

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

“Over the last several decades, Congress has created administrative processes that authorize” the United States Patent and Trademark Office (PTO) “to reconsider and cancel patent claims that were wrongly issued.” *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1370 (2018). In 2011, the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, replaced one of those administrative processes with a new mechanism known as inter partes review, which applies “to any patent issued, before, on, or after” the AIA’s “effective date.” *Id.* § 6(c)(2)(A), 125 Stat. 304. Although inter partes review provides new procedures for reconsidering patents, it does not change the standard of review applicable in PTO reexamination proceedings or the substantive patentability standards.

The question presented is:

Whether Congress’s express decision to apply inter partes review to patents issued before the AIA’s effective date violates the Due Process Clause.

CORPORATE DISCLOSURE STATEMENT

Respondent Becton, Dickinson and Company has no parent corporation. T. Rowe Price is the only publicly held company that owns more than 10% of Respondent's stock.

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INTRODUCTION

Enzo does not challenge the Federal Circuit's detailed discussion of the evidence showing that its patent claims were unpatentable and never should have issued. Instead, Enzo argues that Congress violated the Due Process Clause when it permitted the United States Patent and Trademark Office (PTO) to reconsider the patentability of Enzo's claims in an inter partes review. Enzo's petition, however, rests on a false premise. Enzo never had a "vested right" to a presumption of validity in PTO proceedings to reconsider the validity of its patent. Nor do the procedural changes Congress applied to preexisting patents come close to establishing a Due Process violation. The petition should be denied.

For nearly forty years, patents have been issued subject to the possibility of reconsideration and cancellation by the PTO. Starting with ex parte reexamination proceedings before the PTO, patents have never enjoyed the presumption of validity that is, by statute, applicable in infringement litigation in district court, *see* 35 U.S.C. § 282. In 2011, Congress enacted the Leahy-Smith America Invents Act (AIA), which created a new mechanism for the PTO to reconsider previously issued patents: inter partes review. Inter partes review replaced inter partes reexamination without altering the underlying substantive patentability standards that apply when a patent is first examined or reconsidered in reexamination proceedings. It merely allowed for more participation by the party challenging the patent, using some of the traditional tools found in adversarial proceedings. *See Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1378 (2018).

Congress expressly decided to make all patents subject to inter partes review by specifying that it “shall apply to any patent issued before, on, or after [the Act’s] effective date.” Pub. L. No. 112-29, § 6(c)(2)(A), 125 Stat. 304. This provision, Enzo contends, violates the Due Process Clause of the Constitution because it retroactively “eviscerates” the presumption of validity, which Enzo claims is a “vested patent right,” subject to due process protection. Pet. 24.

A fundamental flaw with Enzo’s theory, however, is that since its issuance, Enzo’s patent has *never* been guaranteed a presumption of validity in the PTO. The patent was issued over two decades *after* the creation of ex parte reexamination, where no presumption of validity applies. Thus, Enzo’s argument fails on its own terms. Even if the vested rights doctrine protected statutory standards of proof, there has been no “retroactive diminishment” (Pet. 24) in this case. Rather, the AIA’s inter partes review provisions impose new procedures that are applied *prospectively*, which does not give rise to due process concerns. And even if that were not the case, there would be no due process violation because Congress’s choice to apply inter partes review to pre-AIA patents is justified by a rational legislative purpose.

Enzo alternatively suggests that this Court should vacate the judgment below as an exercise of error correction because the court of appeals referenced the Takings Clause in its decision instead of the Due Process Clause. Pet. 18-19. This request should also be denied. Because Federal Circuit precedent squarely forecloses Enzo’s due process claim, its request for fact-bound error correction is futile. In any event, there is no error in this case to correct. The case on which the Federal Circuit relied may have been a Takings case,

but its reasoning forecloses due process claims as well. Moreover, Enzo can hardly complain of inexactitude when it raised its constitutional challenge only briefly in the Federal Circuit and did not expressly mention the Due Process Clause until its reply brief. *See* Pet. C.A. Br. 59-61; Pet. C.A. Reply Br. 27. The petition should accordingly be denied.

STATEMENT

A. The PTO's Post-Issuance Review Procedures

Under the Patent Act of 1952, the United States Patent and Trademark Office (PTO) is “responsible for the granting and issuing of patents.” 35 U.S.C. § 2(a)(1). When determining whether a patent should issue, the PTO reviews the application and assesses whether, in light of prior art, the claims satisfy the Patent Act’s substantive requirements, including novelty and non-obviousness. *Id.* §§ 101-103. If the application meets all of the requirements, the Director of the PTO “shall issue a patent.” *Id.* § 131.

“Sometimes, though, bad patents slip through.” *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018). Congress has accordingly established multiple administrative proceedings under which the PTO may “reexamine—and perhaps cancel—a patent claim that it had previously allowed.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137 (2016).

One of these administrative proceedings is *ex parte* reexamination. Created in 1980 and still in effect today, *ex parte* reexamination permits “[a]ny person at any time” to “file a request for reexamination” of an issued patent based on “prior art ... bearing on [its] patentability.” 35 U.S.C. §§ 301(a)(1), 302; *see also* Act of Dec.

12, 1980 (1980 Act), Pub. L. No. 96-517, 94 Stat. 3015. The Director may also revisit the question of patentability at “any time” “[o]n his own initiative.” 35 U.S.C. § 303(a). If the PTO Director finds that there is a “substantial new question of patentability,” the PTO may reexamine the patent. *Id.* “The reexamination process” then “follows the same procedures as the [PTO’s] initial examination.” *Oil States*, 138 S. Ct. at 1370 (citing 35 U.S.C. § 305). Accordingly, unlike in infringement litigation, the statutory presumption of validity in 35 U.S.C. § 282 does not apply. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 605 (Fed. Cir.), *reh’g granted in part on other grounds*, 771 F.2d 480 (Fed. Cir. 1985).

When Congress established *ex parte* reexamination, the statute authorized the PTO to reexamine all “patents in force as of” the statute’s effective “date or issued thereafter.” 1980 Act, § 8(b), 94 Stat. 3027. Owners of patents issued prior to that effective date subsequently raised various constitutional challenges, including under the Due Process Clause and Takings Clause. Those challenges were all rejected by the Federal Circuit. *See Joy Techs., Inc. v. Manbeck*, 959 F.2d 226, 228 (Fed. Cir.), *cert denied*, 506 U.S. 829 (1992); *Patlex*, 758 F.2d at 602-603.

In 1999, Congress established a second administrative reconsideration proceeding, called *inter partes* reexamination. Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, §§ 4601-4608, 113 Stat. 1501A-567 to 1501A-572; *see also* Patent and Trademark Office Authorization Act of 2002, Pub. L. No. 107-273, §§ 13101-13106, 116 Stat. 1899-1901. *Inter partes* reexamination was similar to *ex parte* reexamination, but it provided “third parties greater oppor-

tunities to participate in the ... proceedings.” *Cuozzo*, 136 S. Ct. at 2137.

In 2011, the Leahy-Smith America Invents Act (AIA) replaced inter partes reexamination with the procedure at issue in this case: inter partes review. *See* Pub. L. No. 112-29, 125 Stat. 284. “Any person other than the patent owner can file a petition for inter partes review.” *Oil States*, 138 S. Ct. at 1371 (citing 35 U.S.C. § 311(a)). The PTO Director may institute review proceedings if he finds “that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged.” 35 U.S.C. § 314(a); *see also* *Cuozzo*, 136 S. Ct. at 2140.

Inter partes review proceedings take place before the Patent Trial and Appeal Board. 35 U.S.C. § 316(e). The proceedings permit the petitioner and patent owner to conduct limited discovery, submit evidence and written briefs, and participate in an oral hearing before the Board. *See id.* § 316(a)(5), (8), (10). The petitioner must ultimately prove unpatentability by a preponderance of the evidence. *Id.* § 316(e). Thus, like in ex parte reexamination, the presumption of validity does not apply.

The inter partes review provisions of the AIA became effective on September 16, 2012. § 6(c)(2)(A), 125 Stat. 304. Consistent with its approach to adopting ex parte reexamination, Congress provided that inter partes review “shall apply to any patent issued before, on, or after that effective date.” *Id.*

B. Proceedings Below

Petitioner Enzo Life Sciences, Inc. is the holder of U.S. Patent No. 7,064,197 (the ’197 patent), which “relates generally to the detection of genetic material by

polynucleotide or oligonucleotide probes.” Pet. App. 21a-22a. When the patent was issued on June 20, 2006, it was subject to possible cancellation through *ex parte* reexamination, but Congress had not yet created *inter partes* review.

In 2016, after the AIA had taken effect, Hologic, Inc. filed two petitions for *inter partes* review of the ’197 patent. The Patent Trial and Appeal Board subsequently instituted *inter partes* review proceedings, and Becton, Dickinson and Company (BD) joined the proceedings as Hologic’s co-petitioner. At the conclusion of the proceedings, the Patent Trial and Appeal Board determined that the challenged claims were unpatentable as either anticipated or obvious in light of the prior art. Pet. App. 19a-143a.

Enzo appealed, contending primarily that the Board erred in finding the claims unpatentable. *See* Pet. C.A. Br. 23-58. Enzo also briefly argued—in the final three brief pages of its principal brief—that “the retroactive application of the AIA to pre-AIA patents ... unconstitutionally destroys ... vested patent rights.” *Id.* at 59-61. Enzo did not specifically mention the Due Process Clause in its opening brief.¹

The Federal Circuit affirmed the Board’s decision in all respects. *See* Pet. App. 1a-18a. It held that an article published in 1981 anticipated most of Enzo’s patent claims, and rendered the remaining claims obvious, either alone or in combination with other references. Pet. App. 4a n.1, 7a-17a. The Federal Circuit also rejected Enzo’s constitutional challenge, citing the recent

¹ The federal government intervened to defend the constitutionality of *inter partes* review, and Hologic later withdrew from the case. *See* Pet. App. 5a-6a.

decision in *Celgene Corp. v. Peter*, 931 F.3d 1342, 1362 (Fed Cir. 2019), *petition for cert. pending*, No. 19-1074 (U.S. Feb. 26, 2020). *See* Pet. App. 18a. Issued while Enzo’s appeal was pending, *Celgene* held that the “retroactive application” of inter partes review to “pre-AIA patents is not an unconstitutional taking under the Fifth Amendment.” 931 F.3d at 1362. In reaching that conclusion, the *Celgene* court explained that, “[f]or forty years,” patent owners have been under the expectation “that the PTO could reconsider the validity of issued patents on particular grounds, applying a preponderance of the evidence standard.” *Id.* at 1362-1363. The *Celgene* court also cited prior Federal Circuit decisions “reject[ing] constitutional challenges to retroactive application of the pre-AIA *ex parte* reexamination mechanism.” *Id.* at 1358 (citing *Joy Techs.*, 959 F.2d at 228-229; *Patlex*, 758 F.2d at 603-605). Those prior decisions, the *Celgene* court said, “control[led] the outcome” with respect to inter partes review. *Id.* Thus, “application of [inter partes review] proceedings to the ’197 patent ... is not an unconstitutional taking under the Fifth Amendment.” Pet. App. 18a.

ARGUMENT

The question of whether the application of inter partes review to a pre-AIA patent violates the Due Process Clause was previously presented in the cert petition filed in *Collabo Innovations, Inc. v. Sony Corp.*, No. 19-601 (U.S. Nov. 4, 2019). BD does not here endeavor to repeat all of the convincing arguments that the government made in opposing cert in *Collabo*, and may make in some form again here. Instead, BD focuses on several core deficiencies that are fatal to Enzo’s petition.

I. INTER PARTES REVIEW DOES NOT RETROACTIVELY DIMINISH THE PRESUMPTION OF VALIDITY

1. Enzo's entire petition is constructed around an incorrect factual premise. Enzo argues that that the application of inter partes review to its pre-AIA patent "eviscerates" its vested right to a presumption of validity under 35 U.S.C. § 282. Pet. 24. But when the '197 patent was issued in 2006, it was already subject to possible cancellation in ex parte reexamination proceedings, where no presumption of validity applies. See *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 605 (Fed. Cir. 1985); 1980 Act, Pub. L. No. 96-517, 94 Stat. 3015. Accordingly, a presumption of validity in administrative proceedings was not a part of the "bundle of rights" (Pet. 21) that vested when Enzo was granted the '197 patent.

Enzo's reliance on "vested rights" cases such as *Ward v. Board of County Commissioners*, 253 U.S. 17 (1920), or *Choate v. Trapp*, 224 U.S. 665 (1912), is thus misplaced. See Pet. 20-21. Both of those cases involved tax exemptions created by a statute under which Native Americans' equitable interest in land held collectively by the Tribe was exchanged for individual, non-taxable parcels. See *Choate*, 224 U.S. at 677; see also *id.* at 668-670; *Ward*, 253 U.S. at 19. In contrast, the presumption is not "a property right subject to the protection of the Constitution." *Patlex*, 758 F.2d at 605. More importantly, there is no need to reach that question because Enzo's patent was never subject to a presumption of validity in the PTO. Any such presumption had been eliminated when ex parte reexamination was created in 1980, long before the AIA was enacted and long before the '197 patent was issued. Enzo's due process claim, in other words, is grounded in a right that Enzo

never possessed. For that reason alone, Enzo's due process claim fails.

2. Presumably aware of this fatal defect, Enzo attempts to move the goalposts by arguing that the AIA diminished its right to a presumption of validity "*in adversarial proceedings*." Pet. 22 (emphasis added). According to Enzo, because the presumption of validity applies in infringement litigation, and because inter partes review in some ways resembles litigation, the presumption must apply in inter partes review too. Or put differently, Enzo's argument is that the '197 patent must now—for the first time since the patent was issued in 2006—be presumed valid in PTO proceedings because inter partes review has made the PTO's procedures too much like those used in civil litigation.

This contention is just a dressed-up version of an argument against application of the *procedures* that govern inter partes review. "No one has a vested right in any given mode of procedure." *Denver & Rio Grande W. R.R. Co. v. Brotherhood of R.R. Trainmen*, 387 U.S. 556, 563 (1967). Indeed, "[b]ecause rules of procedure regulate secondary rather than primary conduct, the fact that a new procedural rule was instituted after the conduct giving rise to the suit does not make application of the rule at trial retroactive." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 275 (1994). The retroactivity inquiry is instead "whether the new provision attaches new legal consequences to events completed before its enactment." *Id.* at 270. "Changes in procedural rules" generally do not have such effect, so they "may often be applied in suits arising before their enactment" without raising due process concerns. *Id.* at 275.

McClurg v. Kingsland, 42 U.S. (1 How.) 202 (1843)—which Enzo cites (Pet. 21)—actually confirms this notion. There, this Court stated that the patent dispute at issue “must depend on the law as it stood at the emanation of the patent, *together with such changes as ha[d] been since made.*” 42 U.S. (1 How.) at 206 (emphasis added). The Court further made clear that it was “not a sound objection” to say that subsequently enacted procedural rules “may be retrospective in their operation.” *Id.* The Court accordingly held that provisions of a new statute that “prescribe[d] the rules which must govern on the trial of actions for the violation of patented rights” would apply, regardless of whether the patent at issue was “granted before or after [the statute’s] passage.” *Id.* at 207.

The same thing has occurred here. In reconsidering the ’197 patent’s validity, the PTO applied the AIA’s revised inter partes review procedures. Even though those new procedures had not been enacted at the time the patent was issued, they have *prospective* effect, because the “secondary ... conduct” that they regulate is the PTO administrative proceedings themselves. *See Landgraf*, 511 U.S. at 275. That the new procedures may be, in Enzo’s words, more “adversarial” (Pet. 5) is constitutionally immaterial. Rather, what matters for constitutional purposes is whether the AIA imposes new substantive “legal consequences” on patents issued before the statute was passed. *See id.* at 270. It does not: Inter partes review involves the same substantive standards of patentability that were in effect when the ’197 patent was issued. Accordingly, subjecting the ’197 patent to inter partes review comports with due process.

3. Even if the AIA’s inter partes review provisions did have retroactive effect, they would still be

constitutional. Retroactive legislation violates the Due Process Clause only if its retroactive effect is not “justified by a rational legislative purpose.” *Pension Benefit Guar. Corp. v. R. A. Gray & Co.*, 467 U.S. 717, 730 (1984).

In this case, Congress reasonably believed that, under the previous regime, “questionable patents [were] too easily obtained and ... too difficult to challenge.” H.R. Rep. No. 112-98, pt. 1, at 39 (2011). It therefore created inter partes review to provide “a more efficient system for challenging patents that should not have issued.” *Id.* at 39-40. Having decided to establish that system, it also was rational for Congress to make it applicable to patents that had already been improperly granted. Such a scheme is simpler for the PTO to administer, and it furthers the public’s “paramount interest in seeing that patent monopolies are kept within their legitimate scope,” *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 203 (2014) (citation omitted). In light of that interest, it certainly was reasonable for Congress to maximize inter partes review’s reach. That is sufficient for due process purposes.

4. In addition to being meritless, Enzo’s due process challenge is a transitional issue of steadily diminishing importance. The AIA was enacted nearly nine years ago, *see* 125 Stat. 284, and most patents have a term of twenty years from filing (plus any term extensions), *see* 35 U.S.C. §§ 154(a)(2), 156. Thus, many pre-AIA patents have already expired, and the category itself is continuously shrinking. This is not to say that pre-AIA patents are rare, but with every day that passes, the number of pre-AIA patents subject to inter partes review diminishes.

II. THE COURT OF APPEALS COMMITTED NO ERROR

Independent of the merits of its due process claim, Enzo also urges this Court to vacate the judgment below because the court of appeals referenced the Takings Clause in its decision instead of the Due Process Clause. Pet. 18-19. The Court should disregard this request for fact-bound error correction for several reasons.

1. First, with good reason, this Court generally does not devote its scarce time and resources to addressing requests for fact-bound error correction. See Shapiro et al., *Supreme Court Practice* § 5.12(c)(3) (11th ed. 2019) (“[E]rror correction ... is outside the mainstream of the Court’s functions” and “not among the ‘compelling reasons’ (Rule 10) that govern the grant of certiorari.”).

2. Second, a remand would be futile. By the time the opinion in Enzo’s appeal was issued, the Federal Circuit had already relied on *Celgene* to reject a different pre-AIA patent owner’s due process challenge to inter partes review. See *Collabo Innovations, Inc. v. Sony Corp.*, 778 F. App’x 954, 960-961 (Fed. Cir. 2019), *petition for cert. pending*, No. 19-601 (U.S. Nov. 4, 2019). Another panel then reached the same conclusion in a published opinion issued the week after the decision in Enzo’s case. See *Arthrex, Inc. v. Smith & Nephew, Inc.*, 935 F.3d 1319, 1331-1332 (Fed. Cir. 2019), *petition for cert. pending*, No. 19-1204 (U.S. Apr. 6, 2020). As *Collabo* and *Arthrex* make clear, *Celgene* and its predecessors render a due process challenge to inter partes review untenable. Any remand would therefore be futile.

3. Third, as these decisions make clear, there is no error warranting correction here. To the extent the

Federal Circuit did not consider Enzo's argument waived, *see infra* pp. 14-15, the Federal Circuit was correct to conclude that *Celgene* foreclosed Enzo's constitutional challenge. *Celgene*'s core holding may have been grounded in the Takings Clause, but its reasoning applies equally to due process claims.

Just like Enzo does here, the *Celgene* patent owner stressed "that the presumption of validity that applies in district court proceedings ... does not apply in" inter partes review. *Celgene*, 931 F.3d at 1362. In rejecting that argument, the *Celgene* court reasoned that "the presumption of validity" already "did not apply in the preexisting [ex parte] reexamination proceedings," and that, in any event, the presumption is not "a property right subject to the protection of the Constitution." *Id.* (quoting *Patlex*, 758 F.2d at 605). Enzo's vested rights theory fails for the same reasons. *See supra* pp. 8-9.

Similar to Enzo's focus on "adversarial proceedings" (Pet. 22), the *Celgene* patent owner further argued that inter partes review has "adjudicatory characteristics," *Celgene*, 931 F.3d at 1361. But the *Celgene* court correctly responded that those characteristics were mere "procedural differences," and it cited the "longstanding recognition that '[n]o one has a vested right in any given mode of procedure.'" *Id.* (quoting *Denver & Rio Grande*, 387 U.S. at 563). The same logic also applies to Enzo's due process claim. *See supra* pp. 9-10.

Finally, the *Celgene* court took note of the Federal Circuit's "prior decisions ... that rejected constitutional challenges to retroactive application of ... *ex parte* reexamination." 931 F.3d at 1358. Those earlier decisions included not only a failed Takings Clause challenge, *id.* at 1358 n.13 (citing *Joy Techs. Inc. v.*

Manbeck, 959 F.2d 226, 228-229 (1992)), but also a case involving “the due process clause of the Fifth Amendment, the jury trial guarantee of the Seventh Amendment, [and] Article III,” *id.* (citing *Patlex*, 758 F.2d at 602-605). As the *Celgene* court observed, the patent owners in those earlier cases actually “had a stronger argument” than the current challenges brought by pre-AIA patent owners “because, before the creation of *ex parte* reexaminations, there were no PTO reexamination procedures.” *Id.* “In contrast,” the court said, “pre-AIA patent owners ... have known for almost forty years that their patents were issued subject to substantively similar forms of PTO reexamination.” *Id.* Thus, the prior decisions involving *ex parte* reexamination “control[led] the outcome” with respect to *inter partes* review. *Id.* at 1358.

4. Fourth, any imprecision was Enzo’s own doing. Enzo raised its constitutional challenge in only the final three pages of its opening brief below, and, in those three pages, it did not clearly identify the exact source of its challenge. *See* Pet. C.A. Br. 59-61. Indeed, in that opening brief, Enzo cited the Fifth Amendment just one time, and it never used the phrase “due process.” *See id.* When Enzo finally did mention “due process” in its reply brief, it did so only once—in a sentence that also invoked the Takings Clause. Pet. C.A. Reply Br. 27.²

² Enzo makes much of the fact that it eventually did inform the court of appeals that its claim was grounded in the Due Process Clause—in an August 14, 2019 letter to the clerk. *See* Pet. 15, 18; C.A. Dkt. 88. But that was a mere two days before the Federal Circuit issued its opinion, and far too late for Enzo to be clarifying the basis for its challenge, which should have been made clear in its opening brief.

Thus, as BD observed in its own brief before the Federal Circuit, “[t]he exact constitutional basis of Enzo’s challenge [was] unclear.” Resp. C.A. Br. 67 n.8. It rings hollow, then, for Enzo to complain that the court of appeals “erred by relying on a Takings Clause case to reject Enzo’s due process arguments.” Pet. 18. Having contributed to the supposed “error” (Pet. 19), Enzo cannot now ask this Court to fix it. *Cf. Puckett v. United States*, 556 U.S. 129, 134 (2009) (discussing, in context of contemporaneous objection rule, judicial interest in discouraging “sandbagging” (citation omitted)).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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