

No. 19-1097

In the Supreme Court of the United States

ENZO LIFE SCIENCES, INC.,

Petitioner,

v.

BECTON, DICKINSON AND COMPANY,

Respondent.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT*

REPLY BRIEF FOR PETITIONER

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REPLY

When the *inter partes* review (“IPR”) scheme created by the Leahy-Smith America Invents Act (“AIA”) took effect on September 16, 2011, every unexpired patent in the United States—including U.S. Patent No. 7,064,197 (“the ’197 patent”), assigned to Enzo—lost a substantive, statutory right. Pub. L. No. 112-29, 125 Stat. 284 (2011). For the first time, accused infringers could invalidate patents in an adversarial, adjudicative proceeding without meeting the clear-and-convincing standard of proof. An issued patent’s presumption of validity when asserted against competitors—one of the statutory rights giving the government-granted property shape and effect—was gone. This case provides an ideal vehicle for this Court to answer whether eviscerating that right, as retroactive application of the AIA to patents issued before the enactment of that statute has done, violates the Due Process Clause of the Fifth Amendment. Respondents quibble over the Federal Circuit’s error below and the substantive nature of the standard of proof but do not persuasively demonstrate against granting certiorari on a question that this Court reserved two Terms ago. See *Oil States Energy Servs. LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018). This case presents that purely legal question for review. Enzo’s petition should be granted.

I. THE COURT OF APPEALS’ ERROR IN ADDRESSING THE TAKINGS CLAUSE— RATHER THAN THE DUE PROCESS CLAUSE—AT MOST COUNSELS FOR GVR, NOT FORFEITURE OF ENZO’S APPEAL

The United States agrees with Enzo that the Federal Circuit panel erred by addressing Enzo’s challenge of retroactive application of IPRs to pre-AIA patents under the Takings Clause rather than the vested rights doctrine of

the Due Process Clause.¹ (U.S. Opp’n 8.) The United States blames Enzo and argues that Enzo has forfeited its challenge. That is wrong. Enzo, Respondent BD, and the United States all briefed the Due Process Clause issue below; it was fully before the Federal Circuit and is properly the substance of Enzo’s present petition. At most, the panel’s error counsels for a GVR order so that the Federal Circuit can correctly analyze the due process arguments.

1. Enzo’s constitutional challenge has always rested on the vested rights doctrine’s prohibition on retroactivity, which is grounded in the Fifth Amendment.

The United States argues that Enzo forfeited its due process challenge before the Federal Circuit because Enzo’s opening brief did not explicitly cite the “Due Process Clause” and, thus, did not present a sufficiently “developed argument.” (U.S. Opp’n 9–11.) But Enzo’s opening brief below did assert that retroactive application of IPR to pre-AIA patents “cannot be squared with the principle of vested rights” and “unconstitutionally destroys already vested patent rights.” Enzo C.A. Br. 59–61. And, like this Court’s vested rights opinions, Enzo cited the Fifth Amendment. *Id.* at 61 (quoting *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928)). (See also Pet. 19 (collecting cases that applied due process remedies and cited generally the Fifth Amendment)). Rather than seeking just compensation for a taking, Enzo sought a ruling that the ’197 patent cannot

¹ Respondent BD contends that the Federal Circuit did not err because, BD postulates, the Federal Circuit’s reasoning regarding the Takings Clause in *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019), could extend to the Due Process Clause. (BD Opp’n 12–14.) But the panel did not extend *Celgene* to a Due Process Clause challenge; rather, after citing *Celgene*, the panel concluded that “retroactive application of IPR * * * is not an unconstitutional taking under the Fifth Amendment.” (Pet. App. 18a.)

constitutionally “be subject to *inter partes* review.” *Id.* at 61.

As the United States concedes (U.S. Opp’n 10), Enzo’s reply brief and its Notice of Supplemental Authority further made clear that Enzo’s constitutional challenge arose from the vested rights doctrine under the Due Process Clause. Enzo C.A. Reply Br. 25–30; Enzo Notice of Suppl. Authority, D.I. 88 (Aug. 14, 2019). The briefs below from the respondent and the United States also both addressed the constitutional challenge under the Due Process Clause. BD C.A. Br. 65–68; Gov’t C.A. Br. 16–31.

In ruling on Enzo’s appeal, the Federal Circuit panel did not treat Enzo’s constitutional arguments as waived; the panel did address a Fifth Amendment constitutional challenge. (Pet. App. 18a.) Although it erred by addressing the Takings Clause, rather than the Due Process Clause, the court of appeals plainly considered the constitutional issue properly before it—either by Enzo’s briefing or its own discretion. See *Bozeman Fin. LLC v. Fed. Reserve Bank of Atlanta*, 955 F.3d 971, 974–75 (Fed. Cir. 2020) (explaining that the court may exercise discretion to consider issues not raised in the opening brief); see also *Singleton v. Wulff*, 428 U.S. 106, 121 (1976) (“The matter of what questions may be taken up and resolved for the first time on appeal is one left primarily to the discretion of the court of appeals, to be exercised on the facts of the individual cases. We announce no general rule.”). The constitutional issue is, accordingly, also properly the subject of Enzo’s petition.

2. The United States argues that this Court should deny Enzo’s petition rather than “address a constitutional question that was not addressed below.” (U.S. Opp’n 9.) Despite the Federal Circuit’s error, this case presents an ideal vehicle for this Court to resolve the issue—a purely legal question of constitutionality that was fully briefed

below and has not been raised in other petitions for certiorari currently before the Court. (Pet. 34–35.)

Alternatively, an order granting certiorari, vacating the judgment below, and remanding the case to the Federal Circuit would allow the court of appeals to correct its error. See, e.g., *Price v. United States*, 537 U.S. 1152 (2003) (issuing GVR order where, as here, the federal respondent acknowledged that the court of appeals erred). Respondent suggests that “remand would be futile” because the Federal Circuit has recently addressed similar Due Process Clause challenges in other cases. (BD Opp’n 12 (citing *Collabo Innovations, Inc. v. Sony Corp.*, 778 F. App’x 954, 960–61 (Fed. Cir. 2019), petition for cert. pending, No. 19-601 (U.S. Nov. 4, 2019); *Arthrex, Inc. v. Smith & Nephew, Inc.*, 935 F.3d 1319, 1331–32 (Fed. Cir. 2019), petition for cert. pending, No. 19-1204 (U.S. Apr. 6, 2020)).) As Enzo explained in its petition, however, neither case presents the same issue: *Arthrex* concerns patents issued *after* the enactment of the AIA, and *Collabo* concedes that rational basis review is the governing test. (Pet. 35 & nn.12–13.)

Thus, a GVR order would not be futile: it would “assist[] the court below by flagging a particular issue that it does not appear to have fully considered [and] assist[] this Court by procuring the benefit of the lower court’s insight.” *Lawrence v. Chater*, 516 U.S. 163, 167 (1996) (per curiam).

II. RATHER THAN EFFECT A PROCEDURAL CHANGE, RETROACTIVE APPLICATION OF *INTER PARTES* REVIEW TO PRE-AIA PATENTS EVISCERATES A VESTED SUBSTANTIVE RIGHT

1. a. Respondents insist that the presumption of validity that attaches to patents at issuance cannot be a protected vested right because it manifests as a “procedural” standard applicable to the conduct of proceedings. (BD Opp’n 9–10; U.S. Opp’n 12–13.) That argument flatly contradicts this Court’s precedents. The assignment of the burden of proof, and the quantum of that proof, is a “rule of substantive law,” not merely a procedural rule. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 199 (2014) (quoting *Dir., Office of Workers’ Comp. Programs v. Greenwich Collieries*, 512 U.S. 267, 271 (1994)).

Although some burdens of persuasion are concerned with questions of “trial administration,” others are intended “to affect decision of the issue.” Cf. Restatement (Second) of Conflict of Laws § 133 (1971). Even where burdens of proof regulate “secondary conduct” during judicial proceedings to some degree (BD Opp’n 10), statutory provisions often assign presumptions for the very purpose of calibrating the scale to make certain outcomes more difficult to achieve than others. The clear and convincing standard required to invalidate a patent is one of them. It embeds the “universal” understanding that an accused infringer, who is motivated to attack the patent, ought to be held to a higher standard before he may secure revocation of a patent. *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 102–03 (2011) (“[A] preponderance standard of proof was too ‘dubious’ a basis to deem a patent invalid.”). That is a substantive rule, which the AIA

turned on its head by creating adversarial IPR proceedings without the presumption of validity.

b. Moreover, the standard of proof is also a substantive rule that affects the inventor's conduct at the time of patent application.

Statutory rules on patentability and patent term lengths necessarily delimit the bounds of issued patents. So, too, does the burden an accused infringer must meet to rebut an issued patent's validity. A negligible standard of proof, for example, would render a patent of little value due to the resulting difficulty in preserving its validity. Collectively, these statutory rules inform a patent applicant's decision whether to deprive the public and keep secret an invention or to accept the patent *quid pro quo* and increase the collective wealth of American ingenuity. The heightened standard of proof is "an essential component" of the "incentives for inventors to disclose their innovations to the public in exchange for patent protection." *Microsoft*, 564 U.S. at 112.

Thus, the presumption of validity and heightened standard of proof do not "stand[] on a different footing" from the patent itself. *Choate v. Trapp*, 224 U.S. 665, 674 (1912). They are among the vested substantive rights that constitute the patent grant.

2. Both BD and the Government also suggest that retroactive application of the AIA did not deprive Enzo of vested rights because the AIA did not alter the respective standards of proof applicable within district courts and PTO proceedings: "district courts continue to apply the clear-and-convincing standard" (U.S. Opp'n 14), and the '197 patent was "never subject to a presumption of validity in the PTO" (BD Opp'n 8; see also U.S. Opp'n 14).

Respondents urge the wrong comparisons. Preexisting reexamination procedures² provide the PTO opportunity to reevaluate the issuance of previously issued patents; IPRs are different. (See Pet. 8–13.) By congressional design, an IPR gifts patent challengers a friendlier “adjudicative” “alternative” to district court litigation. H.R. Rep. 98, pt. 1, 112th Cong., 1st Sess. 45 (2011). The critical change—the diminishment of the patent owner’s property right—lies in the standard that bulwarks a patent owner’s assertion of its property. After the AIA, an accused infringer who argues that an asserted patent is invalid now need only meet a preponderance standard of proof—a standard this Court has labelled “too ‘dubious’ a basis to deem a patent invalid” in adversarial proceedings. *Microsoft Corp.*, 564 U.S. at 102 (citing *Radio Corp. of Am. v. Radio Eng’g Labs.*, 293 U.S. 1, 8 (1934)). By permitting accused infringers to evade, through *inter partes* review, the higher standard of proof required to prove invalidity in district court litigation, the AIA gutted pre-AIA patents of a critical, substantive right.

3. Both BD and the Government argue that retroactive application of the AIA’s *inter partes* review scheme to preexisting patents withstands rational basis review. (BD Opp’n 10–11; U.S. Opp’n 11–12.) Neither, however, addresses—or even acknowledges—that this Court has not consistently applied rational basis review to Due Process Clause retroactivity challenges. As Enzo explained in its petition, this Court has also held, and this case presents an ideal opportunity to clarify, that the Due Process

² The application that led to the ’197 patent predated the enactment of *inter partes* reexamination. (Pet. 16.) Such patents were not subject to that proceeding. See American Inventors Protection Act of 1999, Pub. L. No. 106-113, tit. IV, § 4608, 113 Stat. 1501, 1501A-572. Any justification of the retroactive application of *inter partes* review to the ’197 patent based on the existence of *inter partes* reexamination is, therefore, inapposite to this case.

Clause prohibits retroactive laws that extinguish identifiable, vested property interests. (Pet. 27–29.) Because of the Fifth Amendment’s heightened emphasis on “property,” merely a rational basis cannot sustain retroactive legislation that strips away vested rights in a patent, such as its presumption of validity.

4. Finally, BD implies that Enzo’s petition should be denied because it “is a transitional issue of diminishing importance.” (BD Opp’n 11.) Patents expire every day, and every day the number of live patents that predate the AIA reduces. Those patent-holders, however, still have vested rights protected by the Constitution.

Enzo’s constitutional challenge to the AIA also implicates more than that diminishing pool of patents. If Congress may retroactively remove a right from those rights vested in an issued patent, public trust in the patent bargain will diminish. Fewer inventors will disclose their inventions. And Congress would be emboldened to enact other retroactive, substantive changes that diminish or destroy other previously granted property rights. Perhaps respondents will argue then, too, that this Court need not consider the constitutionality of those enactments because the affected patents will expire with time. Thus, the possibility that Congress’s retroactive enactments would evade review imbues the present petition with greater urgency—not less importance.

CONCLUSION

The petition should be granted, or, alternatively, the Court should issue a GVR order.

Respectfully submitted,

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