to decide. Not once did it argue to the Federal Circuit that exclusive licenses must be made or transferred in writing. (Rather, it argued that the 1980 license was, in fact, a “virtual assignment”—an argument that it lost on the facts and does not raise again in its petition). Indeed, it has doubly waived the argument that exclusive licenses must be in writing: it did not raise the argument, or any other argument bearing on standing, in its initial appeal, and it did not raise the argument in the appeal below, instead resting on the assertion that the 1980 agreement was a virtual assignment. And Gore never asked the *en banc* Federal Circuit to consider its § 261 argument or anything remotely resembling it.

Third, this Court's discretionary review is not warranted for the basic reason that there is no disagreement over the issue Gore raises. Petitioner's circuit split is utterly illusory. And there is no division of authority within the Federal Circuit.

Indeed, no jurist—in this case or otherwise—has called for revisiting the treatment of exclusive licenses under § 261. Petitioner asks this Court to upend the settled expectations of patentees and licensees but gives no basis for doing so, other than its own disagreement with the overall outcome of its case. Tellingly, Gore cites nothing from the bench or bar suggesting that the law in this area is unworkable.

Fourth, the uniform consensus regarding the interpretation and workability of § 261 is with good reason. The time-tested interpretation that 35 U.S.C. § 261 does not apply to licenses is correct.

I. The Decision Below Does Not Implicate The Question Presented By The Petition

No “compelling reasons” exist for this Court to address the question whether exclusive patent licenses must be in writing. S. Ct. R. 10. This case does not even implicate that question because the exclusive license in this case *was* in writing, as the district court and Federal Circuit both held. To be sure, in its opinion the Federal Circuit reiterated its longstanding holding that “[i]t is well established that the grant of a license does not need to be in writing,” Pet. App. 8. But the Federal Circuit did not resolve Gore’s appeal on that basis, because it also affirmed the district court’s factual finding of a written agreement. Pet. App. 8-9. This Court “reviews judgments, not statements in opinions,” *California v. Rooney*, 483 U.S. 307, 311 (1987) (*per curiam*). The answer to the question Gore asks this Court to resolve—whether exclusive patent licenses must be in writing—would have no effect on the

outcome of this case. That alone requires denial of the petition.

To make its legal argument regarding the meaning of § 261 relevant to the judgment, Gore must ask this Court to disregard the *factual findings* of the district court, affirmed by the Federal Circuit, which render the legal issue moot. As Gore *concedes*, both courts below found “there is no question that in 1997, there *was* a written agreement between the parties affirming Bard’s transfer of its rights to BPV.” Pet. 15 (quoting Pet. App. 9); *see generally* Pet. 14-16. Gore nonetheless brazenly asserts “there is no written instrument transferring Bard’s exclusive license to Impra/BPV.” Pet. 30 (capitalization modified).

No such written agreement exists, according to Gore, because “Bard was not a party to th[e] [1997] agreement—the agreement was only between Goldfarb and BPV.” Pet. 19 n.8; *see also* Pet. 30 (“Bard was not a party to the 1997 Amendment.”). But the district court twice found that C.R. Bard *was* a party to the 1997 agreement, Pet. App. 61, 76-77, 113, and the Federal Circuit “agree[d] with the district court,” Pet. App. 9. Gore does not assert that these factual findings are clearly erroneous, but given those factual findings, its question presented would not affect the outcome of the case.

Even if Gore did seek to overturn the relevant factual findings, that would not warrant this Court’s review. This Court “cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error.” *Exxon Co. v. Sofec, Inc.*, 517 U.S. 830, 841 (1996) (quoting *Graver Tank & Mfg. Co. v. Linde Air*

Prods. Co., 336 U.S. 271, 275 (1949)). And there is no obvious error here. The factual findings below are well-supported by the record.

Beyond all this, Gore's claims about the lack of a written agreement, even if accepted, would only amount to a *prudential* standing argument. The Federal Circuit held Dr. Goldfarb had constitutional standing to assert the '135 patent—a fact-intensive holding Gore does not challenge. Pet. App. 8-10. Any prudential standing problem could be cured by amending the complaint to designate C.R. Bard (which participated throughout the litigation as a counterclaim-defendant) as an additional plaintiff, as the district court indicated a willingness to do if it proved necessary. Pet. App. 77-78 & n.6.

For any (and all) of these reasons, reviewing the question presented would have no effect on the outcome of this case, and thus would be tantamount to an advisory opinion. That is reason enough to deny certiorari.

II. Gore Never Raised The Argument In The Court Below That 35 U.S.C. § 261 Requires All Exclusive Licenses Be In Writing

Even if this case did actually implicate the question presented, Gore never raised the argument that 35 U.S.C. § 261 requires all exclusive licenses be in writing. This Court does not sit to resolve issues that were not presented to the court of appeals.

First, Gore repeatedly failed to raise this argument in the court of appeals thereby making this case an exceptionally poor vehicle in which to consider the issue. Although Gore challenged Dr. Goldfarb's and BPV's standing in its latest appeal, it

did so entirely on the basis that Dr. Goldfarb's 1980 license was a virtual assignment rather than a genuine license, and thus that it was governed by the writing requirement applicable to assignments under the long-established interpretation of § 261. Gore never argued to the court of appeals that Dr. Goldfarb and BPV lacked standing even if the 1980 agreement was merely an exclusive license. To the contrary, Gore explicitly accepted the established interpretation that § 261 only requires *assignments*—whether actual or “virtual”—to be in writing. See Corrected Brief of Appellant Gore at 38, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 14-1114 (Fed. Cir. Jan. 10, 2014), available at 2013 WL 6736194, at *38. For example, Gore argued that, “[u]nder § 261, a written instrument is required to effect a valid transfer of a *patent assignment*, including a ‘*virtual assignment*’ that transfers all substantial rights.” *Id.* (emphasis added).²

Gore specifically told the Federal Circuit, “[t]he linchpin of [its] standing challenge is that the 1980 Agreement was a grant of all substantial rights in the ’135 patent—a ‘*virtual assignment*’—from Goldfarb to Bard.” Reply Brief of Appellant Gore at

² See also *id.* at 37-38 (“Bard failed to transfer its *virtual assignment* to the ’135 patent to IMPRA/BPV through a written instrument as required by 35 U.S.C. § 261.”) (emphasis added); *id.* at 39 (“[A] party attempting to prove standing based on a *virtual assignment of all substantial rights* in the patent ‘must produce a written instrument documenting the transfer of proprietary rights.’”) (emphasis added) (quoting *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000)).

13, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 14-1114 (Fed. Cir. Feb. 10, 2014), available at 2014 WL 692881 (emphasis added). That is a wholly different argument from the one Gore is now making—that every exclusive patent license, even those that do not transfer all substantial rights, must be in writing to be valid.

Because Gore did not challenge the Federal Circuit’s interpretation of § 261—under which patentees and licensees may freely grant or transfer exclusive licenses without a writing—the Federal Circuit did not address any such challenge. Allowing Gore to challenge that rule for the first time now would upset this Court’s traditional refusal to consider questions neither pressed nor passed upon below. *See, e.g., Zivotofsky ex rel. Zivotofsky v. Clinton*, 132 S. Ct. 1421, 1430 (2012); *Youakim v. Miller*, 425 U.S. 231, 234 (1976) (*per curiam*).

It is no answer to say, as Gore does, that the Federal Circuit is so “entrenched” in its position that it need not have raised the issue. Pet. 3, 26. Although *panels* are bound by prior decisions, the *en banc* court is not. Gore filed not one, but two, petitions for rehearing *en banc* in the Federal Circuit and never raised the argument that it makes now. Gore’s waiver of this issue was repeated and deliberate. In its first appeal, Gore abandoned the standing argument and conceded jurisdiction. On rehearing, it made no standing argument. In its first petition to this Court, it made no standing argument and no argument about § 261 at all. On limited remand on the willfulness question, it made neither argument in district court. Only on its second appeal to the Federal Circuit, from a district order confined

by the terms of the limited remand to willfulness—and after judgment was executed on damages not associated with willfulness—did Gore resurrect the standing issue. Even then Gore argued only that the 1980 agreement should have been deemed a virtual assignment. Gore did not argue that § 261 requires all exclusive licenses be in writing.

Gore has simply waived the issue. Gore may argue that the issue is not technically “waived” because (according to Gore’s theory) it is potentially relevant to yet another standing argument Gore might hope to make in the future (but does not make here). That is incorrect for many reasons, including that nothing about § 261’s requirement of a writing purports to be jurisdictional in nature. But even if the Court could theoretically reach the issue, it should not undertake “review” of a question of statutory interpretation that was not passed on by the court of appeals (especially here, where the meaning of the Patent Act is particularly within the expertise of the Federal Circuit).

In sum, when a party repeatedly and intentionally fails to make a pertinent argument, or abandons that argument on appeal, the argument should not be considered for the first time on appeal in this Court. At the very least, Gore’s waiver and the procedural complications resulting from Gore’s gamesmanship make this an exceptionally poor vehicle for addressing the meaning of § 261.

III. Gore’s Alleged Circuit Conflict Is Illusory

Even setting aside that the question presented is not actually implicated in this case and setting aside Gore’s failure to raise the issue in the court below, even on its own terms that question does not warrant

this Court's review because there is no inter- or intra-circuit split. Gore gives no reason for this Court to disturb this settled law and the settled expectations of patentees and licensees who rely on it, and there is none.

Perhaps the best evidence that there is no inter-circuit conflict is Gore's admission that other courts of appeals "have not directly addressed the question of whether an exclusive patent license must be transferred in a written instrument." Pet. 22. Gore instead attempts to cobble together a shallow circuit conflict out of what purportedly "follows from the logic of" Seventh and Ninth Circuit opinions addressing unrelated issues. Pet. 24. This Court does not grant certiorari based on predictions that the circuits may conflict in the future, and regardless, Gore's prediction of a future conflict is misplaced. The Seventh, Ninth, and Federal Circuits all agree that the language Gore relies on in § 261 does not govern exclusive licenses.

Moraine Products. v. ICI America, Inc., 538 F.2d 134 (7th Cir. 1976) was an antitrust case. There, the Seventh Circuit held that a mutual agreement not to sublicense patent rights is neither "illegal per se" under the Sherman Act nor automatically immune from antitrust scrutiny. *Id.* at 145. Along the way, it reviewed 35 U.S.C. § 261 and briefly discussed whether that statute might reach exclusive licenses. But that was entirely dicta because the court ultimately concluded that § 261 "does not help in resolution of the issue in this appeal." *Id.* at 143. "Nothing in 35 U.S.C. § 261," the Seventh Circuit concluded, "sanctions an arrangement wherein

competitors agree with one another that they will not grant further sublicenses.” *Id.*

In any event, the Seventh Circuit’s brief review of § 261 led it to conclude that statute “*does not* really apply at all to patent licenses.” *Id.* (emphasis added). According to the Seventh Circuit, the language Gore believes plainly covers exclusive licenses “was originally intended to apply to neither assignments nor licenses, but rather to what were classified as ‘grants’ in the nineteenth century,” which are assignments limited to a specific geographic area. *Id.* Grants and exclusive licenses, as the Seventh Circuit recognized, are distinct types of interests in a patent. *Id.*

The Seventh Circuit, it is true, did also say that “[e]ven though the statutory section is not directly applicable, this court recognizes that the difference between a ‘grant’ and an exclusive licenses is merely formal nature.” *Id.* But it meant the difference is merely formal *for antitrust purposes*, not as a matter of statutory interpretation. It made no difference from an antitrust perspective, in the Seventh Circuit’s view, that grants are expressly sanctioned by § 261, while exclusive licenses are not. *See id.* This is clear from the opinion itself and from the law review article the Seventh Circuit cites discussing the intersection of antitrust law and patent licensing agreements. *See id.* 143 n.5 (citing Harold Marquis, *Limitations on Patent License Restrictions: Some Observations*, 58 Iowa L. Rev 41, 55-57 (1972)). The “literal” meaning of § 261, according to Professor

Marquis, should not trump sound antitrust policy. *Id.*³

The Ninth Circuit agrees with the Seventh that the relevant language in § 261 “track[s] the historical definitions of assignment, grant, and conveyance,” *In re Cybernetic Servs., Inc.*, 252 F.3d 1039, 1050 (9th Cir. 2001). Indeed, the Ninth Circuit relied in part on the Seventh Circuit’s *Moraine Products* decision to support its holding. *Id.* at 1052. All three types of interests, according to the Ninth Circuit, “involve the transfer of an *ownership interest* in a patent.” *Id.* at 1050-51 (emphasis added). An assignment passes title; a grant is likewise “a transfer of an ownership interest in a patent, but only as to a specific geographic area;” and a conveyance “transfer[s] the legal title ... from the present owner to another.” *Id.* at 1049-50 (second modification in original). The relevant language in § 261, the Ninth Circuit held, accordingly governs transfers of “ownership interests only,” not mere licenses. *Id.* at 1051; *see also id.* at 1052 (holding “a ‘mere license’ ... is not an ‘assignment, grant or conveyance’ within the meaning of 35 U.S.C. § 261”).

But the Ninth Circuit did not address whether an exclusive patent license must be in writing for two reasons. The dispute in *Cybernetic Services* was over the validity of a *written* security agreement. *Id.* at 1044. And the parties were disputing the meaning of

³ Professor Marquis argued that, despite § 261 only covering grants, “any [antitrust] immunity provided by this [statute] should apply to the territorial restrictions in grants and exclusive licenses alike.” 58 Iowa L. Rev. at 57.

the recording provision in § 261's final paragraph—a provision voiding any unregistered “assignment, grant, or conveyance ... as against any subsequent purchaser,” 35 U.S.C. § 261—not the provision relevant here. The Ninth Circuit looked to the “writing” language only for context. *See Cybernetic Servs.*, 252 F.3d at 1050-51.

At bottom, neither the Seventh nor Ninth Circuits have purported to resolve the question presented. Nor do they disagree with each other or the Federal Circuit. To the contrary, if anything, both decisions support the historical distinction between assignments and licenses.

Nor does Gore identify any division of authority within the Federal Circuit over the interpretation of § 261. In fact, Gore argues the opposite—that Federal Circuit law is entirely settled on this point. *Pet. 26*. Although it identifies a single non-precedential decision from seven years ago in which a panel of the Federal Circuit acknowledged that prior precedent had not specifically analyzed the “in like manner” language of § 261, that opinion expressed no reservations about the correctness or workability of that precedent. *See Pet. 7* (citing *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 288 F. App'x 697, 705 (Fed. Cir. 2008)). Gore points to no decision, or even any concurring or dissenting opinion, in any case before or since that expresses concern over the interpretation of § 261.

IV. The Federal Circuit's Interpretation Of § 261 Is Correct

The absence of disagreement among the circuits and within the Federal Circuit should come as no surprise. The rule that exclusive licenses need not

be in writing is firmly rooted in the text of 35 U.S.C. § 261 and supported by over a century of precedent in this Court. The relevant language of that statute provides:

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. As the Seventh, Ninth, and Federal Circuits have all concluded, the phrase “grant and convey” in the second sentence is a term of art that excludes mere licenses—exclusive or otherwise. *See Cybernetic Servs.*, 252 F.3d at 1049-50; *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998); *Moraine Prods.*, 538 F.2d at 143.

That phrase has been in the Patent Act since the nineteenth century. *See* Act of July 4, 1836, ch. 357, § 11, 5 Stat. 117, 121; Act of July 8, 1870, ch. 230, § 36, 16 Stat. 198, 203; Act of July 19, 1952, Pub. L. No. 82-593, ch. 26 § 261, 6 Stat. 792, 810 (codified at 35 U.S.C. § 261). Then, as now, it was well understood that a “grant” transfers an ownership interest in a patent—much like an assignment, but only in a specific geographic area. 2 William C. Robinson, *The Law of Patents* § 763, at 518 (1890) (noting that the “essential difference” between an assignment and a grant is “the territorial area to which they relate”). That understanding is reflected in this Court’s nineteenth-century patent cases,

which consistently give the word “grant” this specialized meaning. *See, e.g., Littlefield v. Perry*, 88 U.S. (21 Wall.) 205, 219-20 (1875); *Moore v. Marsh*, 74 U.S. (7 Wall.) 515, 521 (1869). There thus exists an essential difference between a grant under § 261 and the creation or transfer of an exclusive license. An exclusive license, unlike a grant, “giv[es] the licensee no title in the patent.” *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891).

This understanding of “grant and convey” is consistent with the remainder of that sentence of § 261, which authorizes granting or conveying “an exclusive right ... to the whole or any specified part of the United States.” An assignment of rights under a patent or patent application only in a specified geographic area is the very definition of a grant. Nor does the statute’s reference to “the whole” of the United States undermine this interpretation. International agreements, such as the Patent Cooperation Treaty most recently, have long allowed patent applicants to obtain rights in multiple countries through a single patent application. *See* Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645; Paris Convention for the Protection of Industrial Property of 1883, Art. IV, 25 Stat. 1372 (1887). An assignment of rights in an application filed under one of these agreements limited to the “whole” United States rather than worldwide is still a grant, not an assignment.

Giving the phrase “grant and convey” its customary meaning in the patent context is also consistent with the structure of § 261. The title of § 261 indicates that statute does not govern exclusive licenses. Section 261 is entitled “ownership;

assignment.” That title implies that the statutory provisions under that heading relate to transfer of patent ownership rights—not “mere licenses,” *Waterman*, 138 U.S. at 255; see *Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) (“[T]he title of a statute and the heading of a section are tools available for the resolution of a doubt about the meaning of a statute.”). So does the structure of § 261, with the first sentence of the relevant paragraph covering ownership transfers amounting to an assignment, and the second “in like manner” sentence covering transfers of *ownership* that are less than a complete assignment. 35 U.S.C. § 261.

The events leading to the enactment of § 261’s statutory predecessor confirm this reading of the statute is correct. The Patent Act of 1793 authorized a patentee to assign his patent, established a recording system for assignments, and granted assignees the right to sue to enforce assigned patent rights. Act of Feb. 21, 1793, ch. 11, §§ 4-5, 1 Stat. 318. In *Tyler v. Tuel*, however, this Court held a grant of ownership of a patent everywhere but in certain counties in Vermont was not an assignment under the 1793 Act. See 10 U.S. (6 Cranch) 324, 326 (1810) (“It is evident from the whole purview of the statute ... that no person can be considered an assignee under the statute, who is not the assignee of the *whole* right of the original patentee.”) (original emphasis). When Congress next revised the Patent Act in 1836, it overturned *Tyler* by providing “grantees” could sue for infringement and that, like patent assignments, “every grant and conveyance of the exclusive right under any patent ... within and throughout any specified part or portion of the United States” must be registered with the Patent

Office. Act of July 4, 1836, ch. 357, §§ 11, 14, 5 Stat. 117, 121, 123 (1836). This history, like every other piece of statutory context, demonstrates that the relevant language in § 261 is directed towards grants and grantees, not exclusive licenses.

Thus, far from faithfully applying the statutory text, Gore does violence to both the text and congressional purpose by focusing on the “exclusive right” language in § 261 to the exclusion of all else. Pet. App. 18. That myopic focus leads Gore to conclude, incorrectly, that all exclusive rights in a patent must be transferred in writing. Not so. As this Court has recognized, “[t]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000). Context here makes clear the “exclusive right” referred to in § 261, as the object of “grant or convey,” is an ownership interest in the patent—not licensed rights. There is accordingly no inconsistency between that statutory language, the structure and history of § 261, and a rule that licenses may be oral or implied-in-fact.

Further, in asking this Court to overturn what it admits is a settled interpretation of § 261 in the name of “transparency”—a concern unsupported by citation to scholarly commentary or *amici*—Gore would undo the settled expectations of patentees and licensees who have relied on the line between assignments and licenses in ordering their affairs. By Gore’s own account, that line has been settled law for *at least* 20 years, Pet. 3, 20, and it has been reflected in this Court’s interpretation of “grant” for nearly 150 years. If Congress becomes concerned

that the longstanding interpretation of § 261 is incorrect or produces untoward results, it would be a straightforward matter for it to prospectively amend the statute from “grant and convey” to “grant and convey, or license.” To impose a writing requirement on exclusive licenses at this late date would upset long-term business relationships and introduce confusion into the law. For decades, if not longer, patent owners have conducted their affairs on the assumption that exclusive licenses need not be in writing; indeed, that they may be proven through evidence of course of conduct. If Gore’s interpretation of § 261 were adopted in this case, every one of those licenses would become bait for litigation on the basis of contrived standing arguments. That is yet another reason to deny the petition. *Cf. Kimble v. Marvel Entertainment, LLC*, 135 S. Ct. 2401, 2409-10 (2015).

Finally, Gore’s policy arguments in support of certiorari here—and its reinterpretation of § 261 more broadly—ultimately depend on *factual* claims rejected by the courts below. Gore asserts that this case presents the “type of revisionist history that the written instrument requirement of Section 261 is meant to guard against,” Pet. 28, asserting that C.R. Bard and BPV made “a strategic decision” in 2003 to have BPV rather than C.R. Bard file suit to increase the “amount of damages” available. Pet. 29. Gore made similar arguments in support of its “virtual assignment” argument below and the Federal Circuit rightly found them unpersuasive. In fact, BPV filed this suit because, after 1997, BPV—not C.R. Bard—was the exclusive licensee to the ’135 patent. Pet. App. 8-9. Nor is BPV asserting an exclusive license based solely on “self-serving oral testimony” or even

a long-after-the-fact written confirmation executed in the middle of litigation. Pet. 29. The 1997 agreement granting BPV an exclusive license was executed *six years* before Dr. Goldfarb and BPV ever filed suit. Pet. App. 8-9, 61. Gore's other arguments depend on factual assertions that the district court and Federal Circuit considered and rejected, which in some cases are not even properly part of the record.⁴

CONCLUSION

For the foregoing reasons, the Court should deny the petition.

⁴ For example, Gore makes much out of testimony from a former employee who said he did not have knowledge of an assignment of the 1980 license agreement from C.R. Bard to BPV. But that testimony does not say what Gore says it does. Mr. Flink did not testify there was no transfer from C.R. Bard to BPV, only that he had no personal knowledge one way or the other. JA4220 (“And if my assumption or my knowledge is incorrect and in fact it did occur, then I’m incorrect.”). The district court also found that this testimony was not properly part of the record. JA51. Gore never appealed that evidentiary ruling. Gore also insinuates that C.R. Bard and BPV obtained some advantage by joining BPV in this suit, while representing in other contexts that C.R. Bard was the exclusive licensee. Pet. 11. Not so. C.R. Bard brought the New Jersey litigation because *C.R. Bard* was the counterparty to the 1984 agreement with Gore at issue in that case—in 1984 C.R. Bard was Dr. Goldfarb’s exclusive licensee. Likewise, Gore’s oblique references to the certificates of interest filed in *Cooper I* and *Cooper II* are makeweight. Pet. 12. Those certificates were to help the Federal Circuit determine recusal issues, and Dr. Goldfarb’s counsel properly identified C.R. Bard as a real party in interest, because it is the publicly traded entity that wholly owns BPV.

Respectfully submitted,

JOHN C. O'QUINN
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
john.oquinn@kirkland.com