

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., C.R. BARD, INC.,
Respondents.

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

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER**A. This Is the Proper Case for Review of the Federal Circuit’s “Well Established” Interpretation of Section 261.**

This case is a superior vehicle for this Court to resolve the important issue of whether 35 U.S.C. § 261 requires that a grant or conveyance of an exclusive patent license be in writing. In affirming the \$1 billion-plus judgment, the Federal Circuit held that it is “well established” that the “grant” of an exclusive license “does not need to be in writing.” App. 8; *see also, e.g., Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995) (en banc). However, the Federal Circuit’s “well established” principle starkly contradicts Section 261, which states that a patentee may only “grant” an “exclusive” right “by an instrument in writing.” This case therefore squarely raises the issue of whether the Federal Circuit’s “well established” interpretation of Section 261 is incorrect.

Faced with the plain language of Section 261, Respondents spend most of their brief trying to convince the Court to ignore the Federal Circuit’s conflicting interpretation. Respondents argue, for example, that even if Gore’s reading of Section 261 was correct, it would not affect the outcome of the case because although the 1996 transfer was not in writing, “there is no question that in 1997, there *was* a written agreement between the parties affirming Bard’s transfer of its rights to BPV.” Resp. 15 (emphasis in original). But Respondents are wrong.

The 1997 agreement could not have been a “grant” of an exclusive license from Bard to IMPRA/BPV. Bard

was not a party to the 1997 agreement—there literally is no signature block for Bard. App. 154. The only portion of the 1997 agreement that refers to a transfer from Bard to IMPRA/BPV is a “WHEREAS” clause. App. 150. But a “WHEREAS” clause is not a “grant” of anything because it “cannot create any right beyond those arising from the operative terms of the document.” *United States v. Hamdi*, 432 F.3d 115, 123 (2d Cir. 2005); *Time Warner Entm’t Co. v. Everest Midwest Licensee, L.L.C.*, 381 F.3d 1039, 1057 (10th Cir. 2004); *Grynberg v. FERC*, 71 F.3d 413, 416 (D.C. Cir. 1995). Thus, as a matter of law, the “WHEREAS” clause of the 1997 agreement cannot qualify as a written “grant” of an exclusive license from Bard to IMPRA/BPV.

If this Court holds that under Section 261 a patentee may only grant or convey an exclusive license “by an instrument in writing,” the Court should at a minimum remand to the Federal Circuit the issue of whether the after-the-fact 1997 agreement somehow qualifies as a written “grant” of an exclusive license. While the Federal Circuit noted that there was a written agreement in 1997 memorializing the purported unwritten transfer in 1996, it did so only after emphasizing that a written agreement was not a requirement, and it did not address the sufficiency of that writing to qualify as an appropriate written instrument under Section 261.¹

¹ The lack of any analysis is particularly important here, where the after-the-fact writing purports to be between Goldfarb and BPV (not Bard) and does not even include a place for a Bard representative to sign. BPV’s representative tried to account for this glaring omission by testifying at trial (ten years later) that he was orally authorized by

In addition, contrary to Respondents' assertion, Gore is not requesting that the question presented "be considered for the first time on appeal in this Court." Resp. 19. In reaching its decision, the Federal Circuit expressly addressed the issue, first explaining that "BPV's position is only that it was an exclusive licensee with the right to sue for infringement," and then holding that "[it] is well established that the **grant** of a license **does not need to be in writing.**" App. 8 (emphasis added). The Federal Circuit therefore not only passed on the question presented, but explicitly relied on its "well established" precedent that exclusive licenses do not need to be in writing. *Id.* Respondents even concede that 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." Resp. 2-3. Thus, the Federal Circuit is entrenched in its interpretation of Section 261 and the issue is ripe for review.²

Bard to enter an agreement on its behalf. Pet. 30, n.10. But **oral** testimony about an **oral** authorization is the opposite of the "instrument in writing" required by Section 261. The point is not, as Respondents suggest, for Gore to reargue the factual underpinnings of the case. The point is that the Federal Circuit approved of an oral or partially oral exclusive license where it should not have done so. At a minimum, the Federal Circuit should be required to analyze the 1997 agreement in light of the correct interpretation of Section 261.

² Respondents' suggestion that the Court should not review this issue until a more distinct circuit split develops has no merit. Resp. 1-3. The Federal Circuit has exclusive jurisdiction over patent cases, 35 U.S.C. § 1295(a), which means other circuit courts are unlikely to weigh into this issue in the foreseeable future. There also is no reason to allow the issue to percolate any longer in the Federal Circuit given that it has declared its rule "well established."

Respondents' waiver arguments also fail for multiple reasons. First, the Federal Circuit expressly passed on the issue presented in this case, holding that "[it] is well established that the **grant** of a license **does not need to be in writing**." App. 8 (emphasis added). This Court's "traditional [waiver] rule . . . precludes a grant of certiorari only when the question presented was not pressed or passed upon below." *United States v. Williams*, 504 U.S. 36, 40-46 (1992) (internal citation omitted). Second, Gore's Petition raises fundamental standing issues, which are "jurisdictional and not subject to waiver." *Lewis v. Casey*, 518 U.S. 343, 369 n.1 (1995); *see also Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 240 F.3d 1016, 1018-19 (Fed. Cir. 2001). Third, Gore raised BPV's standing problem stemming from its lack of a written instrument under Section 261 throughout the litigation, both in the district court and Federal Circuit. Pet. 14-16.

The issue presented is too important for Respondents to try to brush the Federal Circuit's misinterpretation of Section 261 under the table. Contrary to the Federal Circuit's entrenched position, the plain language of Section 261 requires that a transfer of exclusive patent rights be "by an instrument in writing." There is no dispute that the alleged 1996 transfer of exclusive rights from Bard to IMPRA/BPV was not in writing. Likewise, there is no dispute that the only mention of the alleged unwritten 1996 transfer in the 1997 agreement (which did not even include Bard as a party) is in a "WHEREAS" clause, which could not have been a transfer of exclusive rights because a "WHEREAS" clause "cannot create any right" on its own. *Hamdi*, 432 F.3d at 123. The Court

should grant certiorari to correct the Federal Circuit's incorrect treatment of Section 261.

B. The Federal Circuit's Well-Established Rule Is Inconsistent With Section 261, and Needs to Be Corrected By This Court.

Section 261 states that a grant or conveyance of "an exclusive right" must be "by an instrument in writing":

The applicant, patentee, or his assigns or legal representatives may **in like manner** ["**by an instrument in writing**"] **grant and convey an exclusive right** under his application for patent, or patents, to the whole or any specified part of the United States.

The only logical reading of this passage in Section 261 is that a grant or conveyance of an exclusive license must be in writing. By using the phrase "in like manner," the statute is plain that the "instrument in writing" requirement in the previous sentence of Section 261 applies to transfers of "an exclusive right." And the very purpose of an exclusive license is to transfer "an exclusive right" in the patent—that is why it is called an "exclusive" license.

Respondents appear to concede that the "in like manner" language of Section 261 requires an "instrument in writing" and that an exclusive license constitutes an "exclusive right." Yet Respondents focus on the word "grant" to argue that, historically, a "grant" was different than a license, so this Court should not consider a transfer of an exclusive license to be a "grant" of an "exclusive right" under Section 261. Resp. 24-25. In particular, Respondents argue that a "grant" cannot include a license, because back in the

1800s a “grant” was viewed as something distinct from a “license.” Resp. 24-25. Respondents then go so far as to assert that “[t]hen, as now, it was well understood that a ‘grant’ transfers an ownership interest in a patent,” but not a license. *Id.* at 24 (emphasis added). But Respondents are wrong and their argument contradicts the long-established usage of the term “grant” in intellectual property transactions to describe the transfer of exclusive licenses.

One need look no further than the Federal Circuit decision **in this case** to see that “grant” is a term that is commonly used to denote the transfer of exclusive patent licenses. The very statement from the Federal Circuit panel that frames the issue in this Petition uses the word “**grant**” to refer to a transfer of an exclusive license: “It is well established that the **grant of a license** does not need to be in writing.” App. 8 (emphasis added). Likewise, the 1980 Agreement between Goldfarb and Bard repeatedly uses the term “**grant**” to refer to transferring various types of license rights, including the exclusive patent rights at issue in this case:

- “WHEREAS, DR. GOLDFARB . . . has offered to **grant USCI exclusive, worldwide licenses . . .**” App. 125 (emphasis added).
- “**Grant.** DR. GOLDFARB hereby **grants** to USCI **worldwide, exclusive licenses . . .**” App. 127 (emphasis added).
- “USCI shall have the right in its sole discretion to file, control, defend and settle, by **granting a sublicense** or otherwise, all actions and claims against third parties for infringement of any

PATENTS . . .” App. 137 (emphasis added); *see also* App. 138.

Not surprisingly, this Court, the Federal Circuit, and other federal courts have also long recognized the word “grant” to apply to transfers of patent licenses, including exclusive licenses. *See, e.g., Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 135 (1969) (“We hold that conditioning the **grant of a patent license** upon payment of royalties on products which do not use the teaching of the patent does amount to patent misuse.”) (emphasis added); *Rite-Hite*, 56 F.3d at 1553 (“The **grant of a bare license** to sell an invention in a specified territory, even if it is the only **license granted** by the patentee, does not provide standing without the **grant of the right to exclude others.**”) (emphasis added); *Vulcan Mfg. Co. v. Maytag Co.*, 73 F.2d 136, 138 (8th Cir. 1934) (“[T]he Supreme Court has said that the patentee may **grant a license . . .**”) (emphasis added). And these are just examples. *See also, e.g., Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938) (referring to a “grant” of a “license”); *E. Bement & Sons v. Nat’l Harrow Co.*, 186 U.S. 70, 91 (1902) (same); *Day v. Union India Rubber Co.*, 61 U.S. 216, 217 (1857) (same); *Imation Corp. v. Koninklijke Philips Elecs. N.V.*, 586 F.3d 980, 985 (Fed. Cir. 2009) (same); *Kaempe v. Myers*, 367 F.3d 958, 965 (D.C. Cir. 2004) (same); *Mid-West Conveyor Co. v. Jervis B. Webb Co.*, 92 F.3d 992, 997 (10th Cir. 1996) (same); *Southern Research Inst. v. Griffin Corp.*, 938 F.2d 1249, 1252 (11th Cir. 1991) (same); *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 686 (Fed. Cir. 1986) (same); *Minnesota Min. & Mfg. Co. v. E. I. du Pont de Nemours & Co.*, 448 F.2d 54, 56-57 (7th Cir. 1971)

(same); *Fromberg, Inc. v. Thornhill*, 315 F.2d 407, 412 (5th Cir. 1963) (same); *Duncan Shaw Corp. v. Standard Mach. Co.*, 196 F.2d 147, 150 (1st Cir. 1952) (same); *Am. Chain & Cable Co. v. Rochester Ropes, Inc.*, 199 F.2d 325, 330 (4th Cir. 1952) (same); *Cutter Labs. v. Lyophile-Cryochem Corp.*, 179 F.2d 80, 93 (9th Cir. 1949) (same); *Frederick B. Stevens, Inc. v. Steel & Tubes, Inc.*, 114 F.2d 815, 819 (6th Cir. 1940) (same); *Cold Metal Process Co. v. United Eng'g & Foundry Co.*, 79 F.2d 666, 669 (3d Cir. 1935) (same); *Adriance, Platt & Co. v. Nat'l Harrow Co.*, 121 F. 827, 830 (2d Cir. 1903) (same); *Mine Safety Appliances Co. v. United States*, 364 F.2d 385, 391 (Ct. Cl. 1966) (same); *Washburn & Moen Mfg. Co. v. Wilson*, 19 F. 233, 234 (C.C.S.D.N.Y. 1884) (same); *Howe v. Newton*, 12 F. Cas. 670, 671 (C.C.D. Mass. 1865) (same).

Respondents' narrow reliance on cases and sources from the 1800s to argue for a departure from the ordinary and commonplace meaning of "grant" only highlights the need for review by this Court. *See* Resp. 24-25. And even on this point, Respondents are wrong to suggest that a more limited definition of "grant" was clear-cut in the 1800s; this Court itself referred to a party's ability to "grant [a] license" at least as far back as 1857. *See Day*, 61 U.S. at 217. By granting certiorari, the Court will be able to resolve any interpretive questions stemming from the use of "grant" in the 1800s.

Finally, Respondents' representation that Gore is the only litigant that has ever expressed concern with the Federal Circuit's treatment of exclusive licenses under Section 261 is not correct. In *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, a Federal Circuit panel

specifically noted that the appellant raised the “in like manner” provision of Section 261 to challenge the Federal Circuit’s rule that exclusive licenses do not need to be in writing, but the panel concluded that it was “bound to follow our precedent.” 288 Fed. Appx. 697, 706 (Fed. Cir. 2008). A leading patent law treatise also questions whether the Federal Circuit’s precedent is at odds with Section 261. 1 Annotated Patent Digest (Matthews) § 9:58 (2015).

C. The Correct Interpretation of Section 261 Would Promote Certainty in the Patent System.

Respondents’ own gamesmanship with respect to the ’135 patent provides a striking example of the uncertainty that the Federal Circuit’s incorrect interpretation of Section 261 brings to the patent system. The lack of a written exclusive license to IMPRA/BPV has allowed Respondents to make repeated contradictory statements to federal courts about which entity actually possesses exclusive rights to the patent, changing their position according to the needs of the situation. Pet. 10-13. The most recent example of Respondents’ manipulation of exclusive license status is the self-serving **oral** trial testimony of BPV’s president who, in trying to explain away Bard’s absence as a party to the 1997 agreement, testified (ten years after the fact) that Bard **orally** authorized him to enter into the 1997 agreement on Bard’s behalf. Pet. 30, n.10. This is precisely the type of “revisionist history” that Section 261’s written instrument requirement is intended to prevent. *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998).

Respondents have it backwards when they assert that imposing “a writing requirement on exclusive licenses at this late date would upset long-term business relationships and introduce confusion into the law.” Resp. 28. Nothing could be more confusing for courts and litigants than a constant guessing game as to what entity actually possesses exclusive rights that confer standing to assert a patent in federal court litigation. And nothing could be more uncertain for businesses than the current state of the law on Section 261, where the Federal Circuit requires one type of exclusive licenses—“virtual assignments”—to be in writing, but does not require other types of exclusive licenses to be in writing. Pet. 21; *Enzo*, 134 F.3d at 1093.³ As Federal Circuit law stands now, a grantee might believe it received an exclusive license through an oral transfer, only to later find out, after years of litigation, that what it obtained was actually a “virtual assignment,” which is now invalid because it was not in writing. The proper reading of Section 261 therefore brings certainty and consistency to all grants of exclusive licenses, by requiring that they all be in writing.

Respondents’ concern for the “long-term business relationships” of others is baseless. It would be

³ And determining whether an exclusive license is a “virtual assignment” or a regular exclusive license is a complex analysis with unpredictable results. See, e.g., *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1358-63 (Fed. Cir. 2010) (“Our prior decisions have never purported to establish a complete list of the rights whose holders must be examined to determine whether a licensor has transferred away sufficient rights to render an exclusive licensee the owner of a patent.”).

surprising if companies engaged in successful “long term business relationships” frequently depart from the sound business practice of putting the transfer of exclusive patent rights in writing. And if there are in fact other companies like Bard and BPV that have avoided putting exclusive patent rights in writing to allow them to adjust to the exigencies of the moment, that is exactly the conduct that Section 261 is meant to stop.

Finally, Respondents’ suggestion that this issue is better left to Congress misapprehends the situation. Congress **already** enacted Section 261 and expressly provided, in the plainest possible language, that a grant or conveyance of an “exclusive right”—which is the essence of an exclusive license—must be “by an instrument in writing.” It is the Federal Circuit’s deviation from this statutory requirement which must be corrected.

CONCLUSION

For the foregoing reasons and those stated in the Petition for writ of certiorari, the Petition should be granted.

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