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Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information has a valid OMB control number.

#### List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, 37 CFR part 1 is amended as follows:

#### PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR part 1 continues to read as follows:

**Authority:** 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Section 1.27 is amended by revising paragraph (a)(4) to read as follows:

**§ 1.27 Definition of small entities and establishing status as a small entity to permit payment of small entity fees; when a determination of entitlement to small entity status and notification of loss of entitlement to small entity status are required; fraud on the Office.**

(a) \* \* \*

(4) *Federal Government Use License Exceptions.* In a patent application filed, prosecuted, and if patented, maintained at no expense to the Government, with the exception of any expense taken to deliver the application and fees to the Office on behalf of the applicant:

(i) For persons under paragraph (a)(1) of this section, claiming small entity status is not prohibited by:

(A) A use license to the Government resulting from a rights determination under Executive Order 10096 made in accordance with § 501.6 of this title;

(B) A use license to the Government resulting from Federal agency action pursuant to 15 U.S.C. 3710d(a) allowing the Federal employee-inventor to obtain or retain title to the invention; or

(C) A use license to a Federal agency resulting from retention of rights under 35 U.S.C. 202(d) by an inventor employed by a small business concern or nonprofit organization contractor, provided the license is equivalent to the license under 35 U.S.C. 202(c)(4) the Federal agency would have received had the contractor elected to retain title, and all the conditions applicable under § 401.9 of this title to an employee/inventor are met.

(ii) For small business concerns and nonprofit organizations under paragraphs (a)(2) and (3) of this section, a use license to a Federal agency resulting from a funding agreement with that agency pursuant to 35 U.S.C. 202(c)(4) does not preclude claiming small entity status, provided that:

(A) The subject invention was made solely by employees of the small business concern or nonprofit organization; or

(B) In the case of a Federal employee co-inventor, the Federal agency employing such co-inventor took action pursuant to 35 U.S.C. 202(e)(1) to exclusively license or assign whatever rights currently held or that it may acquire in the subject invention to the small business concern or nonprofit organization, subject to the license under 35 U.S.C. 202(c)(4).

(iii) For small business concerns and nonprofit organizations under paragraphs (a)(2) and (3) of this section that have collaborated with a Federal agency laboratory pursuant to a cooperative research and development agreement (CRADA) under 15 U.S.C. 3710a(a)(1), claiming small entity status is not prohibited by a use license to the Government pursuant to:

(A) 15 U.S.C. 3710a(b)(2) that results from retaining title to an invention made solely by the employee of the small business concern or nonprofit organization; or

(B) 15 U.S.C. 3710a(b)(3)(D), provided the laboratory has waived in whole any right of ownership the Government may have to the subject invention made by the small business concern or nonprofit organization, or has exclusively licensed whatever ownership rights the Government may acquire in the subject invention to the small business concern or nonprofit organization.

(iv) Regardless of whether an exception under this paragraph (a)(4) applies, no refund under § 1.28(a) is available for any patent fee paid by the Government.

\* \* \* \* \*

■ 3. Section 1.29 is amended by revising paragraphs (a)(1) and (d)(1) to read as follows:

#### § 1.29 Micro entity status.

(a) \* \* \*

(1) The applicant qualifies as a small entity as defined in § 1.27 without relying on a government use license exception under § 1.27(a)(4);

\* \* \* \* \*

(d) \* \* \*

(1) The applicant qualifies as a small entity as defined in § 1.27 without relying on a government use license exception under § 1.27(a)(4); and

\* \* \* \* \*

**Andrei Iancu,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

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#### DEPARTMENT OF COMMERCE

#### Patent and Trademark Office

#### 37 CFR Part 42

[Docket No. PTO-P-2019-0011]

RIN 0651-AD34

#### Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** The United States Patent and Trademark Office (USPTO or Office) revises the rules of practice in *inter partes* review (IPR), post-grant review (PGR), and the transitional program for covered business method patents (CBM) (collectively post-grant trial) proceedings before the Patent Trial and Appeal Board (PTAB or Board) to allocate the burdens of persuasion in relation to motions to amend and the patentability of substitute claims proposed therein. In light of Federal Circuit case law, and to better ensure the predictability and certainty of post-grant trial proceedings before the Board, the Office revises the rules of practice governing motions to amend, to expressly assign to the petitioner the burden of showing the unpatentability of substitute claims proposed in a motion to amend. In addition, the Office revises the rules to expressly assign to the patent owner the burden of showing that a motion to amend complies with certain statutory and regulatory requirements for such a motion. Notwithstanding the adversarial nature

of the proceedings and the burdens described above, however, the Office further revises its rules to expressly provide that the Board itself may, in the interests of justice, exercise its discretion to grant or deny a motion to amend only for reasons supported by readily identifiable and persuasive evidence of record in the proceeding. The Office anticipates the Board will exercise its discretion in the interests of justice only in rare circumstances. In doing so, the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice. Where the Board exercises its discretion in such circumstances, the parties will have an opportunity to respond.

#### DATES:

*Effective date:* The changes in this final rule are effective January 20, 2021.

*Applicability date:* This final rule applies to all motions to amend filed in an IPR, PGR, or CBM proceeding on or after January 20, 2021.

#### FOR FURTHER INFORMATION CONTACT:

Christopher L. Crumbley, Lead Administrative Patent Judge, or Susan L. C. Mitchell, Lead Administrative Patent Judge, by telephone at 571–272–9797.

#### SUPPLEMENTARY INFORMATION:

##### Executive Summary

*Purpose:* This final rule amends the rules of practice for IPR, PGR, and CBM proceedings that implement provisions of the Leahy-Smith America Invents Act, Public Law 112–29, 125 Stat. 284 (2011) (AIA) providing for post-grant trials before the Office.<sup>1</sup>

Pursuant to the AIA, during the course of an IPR, PGR, or CBM proceeding, a patent owner may file a motion to amend the patent by canceling any challenged patent claim or by proposing a reasonable number of substitute claims for each challenged claim. 35 U.S.C. 316(d)(1), 326(d)(1).

Previously, relying on a general rule that a movant bears the burden of proof with respect to motions before the Board (37 CFR 42.20(c)), the Office placed the burden of showing the patentability of proposed substitute claims on the patent owner moving to amend a patent in a trial proceeding. On October 4, 2017, the United States Court of Appeals for the Federal Circuit issued an *en banc* decision in *Aqua Prods., Inc. v. Matal*,

872 F.3d 1290 (Fed. Cir. 2017) (*en banc*) (*Aqua Products*), in which a majority of the judges concluded that the Office had not adopted a rule allocating the burden of persuasion with respect to the patentability of proposed substitute claims and that, in the absence of any rulemaking, the burden of proving the unpatentability of the proposed substitute claims could not be placed on the patent owner.

In light of *Aqua Products*, as well as public comments provided in response to a request for comments (*see* 83 FR 54319), the Office issued a notice of proposed rulemaking, which proposed specific rules allocating the burdens of persuasion in relation to motions to amend (*see* 84 FR 56401). The proposed rule, as modified herein, is now made final.

The final rule assigns the burden of persuasion to the patent owner to show, by a preponderance of the evidence, that a motion to amend complies with certain statutory and regulatory requirements for a motion to amend (*i.e.*, 35 U.S.C. 316(d) or 326(d); 37 CFR 42.121(a)(2), (a)(3), (b)(1), (b)(2), or 42.221(a)(2), (a)(3), (b)(1), (b)(2)). The final rule also assigns the burden of persuasion to the petitioner to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable. The final rule further specifies, however, irrespective of those burdens and the adversarial nature of the proceeding, that the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend, but only for reasons supported by readily identifiable and persuasive evidence of record in the proceeding. In doing so, the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice. Where the Board exercises its discretion in such circumstances, the parties will have an opportunity to respond.

The Office anticipates that the Board will exercise its discretion in the context of motions to amend only in rare circumstances. Specifically, the “interests of justice” in the final rule means that the Board will apply the same standards articulated in *Hunting Titan, Inc. v. DynaEnergetics Europe GmbH*, IPR2018–00600 (PTAB July 6, 2020) (Paper 67) (*Hunting Titan*). Thus, the phrase “in the interests of justice” in the final rule refers to situations in which the adversarial process fails to provide the Board with potential arguments relevant to granting or denying a motion to amend. *Id.* at 12–13, 25–26.

Such situations may include, for example, those in which the petitioner has ceased to participate in the proceeding or chooses not to oppose the motion to amend, or those in which certain evidence regarding unpatentability has not been raised by either party but is so readily identifiable and persuasive that the Board should take it up in the interest of supporting the integrity of the patent system, notwithstanding the adversarial nature of the proceedings. *Id.* Similarly, such situations may also include those in which a patent owner does not expressly address or establish every statutory and regulatory requirement for a motion to amend in its briefing, but evidence of compliance with those requirements is so readily identifiable and persuasive that the Board should take it up in the interest of supporting the integrity of the patent system, notwithstanding the adversarial nature of the proceedings.

Thus, the final rule clarifies the rules of practice for amending claims in an IPR, PGR, or CBM and is consistent with *Aqua Products* and also with current Board practice as described in the precedential Board decisions in *Hunting Titan* and *Lectrosomics, Inc. v. Zaxcom, Inc.*, IPR2018–01129 (PTAB Feb. 25, 2019) (Paper 15) (*Lectrosomics*). In response to comments seeking clarification, the final rule also provides additional details to the scope of “readily identifiable and persuasive evidence of record” to include only evidence that the Board may make of record, namely, evidence in a related proceeding before the Office (*i.e.*, in the prosecution history of the challenged patent or a related patent or application, or in the record of another proceeding before the Office challenging the same patent or a related patent), or evidence that a district court can judicially notice under Federal Rule of Evidence 201. The final rule further expressly states that in instances where the Board exercises its discretion in the interests of justice, the Board will provide the parties an opportunity to respond before rendering a final decision on the motion to amend. As such, the final rule does not reflect a change from current practice.

*Costs and Benefits:* This rulemaking is not economically significant under Executive Order 12866 (Sept. 30, 1993).

#### Background

On September 16, 2011, the AIA was enacted into law (Pub. L. 112–29, 125 Stat. 284 (2011)), and within one year, the Office implemented rules to govern Office practice for AIA trials, including IPR, PGR, CBM, and derivation

<sup>1</sup> Under Section 18 of the AIA, the transitional program for post-grant review of covered business method patents sunset on September 16, 2020. AIA § 18(a). Although the program has sunset, existing CBM proceedings, based on petitions filed before September 16, 2020, are still pending. For those pending CBM proceedings, the final rule applies to any motion to amend filed after the effective date.

proceedings pursuant to 35 U.S.C. 135, 316, and 326 and AIA sec. 18(d)(2). See Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 FR 48612 (Aug. 14, 2012); Changes to Implement *Inter Partes* Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 FR 48680 (Aug. 14, 2012); Transitional Program for Covered Business Method Patents—Definitions of Covered Business Method Patent and Technological Invention, 77 FR 48734 (Aug. 14, 2012). Additionally, the Office published a Trial Practice Guide to advise the public on the general framework of the regulations, including the structure and times for taking action in each of the new proceedings. See Office Patent Trial Practice Guide, 77 FR 48756 (Aug. 14, 2012); see also Office Patent Trial Practice Guide, August 2018 Update, 83 FR 39989 (Aug. 13, 2018); Office Patent Trial Practice Guide, July 2019 Update, 84 FR 33925 (July 16, 2019); Consolidated Trial Practice Guide, 84 FR 64280 (Nov. 21, 2019).

In prescribing these regulations, the Office considered “the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted” as required by statute. 35 U.S.C. 316(b), 326(b). The Office also considered the public comments carefully and responded to the comments in these final rules. Among the final rules, the Office promulgated § 42.20(c), which states that a “moving party has the burden of proof to establish that it is entitled to the requested relief.” 37 CFR 42.20(c).

Previously, the Board interpreted the burden of proof requirement of § 42.20(c) to apply to motions to amend filed pursuant to 35 U.S.C. 316 and 326, including the requirement to show that the proposed substitute claims were patentable over the prior art of record. *MasterImage 3D, Inc. v. RealD Inc.*, IPR2015–00040 (PTAB July 15, 2015) (Paper 42) (*MasterImage*). Under *MasterImage*, which was subsequently made precedential, the patent owner in a proceeding, as the moving party in a motion to amend, bore the burden of showing that the proposed substitute claims were patentable. *Id.*

On October 4, 2017, the Federal Circuit issued its *en banc* decision in *Aqua Products*, addressing the burden of persuasion regarding the patentability of substitute claims presented in a motion to amend. The lead opinion of

the decision explains that, in the absence of rulemaking, the USPTO may not place the burden of persuasion on the patent owner to show that proposed substitute claims are patentable.

The only legal conclusions that support and define the judgment of the court are: (1) The PTO has not adopted a rule placing the burden of persuasion with respect to the patentability of amended claims on the patent owner that is entitled to deference; and (2) in the absence of anything that might be entitled deference, the PTO may not place that burden on the patentee.

872 F.3d at 1327 (O’Malley, J.).

A separate opinion joined-in-part by a majority of the *en banc* court observed that “it is well settled that regardless of which party bears the ultimate burden of persuasion, the movant bears a burden of production” and that “the Patent Office has adopted regulations that address what a patent owner must submit in moving to amend the patent.” *Id.* at 1340–41 (Reyna, J., concurring in part) (citing 37 CFR 42.20(a), 42.22(a), 42.121(a)(2)(i)). The opinion explains that these regulations require a patent owner to “assist[] the Board to perform its statutory obligation to ‘issue a final written decision with respect to the patentability of . . . any new claim added under section 316(d).’” *Id.* at 1341 (omission in original) (quoting 35 U.S.C. 318(a)).

In view of the Federal Circuit’s decision in *Aqua Products*, on November 21, 2017, the Office issued formal guidance through a memorandum from the Chief Administrative Patent Judge, explaining that, in light of the *Aqua Products* decision, the Board would no longer place the burden of persuasion on a patent owner with respect to the patentability of any proposed substitute claims presented in a motion to amend. See Guidance on Motions to Amend in view of *Aqua Products*, <https://go.usa.gov/xQGAA> (Guidance Memo). The Guidance Memo also notes that a motion to amend must continue to satisfy the requirements of 37 CFR 42.121 or 42.221 (e.g., provide a reasonable number of substitute claims and written description support in relation to each substitute claim), as applicable, that all parties continue to have a duty of candor under 37 CFR 42.11, and that the page limits, type, and timing of briefs remain unchanged. *Id.*

On December 22, 2017, the Federal Circuit issued a related decision in *Bosch Auto. Serv. Solutions, LLC v. Matal*, 878 F.3d 1027 (Fed. Cir. 2017) (*Bosch*). In that decision, because the petitioner had settled with the patent owner who had proposed substitute

claims, the Federal Circuit remanded the case to the Board to evaluate the patentability of the proposed substitute claims. *Id.* (“[W]here the challenger ceases to participate in the IPR and the Board proceeds to final judgment, *it is the Board* that must justify any finding of unpatentability by reference to the evidence of record in the IPR.”) (emphasis in original) (quoting *Aqua Products*, 872 F.3d at 1311 (O’Malley, J.)).

In view of the decisions by the Federal Circuit regarding motion to amend practice and procedure in AIA trials, the Board de-designated as precedential *MasterImage*, as well as de-designated as informative a prior decision of the Board in *Idle Free Sys., Inc. v. Bergstrom, Inc.*, IPR2012–00027 (PTAB June 11, 2013) (Paper 26), decisions in which the Board panels stated that “[t]he burden is not on the petitioner to show unpatentability, but on the patent owner to show patentable distinction over the prior art of record and also prior art known to the patent owner.” *Id.* at 7; see also *MasterImage*, Paper 42 at 2 (quoting *Idle Free*). Concurrently, the Board designated an order issued in *Western Digital Corp. v. SPEX Techs., Inc.*, IPR2018–00082, –00084 (PTAB Apr. 25, 2018) (Paper 13) (*Western Digital*) as informative to provide an example of how panels can handle several aspects of the motion to amend practice under the *Aqua Products* and *Bosch* precedent. With respect to the burden of persuasion, the *Western Digital* order explained that under the current state of the law, “the burden of persuasion will ordinarily lie with the petitioner to show that any proposed substitute claims are unpatentable” and that the “Board itself may justify any finding of unpatentability by reference to evidence of record in the proceeding.” *Id.* at 4.

On March 7, 2018, the Board designated as precedential an order in *Lectrosanics* and de-designated *Western Digital*. The *Lectrosanics* order provides guidance regarding statutory and regulatory requirements for a motion to amend in light of Federal Circuit case law. For example, the *Lectrosanics* order notes that prior to considering the patentability of any substitute claims, the Board must first determine whether the patent owner has met the statutory and regulatory requirements set forth in 35 U.S.C. 316(d) and 37 CFR 42.121, such as the requirements that the motion proposes a reasonable number of substitute claims and that the amendments do not broaden the scope of the claims. *Lectrosanics*, Paper 15 at 4–5. The *Lectrosanics* order also sets out that “the burden of persuasion

ordinarily will lie with the petitioner to show that any proposed substitute claims are unpatentable by a preponderance of the evidence.” *Id.* at 4.

On October 29, 2018, the Office published a Request for Comments on Motion To Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board in the **Federal Register** (Request for Comments), seeking public comment on various aspects of the Board’s amendment practice. 83 FR 54319. Among the questions on which the Board sought public input were the following, directed to the allocation of the burden of persuasion:

15. Should the Office engage in rulemaking to allocate the burden of persuasion regarding the patentability of proposed substitute claims in a motion to amend as set forth in the *Western Digital* order? What are the advantages or disadvantages of doing so?

16. If the Office continues to allocate the burden as set forth in the *Western Digital* order, under what circumstances should the Board itself be able to justify findings of unpatentability? Only if the petitioner withdraws from the proceeding? Or are there situations where the Board itself should be able to justify findings of unpatentability when the petitioner remains in the proceeding? What are the advantages or disadvantages?

*Id.* at 54325.<sup>2</sup>

In response to the October 2018 Request for Comments, the Office received 49 comments as of December 21, 2018 (the closing date for comments), from intellectual property organizations, trade organizations, other organizations, and individuals. See <https://go.usa.gov/xyeFy> (collected responses to Request for Comments).<sup>3 4</sup>

<sup>2</sup> The October 2018 Request for Comments was published before *Western Digital* was superseded by *Lectrosionics* and thus referred only to the *Western Digital* order. Both orders are identical in their discussion of the burden of persuasion. Therefore, Questions 15 and 16 of the Request for Comments, and the public comments provided thereto, were equally pertinent to the current Board precedent of *Lectrosionics*.

<sup>3</sup> The October 2018 Request for Comments also sought comments on a proposed amendment procedure in post-grant trial proceedings that included the Board providing preliminary non-binding guidance on the merits of a motion to amend, and an opportunity for a patent owner to revise its motion to amend thereafter. The Office addressed that portion of the Request for Comments separately in a Notice Regarding a New Pilot Program Concerning Motion To Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board. 84 FR 9497 (Mar. 15, 2019).

<sup>4</sup> In response to the October 2018 Request for Comments, the Office also received comments and questions relating to reissue or reexamination as an alternative vehicle for claim amendments. The Office addressed those comments and questions

Approximately 25 of the commenters provided specific responses to Questions 15 and 16 of the Request for Comments. In response to Question 15, the majority of commenters were in favor of the Office engaging in rulemaking to allocate the burden of persuasion as set forth in *Western Digital* (as discussed in more detail below). Only three commenters believed rulemaking was unnecessary (either because the Board could simply continue to apply its own precedent or because the statute already allocates the burden of persuasion). A minority of commenters stated that the Office should engage in rulemaking but that the burden of persuasion should be placed on the patent owner.

Additionally, in response to Question 15, some commenters suggested that even if the Office promulgates rules to place the burden of persuasion on the petitioner on the issue of patentability of the proposed substitute claims, the patent owner continues to bear the burden to show that the motion to amend complies with the statutory requirements of 35 U.S.C. 316(d) or 326(d) (for example, that the amendment may not enlarge the scope of the claims), as well as the regulatory requirements of 37 CFR 42.121 or 42.221 (for example, that the motion set forth the support for the amendment in the original disclosure of the patent).

In response to Question 16, the majority of responsive comments stated that the Board should be able to justify findings of unpatentability in any circumstance, for example, even when the petitioner remains in the proceeding. Two commenters responded that the Board should never be able to assume the burden of persuasion on unpatentability itself, and three commenters believed that the Board should be permitted to justify findings of unpatentability of proposed substitute claims itself only in certain circumstances, for example, when a petitioner ceases to participate in a proceeding.

In light of the generally positive support for rulemaking to allocate the burden of persuasion as set forth in the *Western Digital* order (and subsequently made precedential in *Lectrosionics*), and in the interest of providing greater clarity, certainty, and predictability to parties participating in AIA trial proceedings before the Board, the Office issued a proposed rule allocating the burden of persuasion.

separately in a Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. 84 FR 16654 (Apr. 22, 2019).

In the notice of proposed rulemaking issued on October 22, 2019, the Office sought comments on a specific proposed rule clarifying the burdens of persuasion in relation to motions to amend. See Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board, 84 FR 56401. The proposed rule allocated the burdens of persuasion regarding the patentability of proposed substitute claims as set forth in *Lectrosionics* and *Western Digital*. The proposed rule also stated that, irrespective of the burdens of persuasion, the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend for any reason supported by the evidence of record. The Office invited the public to provide comments by December 23, 2019. As discussed in more detail below, the Office received a total of 18 comments in response. See <https://go.usa.gov/xGXCN> (collected responses to notice of proposed rulemaking).

On April 9, 2020, the Federal Circuit issued its opinion in *Nike, Inc. v. Adidas AG*, 955 F.3d 45 (Fed. Cir. 2020) (*Nike*). In that case, the Federal Circuit concluded that “the Board should not be constrained to arguments and theories raised by the petitioner in its petition or opposition to the motion to amend. . . . Otherwise, were a petitioner not to oppose a motion to amend, the Patent Office would be left with no ability to examine the new claims.” *Id.* at 51. As such, the Federal Circuit held that “the Board may sua sponte identify a patentability issue for a proposed substitute claim based on the prior art of record.” *Id.*

Also, on July 6, 2020, the Board’s Precedential Opinion Panel (POP) issued a precedential decision in *Hunting Titan*. This decision addressed two questions: (1) Under what circumstances and at what time during an IPR may the Board raise a ground of unpatentability that a petitioner did not advance or insufficiently developed against substitute claims proposed in a motion to amend; and (2) whether the Board must provide the parties notice and an opportunity to respond to a ground of unpatentability it raises before making a final determination. *Hunting Titan*, Paper 67 at 3. In *Hunting Titan*, the POP determined that the Board may, in certain rare circumstances, raise a ground of unpatentability that a petitioner did not advance, or insufficiently developed, against substitute claims proposed in a motion to amend. *Id.* at 4. Those circumstances are typically limited to situations in which the adversarial

process fails to provide the Board with potential patentability arguments with respect to the proposed substitute claims. *Id.* at 25. Such situations may include, for example, those in which the petitioner has ceased to participate in the proceeding or chooses not to oppose the motion to amend, or those in which certain evidence of unpatentability is not raised by the petitioner but is so readily identifiable and persuasive that the Board should take it up in the interest of supporting the integrity of the patent system, notwithstanding the adversarial nature of the proceedings. *Id.* at 12–13, 25–26.

The POP also determined that due process requires that a patent owner receive notice of how the prior art allegedly discloses the newly-added limitations of each proposed substitute claim, as well as any theory of unpatentability asserted against those claims, and the patent owner must have the opportunity to respond to those factual allegations and legal theories. *Id.* at 15. In addition, the POP cited two examples of adequate notice and opportunity to respond, namely, requesting supplemental briefing from the parties regarding the proposed ground for unpatentability or requesting that the parties be prepared to discuss the prior art in connection with the substitute claims at an oral hearing. *Id.* at 15–16 (citing *Nike*, 955 F.3d at 54).

The final rule adopts, with modifications, the proposed rule allocating the burden of persuasion on motions to amend. The final rule specifies that the burden of persuasion as to patentability of substitute claims proposed in a motion to amend is on the petitioner. In addition, the final rule specifies that the burden of persuasion is on the patent owner to show that the motion complies with the requirements of 35 U.S.C. 316(d) or 326(d) (requiring that a motion to amend propose a reasonable number of substitute claims, and that substitute claims do not enlarge scope of the original claims of the patent or introduce new matter), as well as 37 CFR 42.121(a)(2), (a)(3), (b)(1), and (b)(2), or 42.221(a)(2), (a)(3), (b)(1), and (b)(2) (indicating, for example, that a motion to amend must set forth written description support and support for the benefit of a filing date in relation to each substitute claim, and respond to grounds of unpatentability involved in the trial).

Notwithstanding the adversarial nature of the proceedings and irrespective of the burdens of persuasion discussed above, the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend. But the Board will do so only

in rare circumstances (as described below) and only for reasons supported by readily identifiable and persuasive evidence of record. Thus, in instances where a party has not met its burden in relation to a motion to amend or any substitute claims proposed therein, the Board may, in the interests of justice, reach a determination regarding patentability, or compliance with statutory and regulatory requirements, supported by readily identifiable and persuasive evidence made of record in the proceeding. In such instances where the Board exercises its discretion in the interests of justice, the Board will provide the parties with an opportunity to respond before rendering a final decision on the motion to amend.

In the vast majority of cases, the Board will consider only evidence a party introduces into the record of the proceeding. However, the Board may also consider readily identifiable and persuasive evidence already before the Office in a related proceeding (*i.e.*, in the prosecution history of the challenged patent or a related patent or application, or in the record of another proceeding before the Office challenging the same patent or a related patent). See *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373 (Fed. Cir. 2018) (stating that the Board must consider prior art raised in a related IPR in determining the patentability of dependent claims); see also *Emerson Elec. Co. v. SIPCO, LLC*, 745 F. App'x 369, 373–374 (Fed. Cir. 2018) (non-precedential) (directing the Board to explain its application of prior art cited in a related IPR). Likewise, the Board may consider evidence that a district court can judicially notice under Federal Rule of Evidence 201. See 37 CFR 42.62 (making the Federal Rules of Evidence applicable to AIA trial proceedings and noting that “judicial notice” as used in the Federal Rules of Evidence shall be construed as “official notice”). This approach is consistent with the current practice of the Board, under which the Board may take official notice of facts in appropriate circumstances. See, *e.g.*, *RPX Corp. v. Iridescent Networks, Inc.*, IPR2018–00254 (PTAB Dec. 10, 2018) (Paper 20) (taking official notice of how the URL of the internet Archive provides the date the website was captured); *Ericsson Inc. v. Intellectual Ventures I LLC*, IPR2014–00527, (PTAB May 18, 2015) (Paper 41) (taking official notice that members in the scientific and technical communities who both publish and engage in research rely on the information published on the copyright line of IEEE publications).

As used in the final rule, the “interests of justice” in the final rule

means that, irrespective of the burdens of persuasion on the parties, the Board may exercise its discretion in rare circumstances where the adversarial process fails to provide the Board with potential arguments relevant to granting or denying a motion to amend. *Hunting Titan*, Paper 67 at 12–13, 25–26.

Such circumstances may include those in which a patent owner does not expressly address or establish every statutory and regulatory requirement for a motion to amend in its briefing, but evidence of compliance with those requirements is so readily identifiable and persuasive that the Board should address that evidence in the interest of supporting the integrity of the patent system, notwithstanding the adversarial nature of the proceedings. Thus, for example, the Board may, in the interests of justice, exercise its discretion to determine that a motion to amend complies with the statutory and regulatory requirements of 35 U.S.C. 316(d) or 326(d) and 37 CFR 42.121(a)(2), (a)(3), (b)(1), and (b)(2), or 42.221(a)(2), (a)(3), (b)(1), and (b)(2), even if a patent owner does not expressly address every requirement in its briefing. The Board will do so only when there is readily identifiable and persuasive evidence that the motion complies with the statutory and regulatory requirements, when addressing that evidence would be in the interests of supporting the integrity of the patent system, and only when the petitioner has been afforded the opportunity to respond to that evidence.

Such circumstances also may include those in which a petitioner has ceased to participate in the proceeding altogether (for example, as a result of settlement); those in which the petitioner remains in the proceeding but does not oppose the motion to amend, in whole or in part (for example, does not oppose some proposed substitute claims); or those in which the petitioner previously made an argument (for example, in opposition to a motion to amend) but then later ceases to participate (for example, does not oppose a revised motion to amend). The interests of justice may also support the Board exercising its discretion in the rare circumstances in which the petitioner continues participating in the proceeding, but fails to raise certain evidence of unpatentability that is so readily identifiable and persuasive that the Board should take it up in the interest of supporting the integrity of the patent system, notwithstanding the adversarial nature of the proceedings. In most instances, in cases where the petitioner has participated fully and opposed the motion to amend, the

Office expects that there will be no need for the Board to independently justify a determination of unpatentability.

In sum, the Office expects that the Board will exercise its discretion in the interests of justice to reach a determination of patentability or unpatentability only in rare circumstances and only when the parties have been afforded notice and the opportunity to respond.

#### Discussion of Specific Rules

37 CFR part 42 is amended as follows:

*Section 42.121:* § 42.121 is amended by adding a new paragraph (d) to state that a patent owner bears the burden of persuasion to show that a motion to amend complies with certain statutory and regulatory requirements, but that the petitioner bears the burden of persuasion to show that any proposed substitute claims are unpatentable. The new paragraph (d) also states that in cases in which a party does not meet its burden, the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend only for reasons supported by readily identifiable and persuasive evidence of record. In doing so, the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice. Where the Board exercises its discretion under this paragraph, the parties will have an opportunity to respond.

*Section 42.221:* § 42.221 is amended by adding a new paragraph (d) to state that a patent owner bears the burden of persuasion to show that a motion to amend complies with certain statutory and regulatory requirements, but that the petitioner bears the burden of persuasion to show that any proposed substitute claims are unpatentable. The new paragraph (d) also states that in cases in which a party does not meet its burden, the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend only for reasons supported by readily identifiable and persuasive evidence of record. In doing so, the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice. Where the Board exercises its discretion under this paragraph, the parties will have an opportunity to respond.

#### Differences Between the Final Rule and the Proposed Rule

In response to comments seeking clarification, the final rule seeks to

further clarify the circumstances in which the Board may exercise its discretion to grant or deny a motion to amend, irrespective of whether a party has met its burden on a particular issue and notwithstanding the adversarial nature of the proceeding. The final rule clarifies that the Board may exercise this discretion when it is in the interests of justice, and only for reasons supported by readily identifiable and persuasive evidence of record.

Additionally, in response to comments seeking clarification, the final rule provides additional details regarding the scope of evidence the Board may consider in deciding a motion to amend. The Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice.

Lastly, the final rule clarifies that where the Board exercises its discretion in appropriate circumstances, the parties will have an opportunity to respond. (§§ 42.121(d) and 42.221(d)).

#### Response to Comments

In response to the notice of proposed rulemaking pertaining to the burdens of persuasion in relation to motions to amend, the Office received a total of 18 written submissions of comments from intellectual property organizations, businesses, patent practitioners, and others. The comments provided support for, opposition to, and diverse recommendations on the proposed rule. The large majority of the comments were supportive of placing the burden of showing compliance with the statutory and regulatory requirements of a motion to amend on the patent owner, along the lines presented in the proposed rule. Comments on the question of whether the burden of showing unpatentability should be placed on the petitioner, as in the proposed rule, were mixed in their support and opposition. Similarly, the Office received mixed comments in support and opposition to the question of whether the Board, regardless of the respective burdens on the parties, could exercise its discretion to grant or deny a motion to amend. The Office appreciates the thoughtful comments and has considered and analyzed them thoroughly.

All the comments are posted on the PTAB website at <https://go.usa.gov/xGXrx>. The Office's responses address the comments that are directed to the proposed changes set forth in the notice of proposed rulemaking. Any comments directed to topics beyond the scope of

the notice of proposed rulemaking will not be addressed at this time.

#### A. Burden on the Patent Owner

*Comment 1:* Of the comments addressing this aspect of the proposed rule, almost all supported allocating the burden of persuasion to the patent owner to show a motion to amend complies with statutory and regulatory requirements. Comments noted that the patent owner, as the party drafting the proposed substitute claims, is in the best position to explain how the proposed substitute claims comply with the statutory and regulatory requirements. For example, the comments pointed out that because the patent owner is the party amending a claim, the patent owner is in the best position to identify the subject matter disclosed in the challenged patent's specification that is being incorporated into the proposed substitute claim, thereby addressing the prohibition on new matter.

*Response 1:* The Office agrees with these comments. The statutory requirements of 35 U.S.C. 316(d) specify that the patent owner may file a motion to amend that "propose[s] a reasonable number of substitute claims" and, further, that amendments "may not enlarge the scope of the claims or introduce new matter." Thus, the statute already places the burden on the patent owner to show that its motion to amend meets those requirements. The regulatory requirements set forth in section 42.121(a) or 42.221(a) of 37 CFR part 42 reflect those statutory requirements and further specify that a motion to amend must respond to a ground of unpatentability involved in the trial, include a claim listing clearly showing the amendments, and set forth support in the original patent disclosure for each claim added or amended, as well as support in an earlier-filed disclosure for each claim for which the patent owner seeks the benefit of the filing date of the earlier-filed disclosure. Because the patent owner is the party proposing amendments to the claims of its patent, it follows that the patent owner should be the party with the burden to show that the motion complies with these statutory and regulatory requirements. As commenters have noted, the patent owner necessarily incorporates subject matter from the challenged patent's specification into one or more proposed substitute claims and, thus, the patent owner is in the best position to identify where the specification supports such subject matter and how such subject matter does not enlarge the scope of the claims. Similarly, because the patent

owner is the party proposing the substitute claims, the patent owner is in a better position to explain why the number of substitute claims is reasonable, especially when the patent owner proposes more than one substitute claim for each challenged claim. Likewise, it makes sense for the patent owner to explain why the amendment responds to a ground of unpatentability involved in the trial, given that the patent owner proposes the substitute claims to overcome one or more asserted unpatentability grounds as to the original claims of the challenged patent.

*Comment 2:* A few comments supporting the requirement that the patent owner bears the burden to show a motion to amend complies with statutory and regulatory requirements expressed the view that the burden should be an initial burden of production, but that the burden of persuasion should lie with the petitioner. One comment stated that placing a burden of persuasion on the patent owner unduly limits the patent owner's ability to amend the claims. Another comment stated that allocating a burden of persuasion to the patent owner in a motion to amend is inconsistent with the Federal Circuit's guidance in *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364 (Fed. Cir. 2016) on shifting burdens in an AIA trial proceeding. The comment was further concerned that requiring the patent owner to maintain a burden of persuasion to show statutory and regulatory compliance may lead the Board to deny a motion to amend for procedural reasons unrelated to the substance of the proposed substitute claims.

*Response 2:* The Office appreciates these thoughtful comments. 35 U.S.C. 316(d) appears to specify a burden of persuasion on the patent owner, not merely a burden of production. For example, section 316(d) provides that the patent owner may “[f]or each challenged claim, propose a reasonable number of substitute claims” and that “[a]n amendment . . . may not enlarge the scope of the claims or introduce new matter.” 35 U.S.C. 316(d)(1)(B), (d)(3). The patent owner proposes an amendment; therefore, it would appear to be the patent owner's burden of persuasion to show that the amendment proposes a reasonable number of substitute claims, does not enlarge the scope of the claims, and does not introduce new matter. This is also consistent with the lead opinion of *Aqua Products*, which states that the “patent owner must satisfy the Board that the statutory criteria in

§ 316(d)(1)(a)–(b) and § 316(d)(3) are met and that any reasonable procedural obligations imposed by the Director are satisfied before the amendment is entered into the IPR.” 872 F.3d at 1306 (emphasis added). Because the statutory and regulatory requirements largely overlap, it also makes sense to place the burden of showing compliance with the regulatory requirements on the patent owner. It is unclear how placing this burden on the patent owner limits the patent owner's ability to amend claims.

Further, allocating this burden of persuasion to the patent owner is not inconsistent with *Magnum Oil Tools* because, in that case, the Federal Circuit addressed the burden of persuasion as to *patentability*, not the burden of persuasion as to statutory and regulatory requirements of a motion to amend. As noted above, the lead opinion in *Aqua Products* differentiated between meeting the requirements of a motion to amend and the burden of demonstrating the unpatentability of substitute claims. *Id.* *Magnum Oil Tools* addressed situations in which it was and was not appropriate to shift burdens of production. *See* 829 F.3d at 1375–76. The Federal Circuit explained that a shifting burden of production may be warranted in a situation in which a party asserts an affirmative defense for the first time (e.g., an earlier priority date) after the party who carries the ultimate burden of persuasion challenges patentability. As further noted in *Magnum Oil Tools*, however, “a burden-shifting framework . . . would introduce unnecessary confusion” when a party bears the ultimate burden of persuasion on a particular issue. *Id.* at 1376. Here, because the statute already appears to place the ultimate burden of persuasion on the patent owner regarding the statutory and regulatory requirements, and the Board makes a determination after considering all evidence provided by both parties, a shifting burden of production is not appropriate. *Id.* (“Applying a burden-shifting framework here would introduce unnecessary confusion because the ultimate burden of persuasion of obviousness must remain on the patent challenger and ‘a fact finder must consider *all* evidence of obviousness and nonobviousness before reaching a determination.’”) (citation omitted).

Finally, in March 2019, the Office issued a notice of a pilot program for motion to amend practice and procedures that allows a patent owner to request preliminary guidance from the Board on a motion to amend and to file a revised motion to amend (regardless of whether the patent owner requests preliminary guidance). *See*

Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 FR 9497 (Mar. 15, 2019) (pilot program). Under the pilot program, which applies to all AIA trial proceedings instituted on or after March 15, 2019, the patent owner is able to request preliminary non-binding guidance from the Board regarding the amendment's compliance with the statutory and regulatory requirements. *See id.* at 9497–98. The patent owner may address that preliminary guidance in responsive briefing or by providing new proposed substitute claims in a revised motion to amend. *Id.*; *see also id.* at 9499–9500 (setting forth options for preliminary guidance and a revised motion to amend in more detail). These aspects of the pilot program likewise support placing the burden of persuasion on the patent owner in relation to the statutory and regulatory requirements for a motion to amend.

*Comment 3:* A comment noted that previous Office guidance and Board decisions did not allocate the burden of persuasion to the patent owner and requested an explanation as to why the proposed rule allocates the burden of persuasion to the patent owner.

*Response 3:* As many commenters have requested and noted, clarifying the burdens in the amendment process is desired. Because 35 U.S.C. 316(d) appears to place the burden of persuasion on the patent owner to show statutory compliance, the Office takes this opportunity to bring clarity and predictability to the amendment process through rulemaking specifically assigning that burden.

#### B. Burden on the Petitioner

*Comment 4:* The Office received a mix of comments supporting or opposing the provision of the proposed rule placing the burden of persuasion on the petitioner to show that the substitute claims proposed in a motion to amend are unpatentable, with a slight majority of comments opposing placing the burden on the petitioner. Among the comments supporting the proposed rule, one noted that placing the burden of persuasion on the petitioner is consistent with 35 U.S.C. 282(a), which governs burdens of proof in patent infringement actions in federal court and states that “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” Another comment stated that allocating the burden of persuasion to the petitioner is consistent with the Federal Circuit

holding in *Aqua Products*. One comment, which neither agreed nor disagreed with the proposed rule, noted that the proposed rule is generally consistent with the allocation of burdens set forth in *Lectrosomics* and the Office's prior "Guidance on Motions to Amend in view of *Aqua Products*."

*Response 4:* The Office appreciates and has carefully considered the comments both supporting and opposing placing the burden on the petitioner to show that the proposed substitute claims are unpatentable. Regardless of whether the comments supported the proposed rule or not, commenters overwhelmingly agreed that notice-and-comment rulemaking to allocate the burdens was appreciated and that doing so improves clarity and consistency in AIA trials. Previously, the Office requested comments relating to the assignment of burdens in the October 29, 2018, Request for Comments (83 FR 54319). Among other questions, the Office asked whether it should engage in rulemaking to allocate the burden of persuasion regarding the patentability of proposed substitute claims in a motion to amend as set forth in the order issued in *Western Digital* (superseded by *Lectrosomics*), which allocates the burden of persuasion regarding the patentability of proposed substitute claims to the petitioner. *Id.* at 54325. Of the roughly 20 comments the Office received in 2018 in response to the Request for Comments, a clear majority of comments favored placing the burden to show that the proposed substitute claims are unpatentable on the petitioner, consistent with the rule the Office now adopts.

After carefully considering all relevant comments, the Office's efforts to provide predictability and clarity, the Federal Circuit's decision in *Aqua Products*, the Office's post-*Aqua Products* Guidance Memo, and the Board's experience administering AIA trials since the *Aqua Products* decision, the Office determines that the most balanced approach is to place the burden on the petitioner to show that the proposed substitute claims are unpatentable. Placing the burden of proving unpatentability on the challenger is consistent with other statutory approaches to patentability. As commenters have pointed out, under 35 U.S.C. 282, the "burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." Although the decision in *Aqua Products* left unresolved the question of whether 35 U.S.C. 282 applies only to original claims or also proposed amended claims, placing the burden on the petitioner via this rule

would resolve any ambiguity. Additionally, although patent examination differs from an AIA trial in many respects, it is worth noting that the Office, not the applicant, has the burden of showing unpatentability during examination. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden . . . of presenting a prima facie case of unpatentability."). Further, as multiple commenters have noted, placing the burden to show unpatentability on the petitioner maintains consistency with current Board practice described in the precedential Board decision *Lectrosomics* and the post-*Aqua Products* Guidance Memo. Changing the procedure the Board has been using since 2017 would be disruptive to procedures that the Board and parties have been following for several years. Moreover, the rule is consistent with the lead opinion in *Aqua Products*, which stated, "we believe that Congress intended that the petitioner bear the burden of persuasion as to all claims in an IPR, whether original or amended." 872 F.3d at 1315 (O'Malley, J.). *Aqua Products* held that the Office had not adopted a rule placing the burden of persuasion with respect to the patentability of proposed substitute claims on any party. *See id.* at 1327. The Office responds to that holding and adopts this rule, placing the burden to show unpatentability of substitute claims on the petitioner.

*Comment 5:* Commenters opposing the proposed rule placing the burden on the petitioner to show that proposed substitute claims are unpatentable suggested that, instead, the patent owner should bear the burden of proving patentability. Comments stated that the patent owner, as the party drafting the substitute claims, is best positioned to explain how the proposed substitute claims are patentable over prior art and should provide a detailed explanation of how the substitute claims distinguish over the prior art of record and other prior art known to the patent owner. Comments also stated that placing the burden on the petitioner is inconsistent with the common practice that the moving party bears the burden of proof. Further, at least one comment stated that the Federal Circuit's *Aqua Products* decision does not prohibit the Office from placing the burden on the patent owner. That comment further noted that the Office has eliminated claim construction under the broadest reasonable interpretation, which is one of the safeguards *Aqua Products*

identified as helping to prevent the Office from issuing untested claims.

*Response 5:* Currently, the Office believes that the fair approach is to place the burden on the petitioner to show that the proposed substitute claims are unpatentable, for the reasons discussed above. In presenting proposed substitute claims to the Board, the patent owner already has "a duty of candor and good faith" (37 CFR 42.11(a)), meaning that the patent owner must "disclose to the Board information of which the patent owner is aware that is material to the patentability of the substitute claims." *Lectrosomics*, Paper 15 at 9–10.

In the Board's experience, requiring the patent owner to prove patentability of amended claims in AIA trials has led to confusion because it places duties on the patent owner that are inconsistent with those applied during examination. During examination, for example, although a patent applicant must comply with the duty of candor, there is no separate obligation to prove patentability over prior art "known" to the patent applicant, as the Board's prior approach to amended claims in AIA trials required. *MasterImage*, Paper 42 at 2–3 (citing *Idle Free*, Paper 26 at 7) (referring to "prior art of record and also prior art known to the patent owner" in relation to the patent owner's burden for motions to amend in AIA trials). Much like an examiner during patent examination, the petitioner typically conducts a prior art search before filing an AIA petition, and in most cases is well-positioned and incentivized to identify any patentability issues arising from the proposed amended claims.

Moreover, to the extent one opinion in *Aqua Products* identified the broadest reasonable interpretation standard as relevant to the review of proposed substitute claims, it did so in its analysis of "untested" claims. 872 F.3d at 1314–1315 (O'Malley, J.). Although the Board's claim construction standard has changed from the broadest reasonable interpretation to the standard used in district court proceedings, the statute and regulation governing amendments still require that the claim scope of any proposed amended claims be narrower and require written description support for the proposed amended claims. 35 U.S.C. 316(d)(3); 37 CFR 42.121(a)(2), (b). The same opinion in *Aqua Products* also identified the preponderance of evidence standard as relevant to the review of proposed substitute claims; that standard has not changed. 35 U.S.C. 316(e). In addition, any issued amended claims would be subject to intervening rights and various



other review mechanisms that remain open to challenge the amended claims (e.g., subsequent IPRs, ex parte reexamination, and district court litigation). Furthermore, as explained elsewhere in this rulemaking, the rule allows the Board to exercise its discretion to reach a determination regarding patentability in instances in which the interests of justice warrant such a determination, including those in which the petitioner has ceased to participate in the proceeding altogether or remains in the proceeding but does not oppose a motion to amend. Thus, the rule further limits the likelihood of issuing amended claims that are “untested.”

### C. Board Discretion To Grant or Deny a Motion To Amend

*Comment 6:* Of the comments addressing the proposed rule providing that the Board may, in the interests of justice, grant or deny a motion to amend for any reason supported by the evidence of record, a majority supported the proposed rule. For example, one comment stated that the Board should not procedurally deny a motion to amend for failing to comply with the statutory or regulatory requirements if the lack of compliance can be cured by reference to the evidence of record. Similarly, a comment stated that if a petitioner does not oppose the proposed substitute claims, the Board should have the discretion to deny the motion to amend for any reason supported by the evidence of record rather than automatically adding the proposed substitute claims to the challenged patent.

*Response 6:* The Office agrees with these comments. Under the proposed rule, as modified in the final rule, the Board will have the discretion to grant or deny a motion to amend only for reasons supported by readily identifiable and persuasive evidence of record, when it is in the interests of justice. The Office anticipates that the Board will exercise this discretion only in rare circumstances, such as discussed in *Hunting Titan*.

As noted by the commenters, this discretion allows the Board to address situations in which it would be unjust to deny a motion to amend for a procedural defect, such as those in which a patent owner does not expressly address or establish every statutory and regulatory requirement in its briefing. Where there is readily identifiable and persuasive evidence that the motion complies with the statutory and regulatory requirements, the Board may determine that it is in the

interests of justice to nevertheless grant the motion to amend.

The Office also agrees with the comments that the Board should have discretion to address the patentability of substitute claims under certain rare circumstances in which substitute claims might otherwise issue without any consideration of patentability by the Office, regardless of what is in the record before the Board. In this vein, the final rule permits the Board to address circumstances in which, as explained in *Hunting Titan*, the adversarial process has failed to provide the Board with potential arguments of patentability with respect to the proposed substitute claims. Such circumstances could include, for example, those in which the petitioner ceases to participate in the proceeding altogether (for example, as a result of settlement) or remains in the proceeding but does not oppose the motion to amend, in whole or in part (for example, does not oppose some proposed substitute claims), or those in which the petitioner previously made an argument (for example, in opposition to a motion to amend) but then later ceases to participate (for example, does not oppose a revised motion to amend). In such circumstances, the absence of two actively participating opposing parties (at least in relation to a motion to amend) signals a situation in which the adversarial process may have failed to provide the Board with potential arguments of patentability or unpatentability. In such a situation, the Board will, in the interests of justice, typically independently evaluate the patentability of the proposed substitute claims and exercise its discretion to grant or deny only for reasons supported by readily identifiable and persuasive evidence of record.

As a general matter in the vast majority of cases, the Board will consider only evidence a party introduces into the record of the proceeding. However, the Board may consider readily identifiable and persuasive evidence already before the Office (i.e., in the prosecution history of the challenged patent or a related patent or application, or in the record of another proceeding before the Office challenging the same patent or a related patent). Likewise, the Board may consider evidence that a district court can judicially notice under Federal Rule of Evidence 201. Thus, when referring to the interests of justice, the rule affords the Board the flexibility to address the rare circumstances in which certain evidence of unpatentability has not been raised by the petitioner but is so readily identifiable and persuasive that the Board should take it up in the

interest of supporting the integrity of the patent system, notwithstanding the adversarial nature of the proceedings, as explained in *Hunting Titan*.

As noted above, the Office expects that the Board will exercise its discretion in the interests of justice to reach a determination of unpatentability only in rare circumstances, and only where the patent owner has been afforded the opportunity to respond. In most instances, in cases where the petitioner has participated fully and opposed the motion to amend, the Office expects that the petitioner will bear the burden of persuasion, and there will be no need for the Board to independently justify a determination of unpatentability.

*Comment 7:* One commenter expressed general support for the proposed rule’s codification of the Board’s discretion to grant or deny a motion to amend and the application of the interests of justice standard to govern the exercise of that discretion. The commenter observed that the preamble of the Notice of Proposed Rulemaking identified three exemplary circumstances that may satisfy the interests of justice standard: (1) The petitioner has ceased to participate in the proceeding; (2) the petitioner remains in the proceeding but does not oppose the motion to amend; and (3) the petitioner opposes the motion to amend and has failed to meet the burden of persuasion, but there is easily identified and persuasive evidence of unpatentability in the record. The commenter suggested, however, that the final rule should provide further guidance on the contours of the Board’s discretion under the interests of justice standard, preferably in the rules themselves. The commenter also requested that the final rule clarify the rare circumstances in which the Board will exercise its discretion.

*Response 7:* The Office appreciates these comments and has modified the final rule to more clearly specify the circumstances in which the Board will exercise its discretion to grant or deny a motion to amend. The final rule thus clarifies that such discretion may be used when it is in the interests of justice and when there is readily identifiable and persuasive evidence of record. The final rule language thus follows the formulation set forth in *Hunting Titan*, which focuses on situations in which the adversarial process has failed to provide the Board with potential arguments of patentability with respect to the proposed substitute claims. *Hunting Titan* provides express examples of such situations, including when the petitioner has ceased to

participate in the proceeding altogether or remains in the proceeding but does not oppose the motion to amend, or when certain evidence has not been raised by a party but is so readily identifiable and persuasive that the Board should take it up in the interest of supporting the integrity of the patent system, notwithstanding the adversarial nature of the proceedings. *Hunting Titan*, Paper 67 at 12–13, 25–26. The POP noted in *Hunting Titan* that these examples are not exhaustive, and that the Board will address any other fact-specific situations that satisfy the interests of justice standard as they arise. *Id.* at 12–13.

To the extent that the commenter requested that the final rule explicitly set forth all possible circumstances that may satisfy the interests of justice standard, the comment is not adopted. As modified, the final rule specifies that the Board may exercise its discretion only when its reasons are supported by readily identifiable and persuasive evidence of record. However, the Board may consider readily identifiable and persuasive evidence already before the Office (*i.e.*, in the prosecution history of the challenged patent or a related patent or application, or in the record of another proceeding before the Office challenging the same patent or a related patent). Likewise, the Board may consider evidence that a district court can judicially notice under Federal Rule of Evidence 201. In such instances where the Board exercises its discretion in the interests of justice, the Board will provide the parties with an opportunity to respond before rendering a final decision on the motion to amend.

Regulatory language is not the appropriate vehicle for specifying the exact factual situations that will satisfy the interests of justice standard. Rather, as discussed above, the precedential *Hunting Titan* decision sets forth general categories of situations in which the standard may be satisfied. The decision also provides a specific example of a situation in which the standard is not met, namely the facts of the *Hunting Titan* case itself. The Office expects that future decisions of the Board applying the final rule will continue to provide the public with guideposts as to factual circumstances in which the interests of justice standard is either satisfied or not satisfied, and the Office may designate these decisions as informative or precedential, as appropriate.

*Comment 8:* Some comments supported the proposed rule providing for Board discretion to grant or deny a motion to amend but advocated that the Board's discretion to deny a motion to

amend should be limited. For example, some comments stated that the Board should be limited to addressing grounds of unpatentability raised by the petitioner in opposition to the motion to amend. Two commenters expressed the view that, even in situations in which the petitioner does not oppose the motion to amend, the Board should be limited to addressing grounds of unpatentability raised by the petitioner against the original claims. Additionally, one comment stated that the scope of the Board's discretion should be limited to the new claim limitations proposed by the motion to amend.

*Response 8:* Although the Office appreciates the commenters' interest in further articulating the scope of the Board's discretion, the Office has, through the issuance of the precedential *Hunting Titan* decision, clarified the situations in which the Board may exercise its discretion. Therefore, the Office does not adopt the changes to the rules proposed by the comments. The proposed rule, as modified in the final rule, limits the Board's discretion to situations in which the interests of justice support the Board exercising that discretion. As set forth in the commentary to the proposed rule, and as further explained in *Hunting Titan*, the Office anticipates that this standard will be met only in "rare circumstances" and provides for certain exemplary situations that may justify an exercise of the Board's discretion. For example, the Board may exercise its discretion to grant a motion to amend only when supported by readily identifiable and persuasive evidence of record that the motion complies with the statutory and regulatory requirements. Alternatively, where there is readily identifiable and persuasive evidence in support of its decision, the Board may exercise its discretion to deny a motion to amend in situations in which the adversarial process fails to provide the Board with potential arguments of patentability with respect to the proposed substitute claims, such as when the petitioner has ceased to participate in the proceeding altogether (for example, as a result of settlement) or remains in the proceeding but does not oppose the motion to amend.

Under the proposed rule, as modified in the final rule, the Board may evaluate each motion to amend on a case-by-case basis to determine whether the facts of the case support the interests of justice standard.

Further limitations on the Board's discretion, such as those proposed by the commenters, that set bright-line prohibitions on certain exercises of the

Board's discretion, are not adopted. For example, in cases in which the petitioner is not participating or does not oppose the motion to amend, limiting the Board to addressing only the grounds of unpatentability raised by a petitioner against the original claims may unduly limit the Board's ability to assess the patentability of the amended claims in situations where there is readily identifiable and persuasive evidence of unpatentability. *See Nike*, 955 F.3d at 51 ("[T]he Board should not be constrained to arguments and theories raised by the petitioner in its petition or opposition to the motion to amend. . . . Otherwise, were a petitioner not to oppose a motion to amend, the Patent Office would be left with no ability to examine the new claims."). Such a limit would increase the risk of the Office issuing amended claims that are unpatentable over the existing record in the proceeding. In addition, an amended claim may add a limitation not present in the original claims and not addressed by a ground of unpatentability in the petition, but the limitation (and reason to combine limitations, as relevant) may be disclosed elsewhere in the record before the Board. In such circumstances, the Board may determine that the interests of justice warrant denying the motion to amend on a ground of unpatentability not articulated in the original petition. The Board, however, will not make such a determination without first ensuring that the parties have been given notice and an opportunity to respond to any new factual allegation or legal theory.

Nor does the Office adopt a recommendation that the Board's exercise of discretion in the interests of justice to deny a motion to amend should be restricted to new limitations added by the proposed amendment. Generally, the Office anticipates that this will usually be the case because the limitations of the original claims will have been addressed by the grounds of unpatentability raised in the petition, and the Board is more likely to exercise its discretion when assessing newly added limitations to substitute claims. That said, evaluating the patentability of a claim requires consideration of the claim "as a whole." 35 U.S.C. 103 ("the claimed invention as a whole would have been obvious"); 84 FR at 55 (2019 Revised Patent Subject Matter Eligibility Guidance) ("consider the claim as a whole when evaluating whether the judicial exception is meaningfully limited by integration into a practical application of the exception"). Restricting the Board's ability to exercise its discretion to evaluate the

patentability of proposed substitute claims to only portions of the proposed claim is inconsistent with the holistic evaluation of the patentability of a claim.

*Comment 9:* A minority of commenters opposed the proposed rule providing that the Board may, in the interests of justice, grant or deny a motion to amend for any reason supported by the evidence of record. According to these commenters, the Board must independently assess the potential unpatentability of any proposed substitute claim and has no discretion to grant a motion to amend in the absence of its independent assessment of patentability. One commenter stated that the “interests of justice” standard of the proposed rule is too high and would unduly limit the Board’s ability to address the patentability of proposed substitute claims. The commenter expressed the view that the Office should compel the Board to always independently confirm patentability before granting a motion to amend, regardless of what a petitioner argues and presents to the Board, rather than providing for Board discretion in the interests of justice.

*Response 9:* These comments are not adopted. Removing the Board’s discretion to evaluate each proceeding on a case-by-case basis, and requiring the Board to independently examine the patentability of every proposed substitute claim regardless of whether or not (or how) the motion to amend is opposed by a petitioner, is not consistent with the nature of *inter partes* proceedings. AIA trials are, by their nature, adversarial. As stated in *Hunting Titan*, “relying on the adversarial process to frame the issues for the Board properly places the incentives on the parties to identify the pertinent evidence and make the best arguments for their desired outcome.” *Hunting Titan*, Paper 67 at 11. Thus, in most instances, the Board will “rely on the incentives the adversarial system creates, and expect that the petitioner will usually have an incentive to set forth the reasons why the proposed substitute claims are unpatentable. In most circumstances, then, the Board need not raise its own arguments of unpatentability.” *Id.* at 12. The Office believes, however, that taking into account rare instances that satisfy the interests of justice standard, as set forth above and in *Hunting Titan*, provides a safeguard against the Office issuing unpatentable claims when there is readily identifiable and persuasive evidence of unpatentability while also relying, in most instances, on the adversarial process to surface potential

patentability challenges against a proposed substitute claim.

*Comment 10:* One commenter agreed with the proposed rule to the extent that the Board has discretion to deny a motion to amend when supported by the record, but disagreed that the Board should have discretion to grant a motion to amend. The commenter stated that discretion to deny a motion to amend is consistent with the Board’s role to protect the public against overly broad patent claims, but that the Board should not be able to grant an unwarranted motion to amend.

*Response 10:* The Office agrees with the first part of the comment and believes that Board discretion to deny a motion to amend, regardless of the burdens on the parties, when in the interests of justice, is consistent with the goal of ensuring that claims issued by the Office have appropriate scope. The Office disagrees, however, that the Board should not have similar discretion to grant a motion to amend. Such discretion, when exercised in the interests of justice, protects against denial of a meritorious motion to amend that is supported by the evidence of record for purely procedural reasons, such as when a motion to amend sets forth the basis for concluding that a patent owner has carried its burden but, through inadvertence, fails to state that the motion meets a statutory or regulatory requirement.

#### D. Evidence of Record

*Comment 11:* The Office received several comments regarding the use of the term “evidence of record” in the proposed rule. Some commenters requested clarification of the rule and whether the Board would be permitted to introduce its own evidence into the record. Other commenters expressed the view that the Board should be permitted to supplement the record, if necessary, to support its determination whether to grant or deny the motion to amend. Other commenters stated that the evidence of record should be limited to evidence introduced by the parties.

*Response 11:* The Office appreciates and has carefully considered these thoughtful comments and has modified the rule to state that the Board has the discretion to, when in the interests of justice, grant or deny a motion to amend only for reasons supported by readily identifiable and persuasive evidence of record. The rule also has been modified to state that the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice.

In response to the comments seeking clarification as to the scope of the “evidence of record,” the final rule has been modified to provide additional details as to the scope of evidence upon which the Board may base its decision to grant or deny a motion to amend. The use of “evidence of record” in the rule as adopted signifies that the evidence on which the Board bases its determination on a motion to amend will be entered into the record of the proceeding. In the vast majority of cases, the parties will enter that evidence into the record of the proceeding. The final rule as modified, however, specifies that the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office (*i.e.*, in the prosecution history of the challenged patent or a related patent or application, or in the record of another proceeding before the Office challenging the same patent or a related patent). These rare situations, in which the Board may itself introduce evidence from the record of another proceeding before the Office, help ensure that the Office acts consistently and is cognizant of the complete record before the agency.

Likewise, in response to comments seeking clarification, the final rule as modified specifies that the Board may consider evidence that a district court can judicially notice under Federal Rule of Evidence 201. This provision is consistent with the Board’s ability to, when appropriate (*e.g.*, when necessary to decide issues of claim construction), introduce and rely on well-known dictionaries or treatises, even when the parties have not raised such evidence, or to take official notice of facts as permitted by Federal Rule of Evidence 201. The Board’s existing rules make the Federal Rules of Evidence applicable to AIA trial proceedings and explain that “judicial notice” as used in the Federal Rules of Evidence shall be construed in AIA trial proceedings as “official notice.” *See* 37 CFR 42.62. Thus, the final rule as modified reflects current Board practice and regulations, pursuant to which the Board may take official notice of facts in appropriate circumstances. *See, e.g., RPX Corp. v. Iridescent Networks, Inc.*, IPR2018–00254 (PTAB Dec. 10, 2018) (Paper 20) (taking official notice of how the URL of the internet Archive provides the date the website was captured); *Ericsson Inc. v. Intellectual Ventures I LLC*, IPR2014–00527, (PTAB May 18, 2015) (Paper 41) (taking official notice that members in the scientific and technical communities who both publish and engage in research rely on the

information published on the copyright line of IEEE publications).

Furthermore, as modified in the final rule, the Board will exercise its discretion only for reasons supported by evidence of record that is “readily identifiable and persuasive.” In the context of the final rules, “readily identifiable and persuasive” has the same meaning articulated in *Hunting Titan* and refers to evidence that is so clear from the record that failing to consider it, although it has not been raised by a party, would be inconsistent with the goal of supporting the integrity of the patent system. *Hunting Titan*, Paper 67 at 13.

Entry of the evidence into the record provides to the parties notice of all relevant evidence and the ability to respond to such evidence before the Board, and also permits appellate review of the Board’s final decision should a dissatisfied party appeal. The rule’s statement that the Board’s decision shall be based on the “evidence of record” also signifies that the Board will consider the entirety of the record in the proceeding, including all papers and exhibits, when exercising its discretion to grant or deny a motion to amend. *See Aqua Products*, 872 F.3d at 1325 (“[A]n agency’s refusal to consider evidence bearing on the issue before it is, by definition, arbitrary and capricious within the meaning of 5 U.S.C. 706, which governs review of agency adjudications. . . . That means that the agency must take account of all the evidence of record, including that which detracts from the conclusion the agency ultimately reaches.”) (O’Malley, J.) (internal citations omitted).

Comments that the “evidence of record” should be limited to evidence introduced by the parties and that the Board should not be permitted to introduce evidence itself are not adopted. Absent the rare circumstances described herein, the Board will not supplement the evidence of record with, for example, additional prior art references not introduced by a party. Further, the Board itself will not undertake its own search for prior art in light of a motion to amend. Prohibiting the Board from introducing its own evidence in any and all instances, however, may risk unduly restricting the Board’s ability to fully evaluate the patentability of proposed substitute claims in light of readily identifiable and persuasive evidence known or available to the Office.

#### E. Opportunity To Respond

*Comment 12:* Although commenters generally appear to agree that the Board may, in the interests of justice, exercise

its discretion to grant or deny a motion to amend for any reason supported by the evidence of record, several commenters suggested that the rules should expressly provide that the parties have notice and an opportunity to respond to the Board’s exercise of such discretion before any such decision is made final to ensure compliance with due process, the interests of justice standard, and the Administrative Procedure Act (APA). One commenter stated that in addition to providing notice to the parties concerning the Board’s proposed exercise of discretion, the Board should give written notice of its initial determination to both parties as well as provide an opportunity for each party to respond in writing. One commenter also suggested that the lack of any express provisions concerning the parties’ opportunity to be heard concerning any new ground or evidence upon which the Board relies provides insufficient guidelines for any reviewing court to assess whether the Board’s exercise of such discretion is an abuse of discretion.

*Response 12:* In the notice of proposed rulemaking concerning the allocation of the burden of persuasion on a motion to amend, the Office expressly acknowledged the requirement that any exercise of discretion to grant or deny a motion to amend would involve providing the parties with notice and an opportunity to be heard on those issues not previously addressed by the parties. For instance, if the Board, in the interests of justice, exercises its discretion to determine that a motion to amend complies with all statutory and regulatory requirements, it will do so only “where the petitioner has been afforded the opportunity to respond to that evidence.” 84 FR at 56404. Likewise, if the Board decides to exercise its discretion to deny a motion to amend, it will do so “only where the patent owner has been afforded the opportunity to respond to that evidence and related grounds of unpatentability.” *Id.* As the commenters have noted, and as the Federal Circuit recognized in *Nike*, such notice and opportunity to be heard by all involved parties is required by due process and expressly set forth in the APA. *See Nike*, 955 F.3d at 52 (“[T]he notice provisions of the APA and our case law require that the Board provide notice of its intent to rely on [newly raised references] and an opportunity for the parties to respond before issuing a final decision relying on [those references].”). This requirement was also recently reaffirmed in the

Board’s precedential *Hunting Titan* decision. *Hunting Titan*, Paper 67 at 14–15. *Hunting Titan* also cited two examples of adequate notice and opportunity to respond, namely, the Board requesting supplemental briefing from the parties regarding the proposed ground of unpatentability or requesting that the parties be prepared to discuss the prior art in connection with the substitute claims at an oral hearing. *Id.* at 15–16 (citing *Nike*, 955 F.3d at 55). In order to provide further clarity and in response to public comments seeking an express regulatory provision providing for an opportunity to be heard, the final rule as modified expressly provides that, where the Board exercises its discretion to grant or deny a motion to amend, the parties will have an opportunity to respond.

#### Rulemaking Considerations

*A. Regulatory Flexibility Act:* For the reasons provided herein, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, United States Patent and Trademark Office, has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes set forth in this rulemaking would not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

The changes in this rulemaking are intended to set forth expressly the respective burdens of persuasion on the parties regarding a motion to amend in an AIA proceeding. These changes are consistent with relevant precedential decisions of the Board and Federal Circuit, and as such, do not reflect a change from current practice. The changes do not create additional procedures or requirements or impose any additional compliance measures on any party, nor do these changes cause any party to incur additional cost. Therefore, any requirements resulting from these changes are of minimal or no additional burden to those practicing before the Board.

*B. Executive Order 12866 (Regulatory Planning and Review):* This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

*C. Executive Order 13563 (Improving Regulation and Regulatory Review):* The Office has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rules; (2) tailored the rules to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a

regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

*D. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs):* This rule is not an Executive Order 13771 (Jan. 30, 2017) regulatory action because it is not significant under Executive Order 12866.

*E. Executive Order 13132 (Federalism):* This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

*F. Executive Order 13211 (Energy Effects):* This rulemaking is not a significant energy action under Executive Order 13211 because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

*G. Executive Order 12988 (Civil Justice Reform):* This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

*H. Executive Order 13045 (Protection of Children):* This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

*I. Executive Order 12630 (Taking of Private Property):* This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

*J. Congressional Review Act:* Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the rule and

other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of \$100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not a “major rule” as defined in 5 U.S.C. 804(2).

*K. Unfunded Mandates Reform Act of 1995:* The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of \$100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of \$100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

*L. National Environmental Policy Act of 1969:* This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

*M. National Technology Transfer and Advancement Act of 1995:* The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

*N. Paperwork Reduction Act of 1995:* The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking does not involve an information collection requirement that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549). This rulemaking does not add any additional information requirements or fees for parties before the Board.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to, a

penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

#### List of Subjects in 37 CFR Part 42

Administrative practice and procedure, Inventions and patents, Lawyers.

#### PART 42—TRIAL PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 1. The authority citation for 37 CFR part 42 continues to read as follows:

**Authority:** 35 U.S.C. 2(b)(2), 6, 21, 23, 41, 135, 311, 312, 316, and 321–326; Pub. L. 112–29, 125 Stat. 284; and Pub. L. 112–274, 126 Stat. 2456.

■ 2. Amend § 42.121 by adding paragraph (d) to read as follows:

#### § 42.121 Amendment of the patent.

\* \* \* \* \*

(d) *Burden of Persuasion.* On a motion to amend:

(1) A patent owner bears the burden of persuasion to show, by a preponderance of the evidence, that the motion to amend complies with the requirements of paragraphs (1) and (3) of 35 U.S.C. 316(d), as well as paragraphs (a)(2), (a)(3), (b)(1), and (b)(2) of this section;

(2) A petitioner bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable; and

(3) Irrespective of paragraphs (d)(1) and (2) of this section, the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend only for reasons supported by readily identifiable and persuasive evidence of record. In doing so, the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice. Where the Board exercises its discretion under this paragraph, the parties will have an opportunity to respond.

■ 3. Amend § 42.221 by adding paragraph (d) to read as follows:

#### § 42.221 Amendment of the patent.

\* \* \* \* \*

(d) *Burden of Persuasion.* On a motion to amend:

(1) A patent owner bears the burden of persuasion to show, by a preponderance of the evidence, that the motion to amend complies with the requirements of paragraphs (1) and (3) of 35 U.S.C. 326(d), as well as

paragraphs (a)(2), (a)(3), (b)(1), and (b)(2) of this section;

(2) A petitioner bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable; and

(3) Irrespective of paragraphs (d)(1) and (2) of this section, the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend only for reasons supported by readily identifiable and persuasive evidence of record. In doing so, the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice. Where the Board exercises its discretion under this paragraph, the parties will have an opportunity to respond.

**Andrei Iancu,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 2020–28159 Filed 12–18–20; 8:45 am]

**BILLING CODE 3510–16–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 131

[EPA–HQ–OW–2015–0804; FRL–10017–97–OW]

RIN 2040–AG00

### Withdrawal of Certain Federal Water Quality Criteria Applicable to Maine

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The United States Environmental Protection Agency (EPA or Agency) is taking final action to amend the Federal regulations to withdraw human health criteria (HHC) for toxic pollutants applicable to waters in the State of Maine. EPA is taking this action because Maine adopted, and EPA approved, HHC that the Agency determined are protective of the designated uses for these waters. This final rule amends the Federal regulations to withdraw certain HHC applicable to Maine that the Agency had promulgated, as described in the September 3, 2020 proposed rule. The withdrawal of these certain federally promulgated HHC will enable Maine to implement its EPA-approved HHC, submitted on April 24, 2020, and approved on June 23, 2020, as applicable criteria for Clean Water Act (CWA or the Act) purposes.

**DATES:** This final rule is effective December 21, 2020.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2015–0804. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., CBI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Jennifer Brundage, Office of Water, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566–1265; email address: [brundage.jennifer@epa.gov](mailto:brundage.jennifer@epa.gov) or visit <https://www.epa.gov/wqs-tech/federal-water-quality-standards-applicable-maine>.

**SUPPLEMENTARY INFORMATION:** This final rule is organized as follows:

I. General Information

A. Does this action apply to me?

II. Background

- A. What are the applicable Federal statutory and regulatory requirements?
- B. What are the applicable Federal water quality criteria that EPA is withdrawing?
- C. Comments on the Proposed Rulemaking
- D. Effective Date of Withdrawal

III. Statutory and Executive Order Reviews

- A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
- B. Executive Order 13771 (Reducing Regulations and Controlling Regulatory Costs)
- C. Paperwork Reduction Act
- D. Regulatory Flexibility Act
- E. Unfunded Mandates Reform Act
- F. Executive Order 13132 (Federalism)
- G. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)
- H. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)
- I. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)
- J. National Technology Transfer and Advancement Act of 1995
- K. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)
- L. Congressional Review Act

## I. General Information

### A. Does this action apply to me?

The State of Maine, as well as entities that discharge pollutants to waters of the United States under the State of Maine’s jurisdiction, such as industrial facilities, stormwater and combined sewer overflow (CSO) management districts, or publicly owned treatment works (POTWs), may be interested in this final rule because it withdraws Federal water quality standards (WQS) promulgated by EPA to allow the State of Maine’s WQS to become the applicable WQS for CWA purposes. Entities discharging in Maine’s waters and citizens concerned with water quality in Maine, including members of the federally recognized Indian tribes, may be interested in this final rule. If you have questions regarding the applicability of this action to a particular entity, consult the person identified in the preceding **FOR FURTHER INFORMATION CONTACT** section.

## II. Background

### A. What are the applicable Federal statutory and regulatory requirements?

Consistent with the CWA, EPA’s WQS program assigns to states and authorized tribes the primary authority for adopting WQS.<sup>1</sup> After states adopt WQS, they must be submitted to EPA for review and action in accordance with the CWA. The Act authorizes EPA to promulgate Federal WQS following EPA’s disapproval of state WQS or an Administrator’s determination that new or revised WQS are “necessary to meet the requirements of the Act.”<sup>2</sup>

### B. What are the applicable Federal water quality criteria that EPA is withdrawing?

On December 19, 2016, EPA promulgated Federal HHC for 96 toxic pollutants for waters in Indian lands in Maine based on the Agency’s 2015 disapproval of corresponding State-established HHC and an Administrator’s determination that new or revised WQS were necessary to meet the requirements of the Act. 81 FR 92466 (December 19, 2016). EPA also promulgated a phenol criterion to protect human health from consumption of water plus organisms for waters outside of Indian lands in Maine after disapproving the State’s phenol criterion in 2015 because it contained a mathematical error.

EPA’s 2015 disapproval of the State’s HHC for waters in Indian lands was based on its decision that they were inadequate to protect the sustenance

<sup>1</sup> 33 U.S.C. 1313(a), (c).

<sup>2</sup> 33 U.S.C. 1313(c)(4).