

FEDERAL CIRCUIT TAKES ON TAKINGS
CONCERNS FOR INTER PARTES REVIEW OF PRE-
AIA PATENTS

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In *Celgene Corporation v. Peter*,¹ the Federal Circuit considered the constitutionality of retroactively applying *inter partes* review (“IPR”) proceedings to patents issued before the Leahy-Smith America Invents Act (“AIA”) went into effect. It held that such retroactive application was not a taking in violation of the Fifth Amendment because IPRs are similar to pre-AIA review mechanisms, both substantively and procedurally.

This case arose from IPR petitions filed by the Coalition for Affordable Drugs VI LLC (“CFAD”) challenging the validity of U.S. Patent No. 6,045,501 (“the ’501 patent”) and U.S. Patent No. 6,315,720 (“the ’720 patent”), assigned to Celgene Corporation (“Celgene”). CFAD is a business organization that seeks to invalidate patents assigned to pharmaceutical companies, purportedly in order to drive down stock prices.² The court first affirmed the decision of the Patent Trial and Appeal Board (“Board”) that all claims of the ’501 patent and claims 1–9 and 11–32 of the ’720 patent were unpatentable as obvious, and then reached the constitutional question.³

Both the ’501 and ’720 patents are directed to methods for safely distributing pharmaceutical compounds that are teratogenic or otherwise hazardous to adults, while avoiding exposing fetuses to the drug.⁴ Teratogenic compounds are those known to disturb the development of an embryo or fetus; if a pregnant patient takes a teratogenic drug, it can cause birth defects or fetal death.⁵ Thalidomide, for instance, was not a known teratogen when first synthesized as a sedative in 1957, but was removed from all markets by 1962 after its use was associated with fetal limb malformation.⁶

¹ *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019).

² See Jeffrey Quo & Afia Naaz, *Attack on Pharma Patents: Checking in on the Kyle Bass IPRs*, POLSINELLI (June 2, 2017), <https://www.polsinellionpostgrant.com/blog/2017/6/2/attack-on-pharma-patents-checking-in-on-the-kyle-bass-iprs>.

³ *Celgene*, 931 F.3d at 1346.

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

Celgene created a program known as the System for Thalidomide Education and Prescription Safety (“STEPS”) in order to gain FDA approval for selling thalidomide.⁷ The ’501 patent reflects this design, covering “methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug.”⁸ Claim 1, representative of all ten claims, comprises steps that include registering potential patients, pharmacies, and drug prescribers in a computer-readable storage medium and subsequently using the information in that medium to determine appropriate patients for treatment.⁹ CFAD filed a petition for IPR challenging all ten claims of the ’501 patent as obvious based on three references, and after instituting, the Board found all the claims unpatentable.¹⁰

Celgene also created a modified STEPS program, and the ’720 patent covers related “[i]mproved methods for delivering to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug.”¹¹ Claim 1 expands on the method disclosed in the ’501 patent, with the improvement comprising steps that include inputting patient attributes related to the risk of adverse side effects into the computer storage medium and using that information for determining appropriate patients for treatment.¹² CFAD filed three petitions for IPR, each challenging all thirty-two claims of the ’720 patent based on obviousness. The Board instituted all three IPRs and held, after rehearing, that only claim 10 was patentable. Celgene timely appealed the decisions for all four IPRs, and the Director of the Patent and Trademark Office (“PTO”) intervened. The Federal Circuit considered the four appeals together.

⁷ Brief of Appellant at 8–9, *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019) (No. 18-1171).

⁸ U.S. Patent No. 6,045,501 col. 1 ll. 1–5.

⁹ *Id.* at col. 10 ll. 43–67.

¹⁰ *Celgene*, 931 F.3d at 1347.

¹¹ U.S. Patent No. 6,315,720 at abstract.

¹² *Id.* at col. 18 ll. 16–42.

Writing for a unanimous panel, Chief Judge Prost affirmed the Board's obviousness determinations, despite Celgene's challenges.¹³ However, Celgene had also argued on appeal that applying IPR to pre-AIA patents was an unconstitutional taking of property, although it had not raised the issue before the Board.¹⁴ The court noted that, in general, a party cannot challenge an agency decision on a basis not presented to the agency,¹⁵ but also asserted its discretion to consider issues "raised for the first time on appeal."¹⁶ The court can exercise this discretion in limited circumstances, including after an intervening change in law or when it is in the "interest of justice."¹⁷ The PTO acknowledged that the court may find resolving the constitutional question in the interest of justice,¹⁸ particularly because *Oil States Energy Services v. Greene's Energy Group*¹⁹ left open the question of "retroactive application of inter partes review."²⁰ Additionally, *Oil States* was decided after the Board issued the final written decisions in the instant IPRs, suggesting another explanation for why Celgene did not raise the issue previously.²¹ Noting that the parties had briefed the takings issue sufficiently and addressed it "extensively" at oral argument, the court exercised its discretion to resolve the issue.²²

The Takings Clause of the Fifth Amendment prohibits private property from being "taken for public use, without just compensation."²³ The parties agreed that a valid patent is property within the meaning of the Takings Clause.²⁴ Celgene argued that

¹³ *Celgene*, 931 F.3d at 1349.

¹⁴ *Id.* at 1355–56.

¹⁵ *See, e.g.*, *In re DBC*, 545 F.3d 1373, 1378 (Fed. Cir. 2008).

¹⁶ *Id.* at 1379.

¹⁷ *See Golden Bridge Tech., Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1323 (Fed. Cir. 2018).

¹⁸ Brief of Intervenor at 55–56, *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019) (No. 18-1171).

¹⁹ 138 S. Ct. 1365 (2018).

²⁰ *Id.* at 1379.

²¹ *Celgene*, 931 F.3d at 1356–57.

²² *Id.* at 1357.

²³ U.S. Const. amend. V.

²⁴ *Celgene*, 931 F.3d at 1358.

because IPR did not exist at the time its patents were issued, applying IPR to them “unfairly interferes with its reasonable investment-backed expectations without just compensation.”²⁵ In response, the PTO contended that an IPR that found the claims unpatentable was not a taking because the patents were issued erroneously, meaning the owner never had a valid property right to begin with.²⁶ Alternatively, the PTO argued that IPRs were not takings, given that the PTO has long been able to reconsider and cancel patents in administrative proceedings, and IPRs were merely revised procedures that accomplished the same goal.²⁷

The court concluded that IPRs were similar enough to pre-AIA review mechanisms, both substantively and procedurally, such that their application to pre-AIA patents did not constitute a taking.²⁸ According to the court, pre-AIA patents have been “subject to existing judicial and administrative avenues for reconsidering their validity” for forty years.²⁹ Through *ex parte* reexamination, available since 1980, “[a]ny person at any time” can “file a request for reexamination.”³⁰ If the PTO determines “a substantial new question of patentability affecting any claim of the patent,”³¹ it conducts a reexamination and cancels any claims found to be unpatentable.³² Similarly, *inter partes* reexamination, available for a third party when there is a “substantial new question of patentability,”³³ gives the third party greater participation in the proceedings than *ex parte* reexamination.³⁴

²⁵ *Id.*; see also Brief of Appellant, *supra* note 7, at 49–50.

²⁶ *Celgene*, 931 F.3d at 1358; see also Brief of Intervenor, *supra* note 18, at 56.

²⁷ *Celgene*, 931 F.3d at 1358. See also Brief of Intervenor, *supra* note 18, at 60.

²⁸ *Celgene*, 931 F.3d at 1358.

²⁹ *Id.* at 1359.

³⁰ 35 U.S.C. § 302.

³¹ See *id.* § 303(a).

³² See *id.* § 307(a).

³³ 35 U.S.C. § 312(a) (1999), amended by 35 U.S.C. § 312(a) (2012).

³⁴ See *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137 (2016).

The court noted that IPRs were simply a “legislative modification” of existing PTO reconsideration proceedings.³⁵ This relationship is shown by the many similarities between IPRs and *ex parte* and *inter partes* reexaminations, including the same preponderance of the evidence standard of proof,³⁶ the same broadest reasonable interpretation standard for claim construction,³⁷ and the same substantive grounds — anticipation and obviousness.³⁸ Both *ex parte* reexaminations and IPRs are instituted at the Director’s final and non-appealable discretion,³⁹ and they serve as “administrative remedies”⁴⁰ that allow the PTO to “correct[] prior agency error[s] of issuing patents that should not have issued in the first place.”⁴¹ Although there are procedural differences between the reexaminations and IPRs, including the adjudicatory characteristics of IPRs of discovery, briefing, and oral hearing,⁴² the court noted that no one has a “vested right in any

³⁵ *Celgene*, 931 F.3d at 1359.

³⁶ See 35 U.S.C. § 316(e) (“In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.”); *In re Baxter Int’l Inc.*, 678 F.3d 1357, 1364 (Fed. Cir. 2012) (“In PTO reexaminations ‘the standard of proof [is] a preponderance of the evidence.’”) (quoting *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008)).

³⁷ See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Nov. 13, 2018) (indicating that the claim construction standard at the time of the instant IPRs was the broadest reasonable interpretation); *In re CSB-Sys. Int’l, Inc.*, 832 F.3d 1335, 1340 (Fed. Cir. 2016) (“During reexamination proceedings of unexpired patents, however, the Board uses the broadest reasonable interpretation consistent with the specification standard.”) (internal quotations omitted).

³⁸ 35 U.S.C. § 311(b) (“A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 [covering anticipation] or 103 [covering obviousness] and only on the basis of prior art consisting of patents or printed publications.”).

³⁹ 35 U.S.C. §§ 303(c), 314(d).

⁴⁰ See *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018).

⁴¹ *Celgene*, 931 F.3d at 1361.

⁴² Brief of Appellant, *supra* note 7, at 47.

given mode of procedure.”⁴³ Moreover, patent owners have long known that their patents are “open to PTO reconsideration and possible cancelation . . . if the patents should not have issued in the first place.”⁴⁴

Neither the PTO nor the court explicitly addressed Celgene’s argument that it was being deprived of “reasonable investment-backed expectations” without just compensation.⁴⁵ Arguing that IPRs have broadly diminished pre-AIA patent value,⁴⁶ Celgene pointed to statistics showing that the number of IPRs filed and instituted within the procedure’s first four years of availability nearly equals the number of *inter partes* reexaminations filed in the twelve years they were available.⁴⁷ The court simply stated that Celgene did not and could not show that claims canceled in IPRs would have had a different outcome in prior reexamination procedures, seemingly sidestepping the issue.⁴⁸

The takings issue in this case has probably not been finally resolved. Celgene has petitioned the Federal Circuit for rehearing *en banc*,⁴⁹ and further hearing there or even by the Supreme Court seems likely. However, the instant case may ultimately be unripe for examination of the constitutional question because Celgene did not first file a claim for monetary damages under the Tucker Act.⁵⁰

⁴³ *Celgene*, 931 F.3d at 1361 (citing *Denver & Rio Grande W. R.R. Co. v. Bhd. of R.R. Trainmen*, 387 U.S. 556, 563 (1967)).

⁴⁴ *Id.* at 1361–62.

⁴⁵ *Id.* at 1358.

⁴⁶ Brief of Appellant, *supra* note 7, at 48–49.

⁴⁷ *Id.* at 49.

⁴⁸ *Celgene*, 931 F.3d at 1362.

⁴⁹ See Appellant’s Petition for Rehearing En Banc, *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019) (Nos. 18-1167; -1168; -1169); Appellant’s Petition for Rehearing En Banc, *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019) (No. 18-1171).

⁵⁰ See Matthew Rizzolo & Kathryn Thornton, *Next Steps After Celgene: Federal Circuit Ruling on Takings Clause and IPRs Leaves Open Questions*, IP WATCHDOG (Aug. 7, 2019).

<https://www.ipwatchdog.com/2019/08/07/next-steps-celgene-federal-circuit-ruling-takings-clause-iprs-leaves-open-questions/id=111961/>

Regardless, the Federal Circuit's panel decision is unlikely to be the last word on whether retroactive application of IPR to pre-AIA patents violates the Takings Clause.

(“[T]he Supreme Court has found that where a suit under the Tucker Act is available as a remedy for any uncompensated taking a party may suffer as a result of a challenged statute, any challenges to the constitutionality of the statute are not ripe until and unless a claim under the Tucker Act is brought.”).