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

2018-1167, 2018-1168, 2018-1169

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2015-01096, IPR2015-01102, IPR2015-01103.

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

2018-1171

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2015-01092.

Decided: July 30, 2019

GREGORY A. CASTANIAS, Jones Day, Washington, DC, argued for appellant. Also represented by JIHONG LOU, JENNIFER LORAINE SWIZE; GASPER LAROSA, New York, NY; ANTHONY INSOGNA, San Diego, CA; FRANK CHARLES CALVOSA, F. DOMINIC CERRITO, ANDREW CHALSON, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY.

AMY J. NELSON, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by MEREDITH HOPE SCHOENFELD, THOMAS W. KRAUSE. Also argued by KATHERINE TWOMEY ALLEN, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC. Also represented by MARK R. FREEMAN, SCOTT R. MCINTOSH, JOSEPH H. HUNT.

Before PROST, *Chief Judge*, BRYSON and REYNA, *Circuit Judges*.

PROST, *Chief Judge*.

The Coalition for Affordable Drugs VI LLC ("CFAD") filed a petition for *inter partes* review ("IPR") challenging the validity of all of the claims of U.S. Patent No. 6,045,501 ("the '501 patent") and three petitions for IPR challenging the validity of all of the claims of U.S. Patent No. 6,315,720 ("the '720 patent"). The Patent Trial and Appeal Board

("Board") determined that all of the claims of the '501 patent and claims 1–9 and 11–32 of the '720 patent were obvious. Celgene Corporation ("Celgene") appeals the Board's decisions.

For the reasons explained below, we affirm the Board's decisions finding the appealed claims obvious. We also hold that the retroactive application of IPR proceedings to pre-AIA patents is not an unconstitutional taking under the Fifth Amendment.

I

A

A teratogen is an agent known to disturb the development of an embryo or fetus. Teratogenic drugs can cause birth defects or other abnormalities following fetal exposure during pregnancy. One example of a teratogenic drug is thalidomide. Thalidomide, first synthesized in 1957, was originally marketed for use as a sedative in many countries, not including the United States. *See* '501 patent col. 1 ll. 19–22. Following reports of serious birth defects, thalidomide was withdrawn from all markets by 1962. *Id.* at col. 1 ll. 22–24. Despite these teratogenic effects, thalidomide has proven to be effective in treating other conditions. *See id.* at col. 1 ll. 24–35. The '501 patent and the '720 patent are generally directed to methods for safely distributing teratogenic or other potentially hazardous drugs while avoiding exposure to a fetus to avoid adverse side effects of the drug.

B

In order to obtain FDA approval to sell and distribute thalidomide, Celgene developed a system to safely distribute thalidomide to patients, which it called the System for Thalidomide Education and Prescription Safety ("Original S.T.E.P.S."). Appeal No. 18-1171, Appellant's Br. 8–9. According to Celgene, the '501 patent is directed to its Original S.T.E.P.S. program. *See id.* at 10.

Celgene's '501 patent relates to "methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug." '501 patent at Abstract. Claim 1 is representative and states:

> 1. A method for delivering a teratogenic drug to patients in need of the drug while avoiding the delivery of said drug to a foetus comprising:
>
> a. registering in a computer readable storage medium prescribers who are qualified to prescribe said drug;
>
> b. registering in said medium pharmacies to fill prescriptions for said drug;
>
> c. registering said patients in said medium, including information concerning the ability of female patients to become pregnant and the ability of male patients to impregnate females;
>
> d. retrieving from said medium information identifying a subpopulation of said female patients who are capable of becoming pregnant and male patients who are capable of impregnating females;
>
> e. providing to the subpopulation, counseling information concerning the risks attendant to fetal exposure to said drug;
>
> f. determining whether patients comprising said subpopulation are pregnant; and
>
> g. in response to a determination of non-pregnancy for said patients, authorizing said registered pharmacies to fill prescriptions from said registered prescribers for said non-pregnant registered patients.

Id. at claim 1. Claim 2 recites "[t]he method of claim 1 wherein said drug is thalidomide." The remaining claims depend from claim 1 and are not limited to thalidomide.

CFAD filed a petition for IPR challenging all ten claims of the '501 patent. The Board instituted review of claims 1–10 on a single ground—obviousness based on Powell,[1] Mitchell,[2] and Dishman.[3] *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, No. IPR2015-01092, Paper 20 (P.T.A.B. Oct. 27, 2015).

In its final written decision, the Board held that CFAD had shown by a preponderance of the evidence that claims 1–10 of the '501 patent are unpatentable as obvious over the combination of Powell, Mitchell, and Dishman. *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, No. IPR2015-01092, Paper 73, at 33 (P.T.A.B. Oct. 26, 2016) ("*'501 Final Written Decision*"). The Board denied Celgene's request for rehearing.

C

In the interim, Celgene "overhaul[ed]" its Original S.T.E.P.S. program to create what it called an "Enhanced S.T.E.P.S." program. Appeal No. 18-1167, Appellant's Br.

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[1] R.J. Powell & J.M.M. Gardner-Medwin, *Guideline for the Clinical Use and Dispensing of Thalidomide*, 70 Postgrad Med. J. 901–904 (1994) (Appeal No. 18-1171, J.A. 324–25).

[2] Allen A. Mitchell et al., *A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, 333:2 New Eng. J. Med. 101–06 (July 13, 1995) (Appeal No. 18-1171, J.A. 328–33).

[3] Benjamin R. Dishman et al., *Pharmacists' Role in Clozapine Therapy at a Veterans Affairs Medical Center*, 51 Am. J. Hosp. Pharm. 899–901 (Apr. 1, 1994) (Appeal No. 18-1171, J.A. 334–36).

8–9. According to Celgene, the '720 patent is directed to its Enhanced S.T.E.P.S. program. *See id.* at 10.

Celgene's '720 patent relates to "[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." '720 patent at Abstract. Claim 1, written in Jepson format, states:

> 1. In a method for delivering a drug to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by said drug, wherein said method is of the type in which prescriptions for said drug are filled only after a computer readable storage medium has been consulted to assure that the prescriber is registered in said medium and qualified to prescribe said drug, that the pharmacy is registered in said medium and qualified to fill the prescription for said drug, and the patient is registered in said medium and approved to receive said drug, the improvement comprising:
>
> a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for said drug;
>
> b. defining a set of information to be obtained from said patient, which information is probative of the risk that said adverse side effect is likely to occur if said drug is taken by said patient;
>
> c. in response to said information set, assigning said patient to at least one of said risk groups and entering said risk group assignment in said medium;
>
> d. based upon said information and said risk group assignment, determining whether the

> risk that said adverse side effect is likely to occur is acceptable; and
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> e. upon a determination that said risk is acceptable, generating a prescription approval code to be retrieved by said pharmacy before said prescription is filled.

CFAD filed three petitions for IPR, each challenging all 32 claims of the '720 patent. The Board instituted review of claims 1–32 in all three cases. In the first IPR, the Board instituted review based on obviousness over the Thalomid Package Insert,[4] Cunningham,[5] Zeldis,[6] and other prior art. *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, No. IPR2015-01096, Paper 21 (P.T.A.B. Oct. 27, 2015). In the second IPR, the Board instituted review based on obviousness over Powell and Dishman, in view of Cunningham, and further in view of Mann[7] and other prior art. *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, No. IPR2015-01102, Paper 21 (P.T.A.B. Oct. 27, 2015). In the third IPR, the Board instituted review based on obviousness over the same references as the second IPR but using Mitchell instead of Powell as the base reference.

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[4] *Thalomid™ (Thalidomide) Capsules Revised Package Insert* (July 15, 1998) (Appeal No. 18-1167, J.A. 411–32).

[5] U.S. Patent No. 5,832,449 (Appeal No. 18-1167, J.A. 440–62).

[6] Jerome B. Zeldis et al., *S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide*, Clinical Therapeutics® 21:2, 319–30 (1999) (Appeal No. 18-1167, J.A. 491–502).

[7] Thaddeus Mann & Cecelia Lutwak-Mann, *Passage of Chemicals into Human and Animal Semen: Mechanisms and Significance*, 11:1 CRC Critical Reviews in Toxicology 1, 1–14 (1982) (Appeal No. 18-1167, J.A. 8237–52).

Coalition for Affordable Drugs VI, LLC v. Celgene Corp., No. IPR2015-01103, Paper 22 (P.T.A.B. Oct. 27, 2015).

In each of its final written decisions, the Board held that CFAD had shown by a preponderance of the evidence that claims 1–32 of the '720 patent were unpatentable as obvious over the instituted ground. *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, No. IPR2015-01096, Paper 73 (P.T.A.B. Oct. 26, 2016) ("*-01096 Final Written Decision*"); *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, No. IPR2015-01102, Paper 75 (P.T.A.B. Oct. 26, 2016) ("*-01102 Final Written Decision*"); *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, No. IPR2015-01103, Paper 76 (P.T.A.B. Oct. 26, 2016) ("*-01103 Final Written Decision*"). Following Celgene's request for rehearing, the Board modified its final written decisions to uphold the patentability of claim 10 because CFAD failed to prove that claim obvious by a preponderance of the evidence.

D

Celgene timely appealed all four IPRs. We consolidated the appeals from the three IPRs on the '720 patent (Appeal Nos. 18-1167, 18-1168, 18-1169) and designated the appeal from the IPR on the '501 patent (Appeal No. 18-1171) as a companion case. CFAD did not participate in these appeals. The Director of the United States Patent and Trademark Office ("PTO") intervened pursuant to 35 U.S.C. § 143.

We have jurisdiction over these appeals pursuant to 28 U.S.C. § 1295(a)(4)(A).

II

On appeal, Celgene argues that the Board erred in finding all claims of the '501 patent and claims 1–9 and 11–32 of the '720 patent obvious. Celgene also argues that the retroactive application of IPRs to patents filed before September 16, 2012, when the relevant provisions of the

Leahy-Smith America Invents Act went into effect ("pre-AIA patents"), is an unconstitutional taking. We begin by addressing the merits of these appeals. Then, because we affirm the Board's obviousness determinations, we turn to the constitutional challenge.

A

1

Obviousness is a question of law based on underlying factual determinations. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). We review the Board's ultimate obviousness determination de novo and underlying factual findings for substantial evidence. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). Substantial evidence is "more than a mere scintilla" and means "'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Biestek v. Berryhill*, 139 S. Ct. 1148, 1154 (2019) (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)).

We review the Board's determination of the broadest reasonable interpretation of the claim language de novo. *Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1360 (Fed. Cir. 2015).[8]

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[8] We note that the PTO has since changed the claim construction standard used in IPR proceedings. *See* 37 C.F.R. § 42.100(b); *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). The new standard applies only to petitions filed on or after November 13, 2018, and therefore does not impact these cases. In these IPRs, the claims were to be construed using the broadest reasonable interpretation in light of the

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We begin with the '501 patent. Celgene seeks reversal, or at least vacatur and remand, of the Board's determination that CFAD established by a preponderance of the evidence that claims 1–10 would have been obvious over the combination of Powell, Mitchell, and Dishman. The Board relied on Powell's teachings of the clinical use and dispensing of thalidomide; Mitchell's description of a pregnancy-prevention program for women users of Accutane, another teratogenic drug; and Dishman's disclosure of a registry for pharmacies, prescribers, and users of clozapine, an anti-psychotic drug with serious potential side effects. *'501 Final Written Decision* at 13. The Board determined that a person of ordinary skill in the art would have been motivated to combine Powell, Mitchell, and Dishman "to address the problem of limiting thalidomide access to patients likely to suffer serious adverse side effects, including birth defects in a developing fetus." *Id.* at 24.

On appeal, Celgene challenges three aspects of the Board's obviousness determination: (1) its finding that the prior art satisfies the "computer readable storage medium," limitation, which rises and falls with a claim construction argument; (2) its finding that it would have been obvious to counsel male patients about the risks of teratogenic drugs; and (3) its findings on secondary considerations. We address each in turn.

a

Before the Board, Celgene argued that the term "computer readable storage medium" in claim 1 requires a *centralized* computer readable storage medium, namely "a centralized database that includes all registration

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specification. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016).

information regarding the claimed prescribers, pharmacies, and patients." *'501 Final Written Decision* at 9–10. The Board considered Celgene's proffered construction and rejected its argument that the computer readable storage medium of claim 1 must be centralized. *Id.* at 10–11. First, the Board noted that the term "centralized" does not appear in claim 1. *Id.* at 10. In addition, the Board found that the specification does not require that all registration information be centralized in one database. *Id.* ("'The computer readable storage medium in which the pharmacies are registered may be the same as, or different from the computer readable storage medium in which the prescribers are registered.'" (quoting '501 patent col. 4 ll. 54–57)). Finally, the Board considered and rejected Celgene's prosecution history and extrinsic evidence arguments. *See id.* at 10–11.

On appeal, Celgene again argues that the claims require a *centralized* computer readable storage medium. Appeal No. 18-1171, Appellant's Br. 31–36. According to Celgene, the claims' use of the term "said medium" referring back to "a computer readable storage medium" indicates that it must be a single, centralized computer readable storage medium. *Id.* at 32. But, as the PTO points out, the use of "a" or "an" in an open-ended "comprising" claim connotes "one or more." Appeal No. 18-1171, Intervenor's Br. 26–27; *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008). And "[t]he subsequent use of definite articles 'the' or 'said' in a claim to refer back to the same claim term does not change the general plural rule, but simply reinvokes that non-singular meaning." *Baldwin*, 512 F.3d at 1342. Exceptions to the general rule that "a" or "an" means more than one arise only when "the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule." *See id.* at 1342–43.

Neither the claims themselves, the specification, nor the prosecution history necessitate such a departure.

See '501 Final Written Decision at 10–11. The claims recite "a computer readable storage medium" and do not specify that it is centralized. The specification does not require that the computer readable storage medium be centralized. In fact, the specification envisions that there may be multiple, distinct computer readable storage media, i.e., separate media for prescribers, pharmacies, and patients. *See* '501 patent at col. 4 ll. 54–57, col. 10 ll. 13–17.

Further, we are not persuaded by Celgene's argument that the prosecution history disclaimed a non-centralized computer readable storage medium. *See* Appeal No. 18-1171, Appellant's Br. 33–34. We agree with the PTO that the better reading of the prosecution history is that Celgene distinguished the claimed invention from the prior art on the basis that the invention uses a computer readable storage medium while the prior art used the Internet. *See* Appeal No. 18-1171, Intervenor's Br. 31–33.

Finally, because the intrinsic evidence does not require a *centralized* computer readable storage medium, the Board was correct to not allow the extrinsic evidence, including expert testimony, to "trump the persuasive intrinsic evidence in this case." *'501 Final Written Decision* at 10. Under the broadest reasonable interpretation, the Board was therefore correct in determining that claim 1 was not limited to a *centralized* computer readable storage medium.

Based on the Board's finding that the computer readable storage medium recited in claim 1 need not be centralized, the Board found that Dishman's "computerized lockout system" satisfied the claim limitation. *Id.* at 18–20. Celgene concedes that Dishman teaches a decentralized storage medium and does not dispute that Dishman satisfies this limitation under the Board's construction. *See* Appeal No. 18-1171, Appellant's Br. 37. Because Celgene's challenge relies entirely on its

proposed claim construction and we affirm the Board's construction, Celgene's challenge must fail.[9]

For these reasons, Celgene's arguments on the "computer readable storage medium" limitation are unpersuasive and are not grounds for reversal or vacatur and remand.

b

Claim 1 of the '501 patent requires providing "male patients who are capable of impregnating females" with "counseling information concerning the risks attendant to fetal exposure to said drug." Celgene argues that counseling male patients about the risks of fetal exposure to the drug upon or after fertilization would not have been obvious. Appeal No. 18-1171, Appellant's Br. 25–31.

In finding this limitation obvious, the Board relied on CFAD's expert Dr. Jeffrey Fudin's opinion that at the time of the alleged invention, "the sperm of male patients could be damaged by teratogenic drugs and consequently result in birth defects, if the male was to impregnate a female." *'501 Final Written Decision* at 15–16. For support, Dr. Fudin relied on the Mann study, which showed that thalidomide had negative effects on the sperm of male rabbits and the fetuses resulting from mating with female rabbits. *See id.* at 15–17.

The Board evaluated Dr. Fudin's opinion and the supporting Mann study and credited his testimony that a person of ordinary skill in the art would have "understood

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[9] Even under Celgene's claim construction, the Board determined that its ultimate determination on obviousness would not change. *'501 Final Written Decision* at 11, 20. Specifically, the Board held, in the alternative, that using a centralized database would have been obvious. *See id.* at 20.

the necessity of counseling males, capable of impregnating females, about the risks that attend fetal exposure to a teratogenic drug." *Id.* at 16–17. The Board acknowledged that Powell stated that "[n]o effects on male sperm are recognized," but found that statement alone insufficient to defeat Dr. Fudin's testimony that an ordinarily skilled artisan would have recognized that sperm of male patients treated with teratogenic drugs could lead to birth defects in fetuses. *Id.* at 17.

On appeal, Celgene primarily disputes the Board's reading of Powell, specifically the statement that "[n]o effects on male sperm are recognized." *See* Appeal No. 18-1171, Appellant's Br. 26–29. The Board found that, when read in context, this statement in Powell refers to the *contraceptive* effects thalidomide has on male sperm, not the *teratogenic* effects thalidomide has on male sperm. *See '501 Final Written Decision* at 17. Celgene argues that "[n]o reasonable fact finder could possibly read" this sentence in Powell "as referring to the *contraceptive* effects of thalidomide." Appeal No. 18-1171, Appellant's Br. 27. But, the Board's decision on this limitation relied on Dr. Fudin's opinion, supported by Mann, as described above.

Celgene's main challenge to Dr. Fudin's opinion and his reliance on Mann was that the Mann study was conducted on male rabbits rather than human men. Appeal No. 18-1171, Appellant's Br. 30–31, Reply Br. 7–8. The Board considered and rejected this argument. *See '501 Final Written Decision* at 17 (noting that Celgene previously admitted that studies related to rabbit sperm were relevant to evaluating the effects of thalidomide on human sperm). Substantial evidence supports the Board's ultimate determination, based on Dr. Fudin's opinion as supported by Mann, that it would have been obvious in light of the prior art to counsel male patients about the risks of fetal exposure to the drug.

c

Finally, Celgene challenges the Board's determination that Celgene's evidence of objective indicia of non-obviousness was unpersuasive. The Board considered and weighed Celgene's evidence of long-felt but unmet need, industry praise, and unexpected results. Substantial evidence supports the Board's conclusions on each of these secondary considerations and its conclusion that they do not outweigh the showing of obviousness.

The Board found that Celgene failed to establish a long-felt but unsolved need because it did not show that the prior art methods of controlling the distribution of hazardous drugs—including Mitchell and Dishman—were insufficient to meet any need to control distribution of thalidomide. *'501 Final Written Decision* at 28. The Board acknowledged Celgene's evidence of industry praise and gave it weight. *See id.* The Board also considered Celgene's evidence of unexpected results but ultimately gave it "little weight" because the Board was not persuaded that the results obtained by combining the features of the prior art drug distribution programs to control distribution of thalidomide would have been truly unexpected. *See id.* at 28–29. The Board concluded that the evidence of secondary considerations did not outweigh the strong showing of obviousness. *See id.* at 29.

On appeal, Celgene challenges the Board's findings on unexpected results and long-felt need. Appeal No. 18-1171, Appellant's Br. 38–41, Reply Br. 16–23. On unexpected results, Celgene faults the Board's decision to give its evidence "little weight" and argues that it should have been given "significant, if not dispositive weight." Appeal No. 18-1171, Appellant's Br. 39–40. However, substantial evidence supports the Board's assessment and weighing of this evidence, and we decline to reweigh the evidence on appeal. *See In re NTP, Inc.*, 654 F.3d 1279, 1292 (Fed. Cir. 2011) ("This court does not reweigh evidence on appeal, but

rather determines whether substantial evidence supports the Board's fact findings."); *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1294 (Fed. Cir. 2018) ("We do not reweigh the evidence. It is not our role to ask whether substantial evidence supports fact-findings not made by the Board, but instead whether such evidence supports the findings that were in fact made.").

On long-felt need, Celgene identifies what it contends is an "inconsisten[cy]" between the Board's determination in this IPR on the '501 patent and the IPRs on the '720 patent. Appeal No. 18-1171, Reply Br. 22–23. In this case, the Board found no long-felt but unmet need for a better system to distribute potentially hazardous drugs like thalidomide in part because existing systems were available and adequate. *'501 Final Written Decision* at 28. As explained below, in the IPRs on the '720 patent, the Board found that there was a motivation to improve existing distribution systems for potentially hazardous drugs because of the severity of the possible adverse effects. *See, e.g.*, *-01096 Final Written Decision* at 22–23.

Contrary to Celgene's assertion, this tension is not irreconcilable. The fact that there is no long-felt, unmet need does not necessarily mean that there is no motivation to improve a system. *See Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1336 (Fed. Cir. 2015) (upholding district court's finding that "despite the motivation . . . there was not a long-felt but unmet need"). In fact, Celgene stated that it was "committed to making the S.T.E.P.S. program succeed and will make any modifications to the program that are necessary to ensure its effectiveness." *See* Appeal No. 18-1167, J.A. 501. Especially in this context involving safety, we see no conflict between finding a motivation to improve the safety of existing systems even though the existing systems were mostly successful. We conclude that substantial evidence supports the Board's assessment of Celgene's evidence of long-felt, unresolved need.

Finally, we see no error in the Board's ultimate determination of obviousness. Before concluding that the claims would have been obvious, the Board weighed the "strong showing of obviousness" against the "appropriate weight" given to evidence of industry praise and the "little weight" given to evidence of unexpected results. *'501 Final Written Decision* at 28–29.

We therefore affirm the Board's holding that claims 1–10 of the '501 patent are unpatentable as obvious over the asserted prior art.

3

Turning to the '720 patent, Celgene seeks reversal, or at least vacatur and remand, of the Board's determinations that CFAD established by a preponderance of the evidence that claims 1–9 and 11–32 would have been obvious over the prior art. The Board's analysis relevant to this appeal was nearly identical across all three proceedings. *See -01096 Final Written Decision* at 15–26; *-01102 Final Written Decision* at 16–27; *-01103 Final Written Decision* at 16–27; *see also* Appeal No. 18-1167, Appellant's Br. 27, Intervenor's Br. 26.

On motivation, the Board determined that a person of ordinary skill in the art would have been motivated to improve the existing distribution methods of potentially hazardous drugs because "where significant safety risks exist with a drug, one would continuously search for safer ways to control the distribution of the drug." *-01096 Final Written Decision* at 22–23; *-01102 Final Written Decision* at 24–25; *-01103 Final Written Decision* at 24–25.

The Board construed the claim term "prescription approval code" and adopted Celgene's proposed construction: "[A] code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the

risk of a side effect occurring is acceptable." *-01096 Final Written Decision* at 12–13; *-01102 Final Written Decision* at 13; *-01103 Final Written Decision* at 13.

The Board then considered whether the prior art taught the following disputed limitation: "upon a determination that said risk is acceptable, generating a prescription approval code to be retrieved by said pharmacy before said prescription is filled." The Board determined that it would have been obvious to a person of ordinary skill in the art because they would have appreciated that Cunningham's approval code, used to track and manage trial pharmaceutical products, could likewise be used by prescribers and pharmacies to track and manage prescription pharmaceutical products. *-01096 Final Written Decision* at 24; *-01102 Final Written Decision* at 26; *-01103 Final Written Decision* at 26. The Board concluded that:

> We further hold that the claimed improvement recited in the challenged claims represents a combination of known prior art elements (identifying patient risk groups, collecting patient information relating to the risk, determining whether the risk is acceptable, and controlling dispensation of the drug using both a prescription and an approval code) for their known purpose (control distribution of drug) to achieve a predictable result (avoid giving patients drugs that have an unacceptable risk of side effects).

-01096 Final Written Decision at 24–25; *-01102 Final Written Decision* at 26; *-01103 Final Written Decision* at 26.

On appeal, Celgene challenges two aspects of the Board's obviousness determination: (1) its finding that there was a motivation to improve the existing distribution methods of potentially hazardous drugs; and (2) its finding that a person of skill in the art would have been motivated to develop the claimed invention. We address each below.

a

Celgene first argues that there was no motivation to improve the existing method for avoiding birth defects from exposure to thalidomide (the Original S.T.E.P.S. program) because it was working so well that there had been no reports of birth defects or even potential fetal exposure to thalidomide using that system. Appeal No. 18-1167, Appellant's Br. 32–33, 35–37. Celgene contends that because there were no problems with the Original S.T.E.P.S. program, a person skilled in the art would not have been motivated to improve it. *See id.* Celgene essentially argues that there was no motivation because, "[i]f it ain't broke, don't fix it." *Id.* at 33.

The Board considered and rejected this argument, finding that there was a motivation because there are serious concerns with distributing a drug, like thalidomide, that is known to cause severe adverse side effects. *-01096 Final Written Decision* at 22–23; *-01102 Final Written Decision* at 24–25; *-01103 Final Written Decision* at 24–25 ("[W]here significant safety risks exist with a drug, one would continuously search for safer ways to control the distribution of the drug. Put simply, where significant safety concerns exist[], one of ordinary skill in the art would not wait until an accident occurred to seek out improvements.").

The Board's motivation determination is supported by substantial evidence. For example, in Zeldis, Celgene professed its commitment to making improvements to the S.T.E.P.S. program. Appeal No. 18-1167, J.A. 501 ("Celgene is committed to making the S.T.E.P.S. program succeed and will make any modifications to the program that are necessary to ensure its effectiveness.").

Finally, Celgene challenges the Board's motivation as too "generic." Appeal No. 18-1167, Appellant's Br. 35–37. We disagree. The desire to decrease the risks of administering a drug with adverse side effects, like

thalidomide, is a specific motivation to improve the prior art. *See, e.g.*, *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371–72 (Fed. Cir. 2011) (upholding obviousness determination and motivation finding based on the "need in the prior art for safer utility lighters"); *Hologic, Inc. v. Minerva Surgical, Inc.*, 764 F. App'x 873, 880 (Fed. Cir. 2019) ("The lack of any specific safety concerns does not preclude a motivation to make a device safer."). We disagree with Celgene's assertion that approving of this motivation "leave[s] no room for patents on improvement." Appeal No. 18-1167, Appellant's Br. 37. In a case like this, where safety is a concern and where the potential adverse side effects are so severe, the Board did not err in finding that the desire to improve a system that is working well qualifies as a valid motivation.

b

Celgene also argues that, even if there had been a general motivation to improve the prior art systems, "substantial evidence does not show that there was motivation to overhaul that program with the particular, *prospective*, doctor-interfering system claimed by the '720 patent." Appeal No. 18-1167, Appellant's Br. 38; *see also id.* at 38–43.

First, Celgene faults the Board for allegedly failing to explain "how the prior art renders obvious the claims' required affirmative risk assessment." *Id.* at 40. Contrary to Celgene's assertions, the Board did not "ignore" its affirmative risk assessment argument. In fact, the Board incorporated the notion of affirmative risk assessment into its claim construction and considered it in its obviousness findings. *See -01096 Final Written Decision* at 12–15; *-01102 Final Written Decision* at 13–16; *-01103 Final Written Decision* at 13–16. The Board relied on each of the primary references—Thalomid Package Insert, Powell, and Mitchell—for the teaching of an affirmative risk assessment. *See -01096 Final Written Decision* at 17–18,

20 (Thalomid Package Insert); *-01102 Final Written Decision* at 17–18, 21–22 (Powell); *-01103 Final Written Decision* at 17–18, 21–22 (Mitchell). And the Board found that it would have been obvious to modify the methods for limiting distribution of drugs with adverse side effects to high risk groups, disclosed in Thalomid Package Insert, Powell, or Mitchell, to require issuance of an approval code prior to dispensing the drug as disclosed in Cunningham. *See -01096 Final Written Decision* at 23–25; *-01102 Final Written Decision* at 25–27; *-01103 Final Written Decision* at 25–27. Substantial evidence supports those findings.

Next, Celgene faults the Board for not including the word "prospective" in its final written decisions. Appeal No. 18-1167, Appellant's Br. 40. But the term "prospective" does not appear in claim 1 or in the Board's construction of "prescription approval code." Thus, it is neither erroneous nor particularly surprising that it does not appear in the Board's final written decisions.

Finally, Celgene argues that none of the prior art references disclose a system to "override" a doctor's prescription. *See, e.g.*, Appeal No. 18-1167, Appellant's Br. 40–42, Reply Br. 3–4, 6–7. However, a physician "override" is not required by the language of claim 1 or by the Board's construction of "prescription approval code."

We therefore affirm the Board's determination that claims 1–9 and 11–32 of the '720 patent are unpatentable as obvious over the asserted prior art.

B

We now turn to the constitutional issue of whether the retroactive application of IPRs to pre-AIA patents is an unconstitutional taking.[10]

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[10] The parties' arguments on the constitutional issue are almost identical in the two appeals. Therefore, in this

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We must first decide whether to reach the constitutional challenge even though Celgene did not raise it before the Board and makes the argument for the first time on appeal.

"It is well-established that a party generally may not challenge an agency decision on a basis that was not presented to the agency." *In re DBC*, 545 F.3d 1373, 1378 (Fed. Cir. 2008). But we have discretion to reach issues raised for the first time on appeal, and in *DBC* we recognized that there are exceptions that may justify considering constitutional arguments not raised below. *Id.* at 1379–80 ("Because we retain discretion to reach issues raised for the first time on appeal, we must consider whether this is one of those exceptional cases that warrants consideration of the [constitutional] issue despite its tardy presentation.").

Departing from the general rule of waiver is appropriate only in limited circumstances. *See id.* at 1380 (stating that addressing an issue not raised below is "an exceptional measure" appropriate only in "rare cases"); *see also Golden Bridge Tech., Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1322–23 (Fed. Cir. 2008) (stating that "deviat[ing] from this general rule of waiver" and "hearing new arguments for the first time on appeal" is disfavored "absent limited circumstances"). One such circumstance that can justify departing from the general rule of waiver is an intervening change in the law. *See Golden Bridge*, 527 F.3d at 1323. We also consider whether the "interest of justice" guides us to consider the issue despite the fact that it was not raised below. *See id.*

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section, we cite only to the briefs in Appeal No. 18-1167 unless otherwise noted.

The PTO concedes that we have discretion to deviate from our general rule of waiver and that doing so here to resolve the constitutional issue presented may be in the interest of justice. As the PTO recognized, "[g]iven the growing number of retroactivity challenges apparently prompted by the reference to retroactivity in *Oil States*, however, this Court may nevertheless conclude that the interests of justice warrant addressing the retroactivity question quickly to avert further uncertainty regarding the constitutionality of inter partes review." Intervenor's Br. 37 (footnote omitted).

We have indeed seen a growing number of retroactivity challenges following the Supreme Court's decision in *Oil States*, including several that are currently pending before this court. The Supreme Court left open this challenge with the following passage near the end of its decision in *Oil States*:

> Moreover, we address only the precise constitutional challenges that Oil States raised here. Oil States does not challenge the retroactive application of inter partes review, even though that procedure was not in place when its patent issued. Nor has Oil States raised a due process challenge. Finally, our decision should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause.

Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1379 (2018). While Celgene's constitutional challenge does not rely on a change in the law articulated in *Oil States*, it raises an issue not directly resolved by *Oil States*. *Oil States* was decided on April 24, 2018, well after the Board's October 26, 2016 final written decisions in the IPRs involved in this appeal, which at least partially explains why Celgene did not raise the argument before the Board.

Even if Celgene had raised its constitutional challenge before the Board, it is unclear how the Board could have corrected the alleged constitutional defect as it could have in *DBC*. *See DBC*, 545 F.3d at 1379 ("If DBC had timely raised this issue before the Board, the Board could have evaluated and corrected the alleged constitutional infirmity by providing DBC with a panel of administrative patent judges appointed by the Secretary.").[11]

Moreover, the constitutional challenge presented here is purely a question of law, so addressing it would not require us "to make factual findings" for the first time on appeal. *See Golden Bridge*, 527 F.3d at 1323.

Finally, the briefing on the constitutional issue in this case is sufficiently thorough for our review. *See* Appellant's Br. 44–52; Intervenor's Br. 35–44; Reply Br. 20–28. This case stands in sharp contrast with *Trading Technologies International, Inc. v. IBG LLC*, 921 F.3d 1378, 1385 (Fed. Cir. 2019), where we declined to consider a number of

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[11] The Supreme Court has "stated that 'adjudication of the constitutionality of congressional enactments has generally been thought beyond the jurisdiction of administrative agencies.'" *Elgin v. Dep't of Treasury*, 567 U.S. 1, 16 (2012) (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 (1994)). When asked at oral argument if the Board had authority to adjudicate a constitutional challenge to the AIA, the PTO responded that if the Board determined that the retroactive application of IPRs to pre-AIA patents was an unconstitutional taking, the Board could exercise its discretion to decline to institute the IPR. *See* Oral Argument at 36:52–37:57, *Celgene Corp. v. Peter* (No. 2018-1167), http://www.cafc.uscourts.gov/oral-argument-recordings. That decision, however, would be unreviewable but for the possibility of mandamus. *See Cuozzo*, 136 S. Ct. at 2142.

constitutional challenges to IPRs included in "a total of four sentences" in the appellant's opening brief. *Id.* ("Such a conclusory assertion with no analysis is insufficient to preserve the issue for appeal."). Here, a single constitutional issue received thorough briefing from the parties and was addressed extensively at oral argument. *See* Oral Argument at 5:06–21:50, 50:22–52:56 (Celgene), 36:27–48:47 (Director), *Celgene Corp. v. Peter* (No. 2018-1167), http://www.cafc.uscourts.gov/oral-argument-recordings.[12]

We therefore conclude that this is one of those exceptional circumstances in which our discretion is appropriately exercised to hear Celgene's constitutional challenge even though it was not raised below.

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[12] As to the suggestion that we wait until a case reaches us where the retroactivity challenge was raised below and decided by the Board, the first such case identified is *Agarwal v. TopGolf International, Inc.*, No. 18-2270. In *TopGolf*, the Board allowed additional briefing on the constitutional issues left open by *Oil States*. In a single sentence of analysis, the Board determined that the retroactive application of IPRs was not unconstitutional, reasoning that "the patent at issue here was subject to *ex parte* reexamination, and, therefore, the United States Patent and Trademark Office has always had the ability to look at the patentability of an issued United States Patent." *TopGolf Int'l, Inc. v. Amit Agarwal*, No. IPR2017-00928, Paper 40, at 80 (P.T.A.B. June 13, 2018). On appeal, Mr. Agarwal's constitutional challenge to the retroactive application of IPRs to pre-AIA patents is one page of his opening brief. Brief for Appellant at 69–70, *Agarwal v. TopGolf Int'l, Inc.* (No. 18-2270). The reply brief is due on November 12, 2019, and the case will likely not be argued for at least several months thereafter.

2

We now turn to the merits of Celgene's constitutional challenge that the retroactive application of IPRs to pre-AIA patents is an unconstitutional taking.

The Takings Clause of the Fifth Amendment states that private property shall not "be taken for public use, without just compensation." U.S. Const. amend. V. The PTO does not dispute that a valid patent is private property for the purposes of the Takings Clause. *See* Intervenor's Br. 43 ("A patent holder has a property interest in a valid patent . . . ."); Oral Argument at 41:06–41:22, *Celgene Corp. v. Peter* (No. 2018-1167), http://www.cafc.uscourts.gov/oral-argument-recordings. ("We don't dispute that a valid patent is property for purposes of the Takings Clause.").

Celgene argues that the retroactive application of IPRs to their pre-AIA patents without just compensation is an unconstitutional taking under the Fifth Amendment. Appellant's Br. 44–52. Specifically, Celgene advances a regulatory takings theory and argues that subjecting its pre-AIA patents to IPR, a procedure that did not exist at the time its patents issued, unfairly interferes with its reasonable investment-backed expectations without just compensation. *Id.* at 44–45, 49–51.

The PTO responds on two fronts. First, the PTO argues that when the Board finds claims unpatentable in an IPR, it does not effectuate a taking under the Fifth Amendment because the patent owner "never had a valid property right because the patent was erroneously issued in the first instance." Intervenor's Br. 38; *see also id.* at 38–41. Second, the PTO argues that Celgene's takings claim fails "because patents have been subject to reconsideration and cancellation by the USPTO in administrative proceedings for nearly four decades, and Celgene's own patent[s were] issued subject to this administrative revocation authority." *Id.* at 42; *see also id.* at 42–44. The PTO does not expressly

engage Celgene's reasonable investment-backed expectations argument. But the PTO does respond that "the AIA did not alter patent holders' substantive rights." *See id.* at 43. Rather, the PTO maintains that the AIA "merely revised the procedures by which [the] USPTO conducts these administrative proceedings" and that the procedural differences do not effect a Fifth Amendment taking. *See id.*

In determining whether the retroactive application of IPRs to pre-AIA patents is an unconstitutional taking, we consider the effect that doing so has on the patent right granted by the PTO, and specifically whether IPRs differ from the pre-AIA review mechanisms significantly enough, substantively or procedurally, to effectuate a taking. We conclude that they do not. On this basis, we reject Celgene's challenge even apart from the rationales of our prior decisions—which we also think control the outcome here, but which Celgene asks us to reconsider—that rejected constitutional challenges to retroactive application of the pre-AIA *ex parte* reexamination mechanism.[13]

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[13] In *Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir. 1985), we faced a challenge to the retroactive application of *ex parte* reexaminations and held that it did not violate the due process clause of the Fifth Amendment, the jury trial guarantee of the Seventh Amendment, or Article III. *Id.* at 603, 605. Our retroactivity analysis in *Patlex* relied in part on the "curative" nature of reexaminations and that "[c]urative statutes have received relatively favored treatment from the courts even when applied retroactively." *Id.* at 603.

We later considered a challenge to the retroactive application of *ex parte* reexaminations based on the Takings Clause in *Joy Technologies, Inc. v. Manbeck*, 959 F.2d 226 (Fed. Cir. 1992), *superseded by statute on other*

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. As explained below, IPRs do not differ significantly enough from preexisting PTO mechanisms for reevaluating the validity of issued patents to constitute a Fifth Amendment taking.

By the time Celgene filed the application that became the '501 patent (1998) and the patent was issued (2000), and by the time Celgene filed the application that became the '720 patent (2000) and the patent was issued (2001), *ex parte* reexamination had existed for roughly two decades. *Ex parte* reexamination, created by Congress in 1980 and still available today, allows "[a]ny person at any time" to "file a request for reexamination." 35 U.S.C. § 302. The PTO determines whether the request raises "a substantial new question of patentability affecting any claim of the patent." *Id.* § 303(a). If it does, the reexamination is "conducted according to the procedures established for initial examination," and the patent owner has the opportunity to amend claims. *Id.* § 305. The reexamination results in the confirmation of claims found

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grounds. Applying our reasoning in *Patlex*, we rejected the patent owner's argument that *ex parte* reexamination and subsequent cancellation of some claims of its patent constituted a taking even though no PTO reexamination mechanisms existed when its patent issued. *See id.* at 228–29.

The patent owners in *Patlex* and *Joy Technologies* had a stronger argument than Celgene does here because, before the creation of *ex parte* reexaminations, there were no PTO reexamination procedures. In contrast, 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.

to be patentable and the cancellation of claims found to be unpatentable. *Id.* § 307(a).

Inter partes reexamination, created by Congress in 1999, was also available when Celgene filed the '720 patent, although not when it filed the '501 patent. A third party could request *inter partes* reexamination, and the standard to initiate the reexamination was whether the request raised a "substantial new question of patentability." 35 U.S.C. §§ 311–12 (1999) (amended). *Inter partes* reexamination "granted third parties greater opportunities to participate in the Patent Office's reexamination proceedings," and, following amendments in 2002, also allowed third parties to participate in any appeal of the PTO's final reexamination decision. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137 (2016).

Celgene's pre-AIA patents were therefore granted subject to existing judicial and administrative avenues for reconsidering their validity. Not only were they subject to challenge in district court, "[f]or several decades, the Patent Office has also possessed the authority to reexamine—and perhaps cancel—a patent claim that it had previously allowed." *Id.*

IPRs are the most recent legislative modification to the PTO's longstanding reconsideration procedures.[14] In 2011, as part of the AIA, Congress created IPRs, which replaced *inter partes* reexamination. Leahy–Smith America Invents Act, Pub. L. No. 112-29, § 6, 125 Stat. 284, 299–313 (2011) (codified as amended at 35 U.S.C. §§ 311–19 (2012)). IPRs allow a third party to request that the PTO "reexamine the claims in an already-issued patent and to cancel any claim

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[14] Celgene's suggestion that PTO reconsideration "is a creation of the 2011 AIA legislation" or only available "[s]ince the AIA" is incorrect. *See* Appellant's Br. 46.

that the agency finds to be unpatentable in light of [the] prior art" specified in 35 U.S.C. § 311(b). *Cuozzo*, 136 S. Ct. at 2136.

In this case it suffices for us to decide that IPRs do not differ sufficiently from the PTO reconsideration avenues available when the patents here were issued to constitute a Fifth Amendment taking. Celgene identifies a number of differences between reexaminations and IPRs, including that IPRs are adjudicative and have discovery, briefing, and an oral hearing, Appellant's Br. 47, but as explained below, these differences are not sufficiently substantive or significant to constitute a taking.

Unsurprisingly, Celgene does not grapple with the far more significant similarities between IPRs and their reexamination predecessors. In IPRs, patents are reviewed on the same substantive grounds—anticipation and obviousness, based on the same categories of prior art—as *ex parte* and *inter partes* reexaminations.[15] IPRs and reexaminations use the same preponderance of the evidence standard of proof. *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)). And the same broadest reasonable interpretation standard for claim construction used in reexaminations also applied in these

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[15] It is undisputed that the Board's grounds for determining unpatentability were available under the reexamination procedures in place at the time the '501 patent and '720 patent issued in 2000 and 2001, respectively.

IPRs.[16] *See 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, or BRI." (quoting *In re NTP, Inc.*, 654 F.3d 1268, 1274 (Fed. Cir. 2011)).

IPRs and reexaminations are also similar in that the Director has discretion to initiate the proceeding. In *ex parte* reexamination, the Director determines "whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request." 35 U.S.C. § 303(a). In IPRs, the Director has discretion to institute IPR if there is "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *Id.* § 314(a). In both proceedings, the Director's discretionary determination is final and non-appealable. *See id.* §§ 303(c), 314(d).

Notably, IPRs serve essentially the same purpose as their reexamination predecessors. As the Supreme Court has said:

> The [IPR] proceeding involves what used to be called a *reexamination* (and, as noted above, a cousin of inter partes review, *ex parte* reexamination, 35 U.S.C. § 302 *et seq.*, still bears that name). The name and accompanying procedures suggest that the proceeding offers a second look at an earlier administrative grant of a patent. Although Congress changed the name from "reexamination" to "review," nothing convinces us

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[16] As noted above, the PTO has since changed the claim construction standard used in IPR proceedings to align with the standard used in district court proceedings, a change that is favorable to the patent owner. *See supra* note 8.

> that, in doing so, Congress wanted to change its basic purposes, namely, to reexamine an earlier agency decision.

Cuozzo, 136 S. Ct. at 2144; *see also Oil States*, 138 S. Ct. at 1374 ("Inter partes review is 'a second look at an earlier administrative grant of a patent.'" (quoting *Cuozzo*, 136 S. Ct. at 2144)).[17]

Moreover, the Supreme Court has described district court challenges, *ex parte* reexaminations, and IPRs as different forms of the same thing—reexamination. *See Return Mail, Inc. v. United States Postal Serv.*, 139 S. Ct. 1853, 1860 (2019) ("In sum, in the post-AIA world, a patent can be reexamined either in federal court during a defense to an infringement action, in an ex parte reexamination by the Patent Office, or in the suite of three post-issuance review proceedings before the Patent Trial and Appeal Board."). All three serve the purpose of correcting prior agency error of issuing patents that should not have issued in the first place:

> Sometimes, though, bad patents slip through. Maybe the invention wasn't novel, or maybe it was obvious all along, and the patent owner shouldn't enjoy the special privileges it has received. To remedy these sorts of problems, Congress has long permitted parties to challenge the validity of patent claims in federal court. More recently,

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[17] The legislative history of the AIA confirms that one of the objectives of IPRs was to "revisit and revise" issued patents. *See Cuozzo*, 136 S. Ct. at 2140. In this way, IPRs serve the broader goal of improving patent quality. *See* H.R. Rep. No. 112-98, pt. 1, at 48 (2011), as *reprinted in* 2011 U.S.C.C.A.N. 67, 78 (explaining objective to "improve patent quality and restore confidence in the presumption of validity that comes with issued patents").

> Congress has supplemented litigation with various administrative remedies.

SAS Inst., Inc. v. Iancu, 138 S. Ct. 1348, 1353 (2018) (citation omitted); *see also Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 96 (2011) (describing district court challenges as an "attempt to prove that the patent never should have issued in the first place"); *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1338 (Fed. Cir. 2013) (stating that "ex parte reexamination is a curative proceeding meant to correct or eliminate erroneously granted patents").

There are undoubtedly differences between IPRs and their predecessors. This is not surprising given that Congress passed the AIA with post grant review procedures that were intentionally more robust and would provide a "more efficient system for challenging patents that should not have issued." *See* H.R. Rep. No. 112-98, pt. 1, at 39–40 (2011), as *reprinted in* 2011 U.S.C.C.A.N. 67, 69.[18] Celgene is correct that IPRs are "adjudicatory in nature." *Return Mail*, 139 S. Ct. at 1860. Among the "adjudicatory characteristics" of IPRs Celgene notes are discovery, briefing, and an oral hearing. *See* Appellant's Br. 47. But these procedural differences come with the longstanding recognition that "'[n]o one has a vested right in any given mode of procedure.'" *Denver & Rio Grande W. R.R. Co. v. Bhd. of R.R. Trainmen*, 387 U.S. 556, 563 (1967) (quoting *Ex parte Collett*, 337 U.S. 55, 71 (1949)). These differences do not disrupt the expectation that patent

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[18] Implementing IPRs to create a more robust and efficient system for challenging the validity of patents is not unlike the PTO or Congress making the system more robust by, for example, increasing the budget for or number of examiners in the reexamination unit. While those changes might result in significantly more requests for reexamination and more claims being canceled, we doubt that anyone would argue that they effectuate a taking.

owners have had for nearly four decades—that patents are open to PTO reconsideration and possible cancelation if it is determined, on the grounds specified in § 311(b), that the patents should not have issued in the first place.

Celgene also argues that statistics show that IPRs have caused a permanent reduction in the value of patents granted before the AIA. *See* Appellants' Br. 48–49 (citing statistics); Reply Br. 26–27 (citing statistics and arguing that they show that "patents subjected to *inter partes* review have been clobbered in ways previously unimaginable").[19] But Celgene has made no showing—nor could it—that claims canceled in IPRs, including its own claims, would have fared any better in the preexisting reexamination procedures.

Recognizing that its patents were also always open to challenge in district court, Celgene attempts to distinguish IPRs from district court proceedings by arguing that while IPRs resemble district court proceedings in some respects,[20] IPRs lack the "same process or rights as civil

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[19] Celgene notes that almost as many IPRs were filed and instituted in the first four years after they were created as were filed in the twelve years *inter partes* reexamination were available. Appellant's Br. 48. This statistic, which merely compares the frequency that these procedures are utilized but does not compare ultimate outcomes, does not sway our analysis.

[20] That IPRs resemble district court litigation in some ways is in line with one of the objectives of the AIA, which was to provide an alternative to district court litigation. *See* H.R. Rep. No. 112-98, pt. 1, at 48 (describing IPR as a "quick and cost effective alternativ[e] to litigation"); S. Rep. No. 110-259, at 20 (2008) (describing IPR as "a quick, inexpensive, and reliable alternative to district court litigation"). The fact that IPRs may have shifted some

litigation." *See* Appellants' Br. 47–48; Reply Br. 26–27. But the differences that Celgene identifies between district court proceedings and IPRs only serve to demonstrate that IPRs are similar to reexaminations. For example, IPRs use a preponderance of the evidence burden of proof rather than the district court's clear and convincing evidence burden of proof. And IPRs, at the time of these proceedings, used the broadest reasonable interpretation for claim construction rather than the narrower standard from *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) used in district court. While these IPR standards differ from those used in district court, they were previously used in *ex parte* and *inter partes* reexamination procedures, as explained above. Celgene also notes that the presumption of validity that applies in district court proceedings, overcome only by clear and convincing evidence, does not apply in IPRs. Reply Br. 26–27. However, the presumption of validity also did not apply in the preexisting reexamination proceedings. *See In re Etter*, 756 F.2d 852, 855–56 (Fed. Cir. 1985). Moreover, we long ago explained that "[w]e do not consider the section 282 presumption [of validity] . . . to be a property right subject to the protection of the Constitution." *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 605 (Fed. Cir. 1985), *reh'g granted on other grounds*, 771 F.2d 480 (Fed. Cir. 1985). In any event, because Celgene's patents were granted subject to similar reexamination standards, as discussed above, the differences between IPRs and district court proceedings that Celgene identifies do not create a constitutional issue.

In light of the foregoing, we hold that the retroactive application of IPR proceedings to pre-AIA patents is not an unconstitutional taking under the Fifth Amendment. Patent owners have always had the expectation that the

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validity challenges from the district court to the PTO does not effectuate a taking.

validity of patents could be challenged in district court. For 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. Although differences exist between IPRs and their reexamination predecessors, those differences do not outweigh the similarities of purpose and substance and, at least for that reason, do not effectuate a taking of Celgene's patents.

III

We have considered Celgene's remaining arguments and find them unpersuasive. We affirm the Board's determination that all of the claims of the '501 patent and claims 1–9 and 11–32 of the '720 patent are invalid as obvious.

AFFIRMED