

No. 19-1097

In the Supreme Court of the United States

ENZO LIFE SCIENCES, INC., PETITIONER

v.

BECTON, DICKINSON AND COMPANY, ET AL.

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

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

For almost four decades, the United States Patent and Trademark Office (USPTO) has “possessed the authority to reexamine—and perhaps cancel—a patent claim that it had previously allowed.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137 (2016). In the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, Congress replaced one of the existing mechanisms for administrative reconsideration of issued patents with a new administrative reconsideration proceeding known as inter partes review. Congress further provided that inter partes review “shall apply to any patent issued before, on, or after th[e] effective date” of the AIA. § 6(c)(2)(A), 125 Stat. 304. The question presented is as follows:

Whether Congress’s decision to authorize the USPTO to conduct inter partes review of patents issued before the AIA’s effective date is irrational, and thus violates the Due Process Clause.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-18a) is not published in the Federal Reporter but is reprinted at 780 Fed. Appx. 903. The decisions of the United States Patent and Trademark Office (Pet. App. 19a-81a; 82a-143a) are not published in the United States Patents Quarterly but are available at 2017 WL 4339646 and 2017 WL 4407743.

JURISDICTION

The judgment of the court of appeals was entered on August 16, 2019. A petition for rehearing was denied on December 4, 2019 (Pet. App. 144a-145a). The petition for a writ of certiorari was filed on March 3, 2020. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. The Intellectual Property Clause of the Constitution authorizes Congress to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. Const. Art. I, § 8, Cl. 8. Pursuant to that authorization, Congress has enacted and periodically amended the Patent Act of 1952 (Patent Act), 35 U.S.C. 1 *et seq.*, which assigns to the United States Patent and Trademark Office (USPTO) responsibility “for the granting and issuing of patents.” 35 U.S.C. 2(a)(1). To determine whether patents should issue, USPTO personnel review applications to assess their compliance with the Act’s subject-matter requirements and conditions of patentability, such as utility, novelty, and non-obviousness in light of prior art. See 35 U.S.C. 101 (patent-eligible subject matter and utility), 102 (novelty), 103 (non-obviousness). If an application satisfies all of those criteria, the Director of the USPTO “shall issue a patent.” 35 U.S.C. 131.

The USPTO reviews more than 600,000 patent applications each year. See USPTO, *FY 2019 Performance and Accountability Report* 29 (2019) (table). Occasionally, the USPTO issues a patent for a putative invention that does not actually satisfy the statutory criteria. The Patent Act accordingly provides “several avenues by which [a patent’s] validity can be revisited.” *Return Mail, Inc. v. United States Postal Serv.*, 139 S. Ct. 1853, 1859 (2019).

First, in an infringement action brought by the patent holder, the person accused of infringement may assert as a defense the “[i]nvalidity of the patent or any claim in suit” based on a failure to meet a “condition for patentability.” 35 U.S.C. 282(b)(2). In that setting, a

court may declare the patent invalid if the defendant proves by clear and convincing evidence “that the patent never should have issued in the first place.” *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 96 (2011); see 35 U.S.C. 282(a) (providing that in infringement actions “[a] patent shall be presumed valid”). A final judicial determination of invalidity renders the patent unenforceable against all others. See *Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313 (1971).

Second, for almost four decades, the USPTO has “possessed the authority to reexamine—and perhaps cancel—a patent claim that it had previously allowed.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137 (2016). In 1980, Congress first established an administrative reconsideration procedure known as *ex parte* reexamination, which permits “[a]ny person at any time” to “file a request for reexamination” of an issued patent in light of prior art “bearing on [its] patentability.” 35 U.S.C. 301(a)(1), 302; see Act of Dec. 12, 1980 (1980 Act), Pub. L. No. 96-517, 94 Stat. 3015 (35 U.S.C. 301 *et seq.*). The Director may institute reexamination proceedings based on that third-party request, or on his own initiative, if he finds “a substantial new question of patentability.” 35 U.S.C. 303(a). If the USPTO concludes that the challenged patent claims are unpatentable, the Director—following the opportunity for review by the Federal Circuit—cancels those claims. 35 U.S.C. 306, 307(a).

The statute that created the *ex parte* reexamination mechanism authorized the USPTO to reexamine all “patents in force as of th[e] [effective] date or issued thereafter.” 1980 Act § 8(b), 94 Stat. 3027 (effective date of July 1, 1981). The Federal Circuit subsequently held

that neither the Due Process Clause nor the Just Compensation Clause barred *ex parte* reexamination of patents issued before the reexamination statute was enacted. See *Joy Techs., Inc. v. Manbeck*, 959 F.2d 226, 228 (Fed. Cir.), cert. denied, 506 U.S. 829 (1992); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 602-603 (Fed. Cir.), modified, aff'd in part and rev'd in part on other grounds, 771 F.2d 480 (Fed. Cir. 1985).

In 1999 and 2002, Congress established an additional reconsideration procedure known as *inter partes* reexamination. See Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, Div. B, § 1000(a)(9) [Tit. IV, Subtit. F, §§ 4601 *et seq.*], 113 Stat. 1536, 1501A-567 (35 U.S.C. 311 *et seq.*); Patent and Trademark Office Authorization Act of 2002, Pub. L. No. 107-273, Div. C, Tit. III, Subtit. A, §§ 13105-13106, 116 Stat. 1900. *Inter partes* reexamination similarly permitted third parties to request that the Director institute USPTO reexamination proceedings based on prior art, and authorized him to cancel unpatentable claims following an opportunity for judicial review. See 35 U.S.C. 316(a) (2006). *Inter partes* reexamination, however, “granted third parties greater opportunities to participate in the [USPTO’s] reexamination proceedings as well as in any appeal.” *Cuozzo*, 136 S. Ct. at 2137.

b. In 2011, Congress enacted the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284. As relevant here, the AIA “modifies ‘*inter partes reexamination*,’” and “now calls [it] ‘*inter partes review*.’” *Cuozzo*, 136 S. Ct. at 2137; see AIA § 6(a), 125 Stat. 299. Congress authorized *inter partes* review to provide “a more efficient system for challenging patents that

should not have issued.” H.R. Rep. No. 98, 112th Cong., 1st Sess. Pt. 1, at 39-40 (2011) (House Report).

Any person other than the patent owner may petition for inter partes review of an issued patent on the ground that the invention was not novel or was obvious under Section 102 or 103 of the Patent Act in light of “prior art consisting of patents or printed publications.” 35 U.S.C. 311(b); see 35 U.S.C. 102, 103, 312. If the Director finds a “reasonable likelihood” that the petitioner can establish the unpatentability of “at least 1 of the claims challenged in the petition,” he may institute review proceedings. 35 U.S.C. 314(a).

The Patent Trial and Appeal Board (Board) of the USPTO then conducts inter partes review proceedings to determine the patentability of the challenged claims. 35 U.S.C. 316(c). The petitioner and patent owner may conduct limited discovery, submit briefs and evidence, and obtain an oral hearing. See 35 U.S.C. 316(a)(5), (8) and (10). The petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. 316(e). The patent owner may seek to amend the patent by “propos[ing] a reasonable number of substitute claims.” 35 U.S.C. 316(d)(1)(B). If the Board ultimately issues a final written decision determining the patentability of each challenged claim, a dissatisfied party may appeal to the United States Court of Appeals for the Federal Circuit. 35 U.S.C. 318(a), 319. When judicial review is complete or the time for appeal has expired, the Director cancels any patent claims determined to be unpatentable. 35 U.S.C. 318(b).

The AIA’s inter partes review provisions took effect on September 16, 2012. See AIA § 6(c)(2)(A), 125 Stat. 304. As the 1980 Act did with ex parte reexamination, the AIA specifies that inter partes review “shall apply

to any patent issued before, on, or after that effective date.” *Ibid.*

2. a. Petitioner Enzo Life Sciences, Inc. filed a patent application in 1995, and the USPTO issued U.S. Patent No. 7,064,197 ('197 patent) in 2006. C.A. App. 112.

In July 2012, petitioner brought an infringement action against respondent Becton, Dickinson and Company, alleging infringement of the '197 patent. See 12-cv-275 D. Ct. Doc. 10 (D. Del. July 16, 2012). Another company, Hologic, Inc., subsequently filed two petitions for inter partes review of the '197 patent, and the Board permitted respondent to join those proceedings. Pet. App. 4a; see C.A. App. 137, 3790; see also C.A. App. 613, 4184. The Director instituted review in October 2016, see Pet. App. 20a; C.A. App. 300, 3948, and the infringement action has been stayed during the pendency of the inter partes review proceedings and subsequent appeals, see 12-cv-275 D. Ct. Doc. 338 (D. Del. July 31, 2017).

b. In separate decisions issued in September and October 2017, the Board determined “by a preponderance of the evidence that all of the challenged claims of the '197 patent are unpatentable.” Pet. App. 80a, 142a. In assessing patentability, the Board first gave the patent claims their “broadest reasonable construction.” *Id.* at 26a, 89a; see *Cuozzo*, 136 S. Ct. at 2146.¹ After construing the patent claims, see Pet. App. 26a-36a, 89a-98a, the Board analyzed the challenged claims and

¹ The USPTO has since amended the regulations governing inter partes review to provide that, when conducting reviews in response to petitions filed on or after November 13, 2018, the Board will construe disputed patent claims using the same ordinary-meaning standard that applies in district-court litigation. See 83 Fed. Reg. 51,340 (Oct. 11, 2018) (37 C.F.R. 42.100(b)).

determined that those claims were unpatentable under Sections 102 and 103(a) in light of prior art, see *id.* at 36a-79a, 98a-141a.

3. The court of appeals affirmed the Board's decisions. Pet. App. 1a-18a. The court held that substantial evidence supported the Board's findings that several patent claims were unpatentable because they were disclosed in prior art, see *id.* at 7a-12a, and that the Board had correctly concluded that other claims were unpatentable as obvious, see *id.* at 12a-17a.

The court of appeals also rejected petitioner's challenge, raised for the first time on appeal, that the application of inter partes review to its pre-AIA patent violated the Fifth Amendment. Pet. App. 18a. Petitioner's opening brief did not specify the clause of the Fifth Amendment that inter partes review purportedly violated, but the brief cited decisions of this Court that had addressed the Just Compensation Clause. See Pet. C.A. Br. 59-61 (alleging "violation of the Fifth Amendment" and citing *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331 (1928); and *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 206 (1843)). The court of appeals understood petitioner to allege "an unconstitutional taking under the Fifth Amendment." Pet. App. 18a. The court concluded that its then-recent decision in *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019), petition for cert. pending, No. 19-1074 (filed Feb. 26, 2020), foreclosed petitioner's constitutional challenge. Pet. App. 18a.

In *Celgene*, the Federal Circuit had acknowledged that inter partes review differs from both district court proceedings and prior administrative validity proceedings, but had concluded "that these differences are not sufficiently substantive or significant to constitute a

taking.” 931 F.3d at 1360. The *Celgene* court had also relied on prior Federal Circuit decisions rejecting Just Compensation Clause challenges to the use of ex parte reexamination for patents issued before the reexamination statute’s enactment. *Id.* at 1358 n.13; see *Joy Techs.*, 959 F.2d at 228; *Patlex*, 758 F.2d at 602-603. The Federal Circuit also noted patent owners’ longstanding expectations that their patents could be challenged in district court, and that “the [USPTO] could reconsider the validity of issued patents on particular grounds, applying a preponderance of the evidence standard.” *Celgene*, 931 F.3d at 1363. In holding that petitioner’s Fifth Amendment claim is foreclosed, the court of appeals explained in the decision here that *Celgene* “is now precedent that governs this case.” Pet. App. 18a.

ARGUMENT

Petitioner contends (Pet. 18-24) that the use of inter partes review to reconsider patents issued before the AIA was enacted violates the Due Process Clause. The court of appeals did not address that question below, and petitioner forfeited its current challenge by failing to present it clearly in its opening brief in the court of appeals. In any event, petitioner’s contentions lack merit, because the changes that Congress made to the ways in which the USPTO can review the validity of previously issued patents were not irrational and did not deprive petitioner of any vested right. Further review is not warranted.²

² Other petitions raising related challenges are pending in *Collabo Innovations, Inc. v. Sony Corp.*, petition for cert. pending, No. 19-601 (filed Nov. 4, 2019), and *Celgene Corp. v. Peter*, petition for cert. pending, No. 19-1074 (filed Feb. 26, 2020). The United States has opposed certiorari in those cases as well.

1. a. Petitioner contends (Pet. 18-31) that this Court should grant certiorari to decide whether application of inter partes review to patents issued before the AIA's enactment violates the Due Process Clause. As petitioner acknowledges, however, the court of appeals did not address that issue. See Pet. 16 (noting that the court of appeals' opinion "did not address Enzo's vested rights" or "due process" arguments). Instead, the court below understood petitioner to have presented a challenge under the Just Compensation Clause, and the court held that its recent decision in *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019), petition for cert. pending, No. 19-1074 (filed Feb. 26, 2020), foreclosed that challenge.

Petitioner does not ask this Court to review the court of appeals' actual decision on the application of the Just Compensation Clause to the AIA. Cf. Pet. 15 (distinguishing between "the Takings Clause" and "the Due Process Clause, the basis of [petitioner's] constitutional challenge'") (citation omitted). And while petitioner does ask this Court to address its Due Process Clause claim, this Court is "a court of review, not of first view." *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005). Nothing about this case would warrant the unusual step of granting a petition for a writ of certiorari to address a constitutional question that was not addressed below and had not been directly addressed in any prior precedential court of appeals opinion.

b. Petitioner suggests (Pet. 19) that the court of appeals' decision should be "set aside" because it addressed the Just Compensation Clause rather than the distinct arguments petitioner now makes under the Due Process Clause. The court below, however, was well justified in understanding petitioner's constitutional

challenge to rest on the Just Compensation Clause. Indeed, petitioner’s initial brief in the court of appeals did not even reference the Due Process Clause. See Pet. C.A. Br. 59-61. Instead, petitioner alleged a “violation of the Fifth Amendment,” and it cited Just Compensation Clause precedents for the principle that, “[a]lthough Congress has broad powers under the Intellectual Property Clause, subsequent statutory changes may ‘not *take away* the rights of property in existing patents.’” *Id.* at 59-60 (quoting *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 206 (1843)) (emphasis added).

Petitioner did invoke the Due Process Clause in its reply brief and in a subsequent response to a Notice of Supplemental Authority filed more than a month after oral argument in this case. See Pet. C.A. Reply Br. 27 & n.6; 18-1232 C.A. Doc. 88 (Aug. 14, 2019). But it is “well established” in the Federal Circuit “that arguments not raised in the opening brief are waived,” and that merely adverting in passing to a potential ground for relief is insufficient if the brief does not contain “a developed argument” on that point. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319-1320 (Fed. Cir. 2006); see, e.g., *Impax Labs. Inc. v. Lannett Holdings Inc.*, 893 F.3d 1372, 1377 n.3 (Fed. Cir. 2018) (refusing to address argument made at length in reply brief that was mentioned only in an “oblique reference in [the] opening brief”). Under that longstanding forfeiture doctrine, the court of appeals was under no obligation to address petitioner’s due process arguments.³

³ In its brief in the court of appeals, the government observed that “[t]he precise basis of [petitioner’s] challenge under the Fifth Amendment is not clear,” and explained why, “[t]o the extent [petitioner’s] challenge is based on the Due Process Clause,” that chal-

And petitioner’s case-specific challenge to that application of settled forfeiture principles does not raise any issue of broad importance that might warrant this Court’s review. See Sup. Ct. R. 10.

2. Even if petitioner’s Due Process Clause challenge was properly before the Court, that challenge lacks merit.

a. Due-process requirements are satisfied if retrospective application of particular “legislation is itself justified by a rational legislative purpose.” *Pension Benefit Guar. Corp. v. R. A. Gray & Co.*, 467 U.S. 717, 730 (1984). Such provisions “often serve entirely benign and legitimate purposes,” including by “correct[ing] mistakes” and “giv[ing] comprehensive effect to a new law Congress considers salutary.” *Landgraf v. USI Film Prods.*, 511 U.S. 244, 267-268 (1994).

Congress’s decision to make the inter partes review provisions of the AIA applicable to previously issued patents fully accords with those principles. As the court of appeals observed in a related context, extending inter partes review to existing patents serves a rational purpose. *Celgene Corp.*, 931 F.3d at 1361-1362. Invalid patents sometimes “slip through” the USPTO’s initial review process, and once Congress had created a “more efficient system” for identifying “patents that should not have issued in the first place,” Congress reasonably desired to make that improved system applicable to existing invalid patents. *Id.* at 1361 (citations omitted).

That decision was not only rational, but also consistent with the course Congress had chosen in 1980,

lenge would fail. Gov’t C.A. Br. 16, 24; see *id.* at 24-31. Given petitioner’s failure to offer a developed Due Process Clause argument in its opening brief, however, the court of appeals understandably declined to address the due process issue.

when it made the newly created *ex parte* reexamination process applicable to patents that had been issued at a time when no administrative reconsideration mechanism was in place. See 1980 Act § 8(b), 94 Stat. 3027. As the Federal Circuit explained in upholding that 1980 congressional choice against a Due Process Clause challenge similar to the one petitioner mounts here, the “curative” nature of the new provision—intended to alleviate the ill effect of patents the USPTO had previously issued in error—makes judicial deference to Congress’s choice here especially appropriate. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 603 (Fed. Cir.), modified, *aff’d in part and rev’d in part on other grounds*, 771 F.2d 480 (Fed. Cir. 1985).

b. Petitioner’s due-process challenge fails for the additional reason that *inter partes* review of a pre-AIA patent does not constitute a retroactive application of the AIA. “A statute does not operate ‘retrospectively’ merely because it is applied in a case arising from conduct antedating the statute’s enactment, * * * or upsets expectations based in prior law.” *Landgraf*, 511 U.S. at 269. The relevant question is instead “whether the new provision attaches new legal consequences to events completed before its enactment.” *Id.* at 270. No new legal consequences attached here, since the Board in conducting *inter partes* review applies the same substantive standards of patentability that were applied when the patents were originally issued. While the *procedures* used to conduct *inter partes* review differ from the procedures previously used to reassess issued patents, “[c]hanges in procedural rules may often be applied in suits arising before their enactment without raising concerns about retroactivity.” *Id.* at 275. As the *Celgene* court observed in a related context, “[n]o

one has a vested right in any given mode of procedure.” 931 F.3d at 1361 (quoting *Denver & Rio Grande W. R.R. v. Brotherhood of R.R. Trainmen*, 387 U.S. 556, 563 (1967)) (brackets in original).⁴

Petitioner argues (Pet. 20, 22) that the changes the AIA made were not “procedural” but rather “substantive,” going to a “vested right” in the “burden of proof required to revoke a patent” that supposedly attached at the moment its patent issued. Petitioner focuses (Pet. 22) on the “presumption of validity” and the associated clear-and-convincing-evidence standard that apply in federal district court when a patent holder brings an infringement challenge and the defendant argues that the patent is invalid. See Pet. 22-24; see also *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95, 100-107 (2011); Pet. 4 (“[Petitioner] is the owner of a patent that issued in 2006 bearing the statutorily-secured presumption of validity under 35 U.S.C. § 282 (2006).”). But as

⁴ Petitioner invokes (Pet. 21-22) the Court’s statement in *McClurg* that subsequently enacted legislation “can have no effect to impair the right of property then existing in a patentee.” 42 U.S. (1 How.) at 206. But *McClurg* makes clear that the rule against impairment of existing property rights is not implicated when Congress alters the procedures by which rights under preexisting patents are adjudicated. The Court explained that the resolution of patent disputes “must depend on the law as it stood at the emanation of the patent, together with such changes as have been since made.” *Ibid.* (emphasis added). The Court concluded 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” should apply, regardless of whether the patents were “granted before or after [the statute’s] passage.” *Id.* at 207. Similarly here, Congress simply revised the procedures that the agency may use to reconsider patent claims based on the same substantive conditions of patentability that had previously governed. *McClurg* affirmatively supports the constitutionality of that procedural change.

petitioner ultimately concedes (Pet. 22), the AIA did not change, retroactively or otherwise, the presumption of validity or the clear-and-convincing-evidence standard that apply in federal district court. The Patent Act continues to provide that “[a] patent shall be presumed valid,” 35 U.S.C. 282(a), and district courts continue to apply the clear-and-convincing evidence standard when accused infringers raise the invalidity of a patent as an affirmative defense in litigation. Even if petitioner held a “vested right” in such procedural rules, that right has not been retroactively diminished, let alone “eviscerate[d].” Pet. 24.

Petitioner contends (Pet. 22) that the practical effect of the AIA was to “deprive[] [it] of that vested burden of proof by subjecting [its] [p]atent to [inter partes review] where unpatentability may be established by a mere preponderance of the evidence.” But at the time petitioner’s patent issued, the USPTO was already authorized—and had been authorized for decades—to conduct administrative reconsideration proceedings in which the agency could “reconsider the validity of issued patents on particular grounds, applying a preponderance of the evidence standard.” *Celgene*, 931 F.3d at 1363; see 35 U.S.C. 303-307. Petitioner thus had no “vested” right to avoid the application to its patent of a USPTO reevaluation mechanism that uses an ordinary preponderance standard.

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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