

No. 2018-1167, -1168, -1169

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CELGENE CORPORATION,

Appellant,

v.

LAURA A. PETER, Deputy Under Secretary of Commerce for Intellectual Property
and Deputy Director of the United States Patent and Trademark Office,

Intervenor.

On Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in IPR2015-01096, IPR2016-01102, IPR2015-01103

RESPONSE TO PETITION FOR REHEARING EN BANC

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INTRODUCTION

Because the United States Patent and Trademark Office (USPTO) reviews over a half-million patent applications each year,¹ occasionally “bad patents slip through.” *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018). “Since 1980, the Patent Act has empowered the [USPTO] to reexamine—and perhaps cancel—a patent claim that it had previously allowed.” *Return Mail, Inc. v. USPS*, 139 S. Ct. 1853, 1859 (2019) (quotation omitted). Congress first authorized the USPTO to conduct ex parte reexamination of all existing patents in 1980. *See* 35 U.S.C. § 301 *et seq.* It then established inter partes reexamination in 1999. *See id.* § 311 *et seq.* (2000). Most recently, in 2011, the Leahy–Smith America Invents Act (AIA), revised the inter partes reconsideration procedures and renamed the process inter partes review. *See* 35 U.S.C. § 311 *et seq.*

Appellant Celgene Corp. (Celgene) contends that the application of inter partes review to patents issued before the enactment of the AIA violates the Takings Clause. This is not the first time that the Court has been presented with a claim of this sort. The Court previously rejected a similar takings claim directed at ex parte reexamination, holding that the application of those procedures to patents that had issued before Congress had created any mechanism for the administrative reconsideration of patents was constitutional under the Takings Clause. *Joy Techs., Inc. v. Manbeck*, 959 F.2d 226 (Fed. Cir. 1992); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir.), *reh’g granted in part*,

¹ USPTO, *FY 2018 Performance And Accountability Report* 32 tbl. (2018).

771 F.2d 480 (Fed. Cir. 1985). In this case, the panel reached the same conclusion regarding inter partes review, holding that the application of inter partes review to pre-AIA patents does not violate the Takings Clause.

The panel properly recognized that Celgene’s pre-AIA patents had been “granted subject to existing judicial and administrative avenues for reconsidering their validity.” Op.29. The panel held that the “procedural differences” “between IPRs and their predecessors” do not themselves constitute a taking of property, because “[n]o one has a vested right in any given mode of procedure.” Op.33 (quotation omitted). The panel further concluded that inter partes review does not “differ from the pre-AIA review mechanisms significantly enough, substantively or procedurally, to effectuate a taking.” Op.27.

The panel decision is correct and does not warrant rehearing en banc. Celgene does not seriously dispute that the USPTO may reconsider the validity of its patents through preexisting reconsideration procedures (*e.g.*, *ex parte* reexamination), and may cancel them on the basis of such reconsideration, without effecting a taking of property. Instead, Celgene contends that under the Supreme Court’s precedents, applying reconsideration “provisions added to the Patent Act after a patent” has issued (*i.e.*, inter partes review) violates the Takings Clause. Pet.4. That contention is wrong. The decision here, and the Court’s similar decisions in *Patlex* and *Joy Technologies*, does not conflict with any decision of the Supreme Court. Indeed, the very decisions on which Celgene relies have approved the application of subsequent statutes that “prescribe the rules

which must govern on the trial” of the validity of patents, “whether granted before or after [their] passage.” *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 207 (1843). Celgene’s recasting of the issue in terms of regulatory takings (Pet.6-14) fares no better, because “pre-AIA patent owners, including Celgene, have known for almost forty years that their patents were issued subject to substantively similar forms of PTO reexamination.” Op.28 n.13. The rehearing petition should be denied.

STATEMENT

1. “After a patent issues, there are several avenues by which its validity can be revisited.” *Return Mail*, 139 S. Ct. at 1859. First, in a suit for patent infringement, if an accused infringer demonstrates by “clear and convincing evidence that the patent never should have issued in the first place,” then “the court may deem the patent invalid.” *Id.* (quotation omitted). Second, through ex parte reexamination (from 1980 to present) and inter partes reexamination (from 1999 to 2012), the USPTO has been authorized to reconsider prior patent grants pursuant to a preponderance-of-the-evidence standard. *In re Baxter Int’l, Inc.*, 678 F.3d 1357 (Fed. Cir. 2012). If the agency determines that a patent should not have been issued under Section 102 or 103, and if this Court agrees in any appeal, the Director of the USPTO will “issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable.” 35 U.S.C. § 307(a) (ex parte reexamination); *id.* § 316(a) (2000) (inter partes reexamination).

In 2011, Congress enacted the AIA, which replaced inter partes reexamination with inter partes review. The procedures for inter partes review are similar to, and in

many respects the same as, those previously used in both ex parte and inter partes reexaminations. As in ex parte and inter partes reexaminations, the petitioner in inter partes review must demonstrate to the Board that the patent is invalid by a preponderance of the evidence. 35 U.S.C. § 316(e). And just as with those reexaminations, following an opportunity for this Court’s review, the Director will “issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable.” *Id.* § 318(b). The AIA’s inter partes review provisions took effect on September 16, 2012, and Congress authorized such review of “any patent issued before, on, or after that effective date.” AIA, Pub. L. No. 112-29, § 6(c)(2)(A), 125 Stat. 284, 304 (2011)

2. The USPTO issued Celgene’s patent in November 2001, Appx2115, and the patent was granted “subject to the qualification that the PTO has the authority to reexamine—and perhaps cancel—a patent claim.” *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1376 (2018) (quotation omitted). After the AIA’s enactment, the Board instituted inter partes review of the patent in three separate proceedings and issued final written decisions concluding that a number of challenged claims were unpatentable. On appeal, Celgene asserted that the Board’s application of inter partes review to its patent violated the Takings Clause.

The panel affirmed in a unanimous decision, holding that the application of inter partes review to pre-AIA patents is not an unconstitutional taking under the Fifth Amendment. Op.35. The panel emphasized that the “validity of patents has always been subject to challenge in district court,” and, “for the last forty years, patents have

also been subject to reconsideration and possible cancellation by the PTO.” Op.28. The panel further stressed that, for those “forty years, patent owners have also had the expectation that the PTO could reconsider the validity of issued patents on particular grounds, applying a preponderance of the evidence standard.” Op.35-36.

The panel determined that the AIA’s inter partes review provisions are properly characterized as simply “the most recent legislative modification to the PTO’s longstanding reconsideration procedures.” Op.29. The panel recognized that the AIA did not change the substantive conditions of patentability, because inter partes review only permits the USPTO to consider whether “the patents should not have issued in the first place” under Sections 102 and 103 of the Patent Act. Op.34; *see* 35 U.S.C. § 311(b) (patent may be challenged “only on a ground that could be raised under section 102 or 103”). Agreeing with the United States that mere changes in the administrative reconsideration procedures for patents “do not effect a Fifth Amendment Taking,” Op.27, the panel held that the “procedural differences” “between IPRs and their predecessors” did not themselves effect a taking because “[n]o one has a vested right in any given mode of procedure.” Op.33 (quotation omitted).

The panel also rejected Celgene’s “regulatory takings” argument. Op.26. At its heart, that argument rests on the proposition that the procedural changes involved in inter partes review unconstitutionally impaired the expectations of pre-AIA patent owners. The panel reviewed the different reconsideration procedures and determined that “IPRs do not differ sufficiently from the PTO reconsideration avenues available

when the patents here were issued to constitute a Fifth Amendment taking.” Op.30. The decision found “far more significant similarities between IPRs and their reexamination predecessors” than differences, including that patents continue to be “reviewed on the same substantive grounds—anticipation and obviousness, based on the same categories of prior art.” *Id.* In addition, the Director has “discretion to initiate the proceeding” under each procedure, and “IPRs serve essentially the same purpose as their reexamination predecessors”—namely, “the purpose of correcting prior agency error of issuing patents that should not have issued in the first place.” Op.31-32. Meanwhile, the AIA provisions permitting “discovery, briefing, and an oral hearing” did “not disrupt the expectation that patent owners have had for nearly four decades—that patents are open to PTO reconsideration and possible cancelation if it is determined ... that the patents should not have issued in the first place.” Op.33-34.

ARGUMENT

THE PANEL OPINION IS CORRECT, DOES NOT CONFLICT WITH ANY DECISION OF THE SUPREME COURT, AND DOES NOT WARRANT REHEARING EN BANC

The panel correctly held that the application of inter partes review to pre-AIA patents does not violate the Takings Clause. As the panel recognized, that holding follows *a fortiori* from the Court’s previous decisions in *Patlex* and *Joy Technologies*, which held that the application of ex parte reexaminations to patents issued before the existence of *any* form of administrative reconsideration was consistent with the Takings

Clause. Celgene recognizes (Pet.14-15) that the panel decision accords with those precedents, but nevertheless contends (Pet.1) that the decision is wrong (and by necessary implication, *Patlex* and *Joy Technologies* are, too) and conflicts with several decisions of the Supreme Court.

Celgene is mistaken. The AIA's application of inter partes review procedures to pre-AIA patents neither eliminated any property rights (Pet.3-6), nor constituted a regulatory taking (Pet.6-14), and the panel's decision is in full accord with the Supreme Court's takings jurisprudence. Rehearing en banc is not warranted.

A. The Application Of Inter Partes Review Procedures To Pre-AIA Patents Does Not Effect A Taking Of Property

1. The panel properly concluded that the AIA did not “substantively” modify patent rights in a manner that “effectuate[s] a taking.” Op.27. As the panel recognized, the inter partes review provisions of the AIA do not alter any of the substantive conditions of patentability. *See* 35 U.S.C. § 101 *et seq.* Inter partes review only permits the USPTO to review patents on “the grounds specified in § 311(b),” Op.34, which confines the agency to considering “a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.” As a result, inter partes review permits the cancellation of patents only if and when “the patents should not have issued in the first place,” Op.34, and are in fact “unpatentable in light of [the] prior art,” Op.30 (quoting *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016)). Inter partes review involves “the same basic matter as the grant of

a patent,” requiring a “second look” at whether the claimed invention is indeed patentable. *Oil States*, 138 S. Ct. at 1374 (quotation omitted). The substantive scope of patent rights thus remains the same, both before and after the AIA.

Because the cancellation of a patent following inter partes review rests on a predicate determination that there is no valid property interest—a determination that rests on unchanged substantive patentability standards and that stands only if this Court concurs in it (unless the patent owner chooses to forgo judicial review)—no property is being taken. There is no question that “a *valid* patent is private property for the purposes of the Takings Clause.” Op.26 (emphasis added). But an invalid patent is not. As this Court has long held, a takings challenge requires a threshold inquiry “into the nature of the [property] owner’s estate to determine whether the [property] interest proscribed by the governmental action was part of the owner’s title to begin with.” *M & J Coal Co. v. United States*, 47 F.3d 1148, 1154 (Fed. Cir. 1995); see *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1029-30 (1992) (takings claim depends on “defin[ing] the range of interests that qualify for protection as ‘property’” and “restrictions” that “inhere in the title itself”). It is therefore not a taking of private property, for example, for the government to appropriate a landowner’s submerged lands where state law provided “a pre-existing limitation upon [his] title,” *Id.* at 1028-29 (citing *Scranton v. Wheeler*, 179 U.S. 141, 163 (1900)), that rendered it “a bare technical title,” *Scranton*, 179 U.S. at 163. In the same manner, if an individual holds no valid patent rights whatsoever

under the Patent Act, and his patent claims were originally approved erroneously, no taking occurs when the Director cancels those invalid patent claims.

The panel also correctly held that Congress's "legislative modification" in the procedures for administrative reconsideration of patents did not itself take Celgene's property. Op.29. As the panel recognized (Op.33), "[n]o 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) (quotation omitted). The USPTO's administrative procedures for reconsidering patents are not themselves the private property of patent owners, and the Takings Clause does not preclude changes in those procedures. Far from being property, those procedures are statutory constraints that patents are "[s]ubject to," 35 U.S.C. § 261, and that "qualif[y] any property rights that a patent owner has in an issued patent," *Oil States*, 138 S. Ct. at 1375.

For this reason, Celgene's repeated invocation (Pet.1, 4-6, 13) of the Supreme Court's decision in *McClurg*—which warned against legislation that "take[s] away the rights of property in existing patents"—misses the point. *McClurg* confirms that the modification of reconsideration procedures is not a taking of property. 42 U.S. at 206. *McClurg* explained that patent rights "must depend on the law as it stood at the emanation of the patent, together with such changes as have been since made," and confirmed that it "is not a sound objection to [the] validity" of subsequent statutes to claim that those statutes "may be retrospective in their operation." *Id.* The Supreme Court thus 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 whether the patents were “granted before or after its passage.” *Id.* at 207. As the panel recognized, that same principle applies here: there is nothing constitutionally objectionable about using revised procedures to reconsider patent claims on the basis of the same substantive standards that have always governed them.

2. Celgene states (Pet.1, 4) that valid patents are private property under *Horne v. Department of Agriculture*, 135 S. Ct. 2419 (2015), and *James v. Campbell*, 104 U.S. 356 (1882). The panel itself acknowledged that point. Op.26. But neither *Horne*, *James*, nor any other Supreme Court decision addresses changes in the *procedures* used to reconsider patents, and none stands for the proposition that, simply because valid patents are private property, procedural changes cannot be used in connection with existing patents.

Celgene cites (Pet.1, 3) the plurality opinion in *Eastern Enterprises v. Apfel*, 524 U.S. 498, 532 (1998), for the principle that “[r]etroactivity is generally disfavored in the law.” *Eastern Enterprises* involved the retroactive application of a *substantive* change in the financial obligations of mine operators, not the kind of purely procedural change involved here. *See* 524 U.S. at 529-37. As we explained (Br.43-44), though inter partes review applies to pre-AIA patents, applying new procedures to subsequent administrative proceedings is not properly regarded as “retroactive.” “Because 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). In all events, Celgene fails to mention that the majority of the Court in *Eastern Enterprises* actually rejected the takings challenge there, *see* 524 U.S. at 539-50 (Kennedy, J., concurring); *id.* at 550-68 (dissenting opinions), which was based on the theory that the Takings Clause prohibits certain forms of “retroactive liability,” *id.* at 528 (plurality opinion).

Celgene suggests (Pet.6) that “an IPR cancellation takes away the entirety of the property right,” and counts as a “physical taking.” But Celgene does not seriously dispute that the USPTO could have cancelled its patent claims through prior reexamination procedures without effecting a taking. Celgene indeed concedes that those prior procedures “qualif[y] any property rights that a patent owner has in an issued patent” and that the USPTO could have properly invalidated the patent here through those procedures. Pet.4 (quotation omitted). Inter partes review, like those predecessors, addresses the antecedent question of whether valid property rights exist, by determining whether the patents “should not have issued in the first place,” Op.32, after considering “the same basic matter as the grant of a patent,” *Oil States*, 138 S. Ct. at 1374 (quotation omitted). Regardless of the reconsideration procedure, if a patent claim is determined not to satisfy the patentability requirements in Sections 102 and 103, then no valid property rights exists to be taken.

Moreover, as we explained (Br.39-41), the Director issues a certificate cancelling unpatentable claims only after this Court affirms the Board’s determination that the patent claims were unpatentable (or after the patent owner accepts the determination

and does not appeal). *See* 35 U.S.C. § 318(b). Just as a district court does not effect a Fifth Amendment taking when it invalidates patent claims in infringement litigation, the USPTO does not effect a Fifth Amendment taking when it cancels patent claims. Last, even if administrative cancellation were assumed to “take” property, because that cancellation does not occur until after this Court is able to affirm the Board’s determination of unpatentability, the legitimate market value of the claims following full review will be zero even before the claims are cancelled. As a result, no compensation would be constitutionally due under the Takings Clause. *See Horne*, 135 S. Ct. at 2432 (just compensation “normally is to be measured by the market value of the property at the time of the taking” (quotation omitted)).

**B. Inter Partes Review Of Pre-AIA Patents Does Not
Constitute A Regulatory Taking**

1. The panel also correctly rejected Celgene’s “regulatory takings” argument. Op.26. Generally, “when a regulation impedes the use of property without depriving the owner of all economically beneficial use, a taking still may be found based on a complex of factors, including (1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action.” *Murr v. Wisconsin*, 137 S. Ct. 1933, 1943 (2017) (quotation omitted). As the panel concluded, this framework does not help Celgene, because patent owners have long known that any unpatentable patent claims may be invalidated through “judicial or administrative avenues.” Op.29.

The panel pointed out that “[p]atent owners have always had the expectation that the validity of patents could be challenged in district court,” and, “[f]or forty years, patent owners have also had the expectation that the PTO could reconsider the validity of issued patents on particular grounds, applying a preponderance of the evidence standard.” Op.35-36. Although inter partes review entails certain procedural changes, the panel correctly found “far more significant similarities between IPRs and their reexamination predecessors” than differences. Op.30. Among other things, patents continued to be “reviewed on the same substantive grounds,” the Director has “discretion to initiate the proceeding” under each procedure, and “IPRs serve essentially the same purpose as their reexamination predecessors.” Op.30-32, 35-36. In rejecting the regulatory-takings challenge, the panel held that the AIA provisions permitting “discovery, briefing, and an oral hearing” did “not disrupt the expectation that patent owners have had for nearly four decades” that the USPTO could cancel patent claims found unpatentable. Op.33-34.

Contrary to Celgene’s suggestion (Pet.1, 10), the panel decision does not conflict with the Supreme Court’s decision in *Lucas*. *Lucas* addresses the “relatively rare situations” where government regulation eliminates “*all* economically beneficial uses” in property, but here, the AIA procedures do not themselves impair the use or value of valid patents. 505 U.S. at 1018-19. To the extent Celgene claims that its economically beneficial uses were impaired by the cancellation of the patent, rather than by the procedures used in its antecedent review, *Lucas* recognizes that such a claim must fail if

“the logically antecedent inquiry into the nature of the owner’s estate shows that the proscribed use interests were not part of his title to begin with,” *id.* at 1027. As we explained, that is the case here, where there is no valid property interest to begin with in patent claims determined to be unpatentable.

2. Celgene contends (Pet.7) that “[p]re-AIA patent owners made reasonable investment-backed decisions based on the then-existing (administrative) patent-reconsideration and (court) invalidation schemes.” But there is no reason to believe that individuals make inventive choices and associated investments based on the existence and persistence of particular post-issuance procedures or the absence of other procedures. It is implausible that individuals with valid, patentable inventions would have foregone patent protection, or that those with unpatentable inventions would have changed their inventive practices, had they had known that reconsideration procedures might one day include the procedural changes found in the AIA. And Celgene’s response (Pet.12-13) that it could not have specifically foreseen that Congress would apply a new reconsideration procedure to pre-existing patent grants ignores that this is precisely what Congress did when it created *ex parte* reexamination.

Celgene suggests that the higher invalidation rates under *inter partes* review changes the “patent bargain.” Pet.9-10, 13-14. There is also no reasonable expectation that a patent will be shielded from scrutiny, or that invalid patents will be sheltered from procedural changes that bring their defects to light. As the panel stressed, “pre-AIA patent owners, including Celgene, have known for almost forty years that their patents

were issued subject to substantively similar forms of PTO reexamination.” Op.28 n.13. Inter partes review instead reinforces fundamental features of the patent system, and the parties’ and the public’s legitimate expectations, by protecting only those inventions that satisfy the conditions of patentability.

Celgene points to (Pet.7-9) particular procedural differences between the various reconsideration procedures, arguing, *inter alia*, that ex parte and inter partes reexamination provided an unlimited right to amend claims and more layers of administrative and judicial review. The panel correctly recognized that such procedural differences are not constitutionally “substantive or significant” for a patent owner’s expectations. Op.30. In any event, inter partes review similarly permits a motion to amend challenged claims, *see* 35 U.S.C. 316(d), and authorizes judicial review by this Court. And Celgene’s disagreement (Pet.9) with the USPTO’s broadest-reasonable-interpretation standard in inter partes review is also without merit, as “the same broadest reasonable interpretation standard for claim construction [is] used in reexaminations.” Op.30.

Last, Celgene contends (Pet.11-12) that the Board’s “thin evidence” and “minimal analysis” in this particular case demonstrate that inter partes review upsets its reasonable expectations. The panel concluded, however, that “Celgene has made no showing—nor could it—that claims cancelled in IPRs, including its own claims, would have fared any better in the preexisting reexamination procedures.” Op.34. Celgene’s factbound assertions regarding the strength of its patent do not warrant en banc review.

CONCLUSION

The petition for rehearing en banc should be denied.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 35(b) and Federal Circuit Rule 35(e)(4). This brief contains 3,899 words.

/s/ Dennis Fan
DENNIS FAN

CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2019, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Dennis Fan

DENNIS FAN