



3510-16-P

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: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (“USPTO” or “Office”) proposes changes to 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.

DATES: *Comment Deadline Date:* The Office solicits comments from the public on this proposed rulemaking. Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure consideration.

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: MTABurden2019@uspto.gov. Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal at <http://www.regulations.gov>. See the Federal eRulemaking Portal Web site for additional instructions on providing comments via the Federal eRulemaking Portal. All comments submitted directly to the USPTO or provided on the Federal eRulemaking Portal should include the docket number (PTO-P-2019-0011).

Comments may also be submitted by postal mail addressed to: Mail Stop Patent Board, Director of the United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, marked to the attention of “Lead Administrative Patent Judge Christopher L. Crumbley or Lead Administrative Patent Judge Susan L. C. Mitchell, PTAB Notice of Proposed Rulemaking 2019.”

Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message to more easily share all comments with the public. The Office prefers the comments to be submitted in plain text, but also accepts comments submitted in searchable ADOBE[®] portable document format or MICROSOFT WORD[®] format. Comments not submitted electronically should be submitted on paper in a format that accommodates digital scanning into ADOBE[®] portable document format.

The comments will be available for public inspection at the Patent Trial and Appeal Board, located in Madison East, Ninth Floor, 600 Dulany Street, Alexandria, Virginia. Comments also will be available for viewing via the Office's Internet Web site, <https://go.usa.gov/xXXFW>, and on the Federal eRulemaking Portal. Because comments will be made available for public inspection, information that the submitter does not desire to be made public, such as address or phone number, should not be included in the comments.

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: The proposed rules would amend the rules of practice for IPR, PGR, and CBM proceedings that implement provisions of the Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284 (2011) ("AIA") providing for trials before the Office. Pursuant to the AIA, during the course of an IPR, PGR, or CBM, a patent owner may file a motion to amend the patent by cancelling 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 bore 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. In light of *Aqua Products*, as well as public comment provided in response to a Request for Comments (*See* 83 FR 54319), the Office proposes to issue specific rules applicable to motions to amend. The proposed rules assign the burden of persuasion in relation to the patentability of proposed substitute claims to the petitioner, but permit the Board to exercise its discretion to reach a determination regarding patentability of proposed substitute claims even when a petitioner does not carry its burden of persuasion, when supported by the record and when in the interests of justice. The proposed rules also assign the burden of persuasion in relation to 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)) to the patent owner, but permit the Board to exercise its discretion to determine that the motion to amend complies with the statutory and regulatory requirements of those sections even when the patent owner does not carry its burden of persuasion, when supported by the record and when in the interests of justice. The Office anticipates that the Board will exercise such discretion only in rare circumstances, as

discussed herein. The proposed rules are consistent with *Aqua Products* and also with current Board practice as described in the precedential Board decision *Lectrosonics, Inc. v. Zaxcom, Inc.*, Cases IPR2018-01129, 01130 (P.T.A.B. Feb. 25, 2019) (Paper 15), and as such do not reflect a change from current practice.

The proposed rules would thus clarify the rules of practice for amending claims in an IPR, PGR, or CBM to specify that the petitioner bears the burden of showing that the proposed substitute claims are unpatentable by a preponderance of the evidence, and would address instances where a petitioner does not oppose an amendment or does not meet its burden of persuasion in this regard, for example, where the petitioner ceases to participate in the proceeding or declines to oppose the patent owner's motion to amend. The proposed rules also would specify that the patent owner bears the burden of showing, by a preponderance of the evidence, that a motion to amend complies with certain statutory and regulatory requirements, and would address instances where a patent owner does not meet its burden of persuasion in this regard. In instances where a party does not meet its burden, the Board may, in the interests of justice, justify a determination regarding the patentability of amended claims based on the record as a whole.

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 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 Patent 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, 2018).

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.*, Case IPR2015-00040 (P.T.A.B. 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 United States Court of Appeals for 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.

Id. 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 will no longer place the burden of persuasion on a patent owner with respect to 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.”) (alteration in original) (quoting *Aqua Products*, 872 F.2d 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-designating as informative a prior decision of the Board in *Idle Free Sys., Inc. v. Bergstrom, Inc.*, Case IPR2012-00027 (P.T.A.B. 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 at 2* (quoting *Idle Free*). Concurrently, the Board designated an order issued in *Western Digital Corp. v. SPEX Techs., Inc.*, Cases IPR2018-00082, 00084 (P.T.A.B. 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 *Lectrosonics, Inc. v. Zaxcom, Inc.*, Cases IPR2018-01129, 01130 (P.T.A.B. Feb. 25, 2019) (Paper 15) (“*Lectrosonics*”), and de-designated *Western Digital*. This order provides guidance regarding statutory and regulatory requirements for a motion to amend in light of Federal Circuit case law. For example, the order notes that, prior to considering the patentability of any substitute claims, the Board first must 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, that the motion proposes a reasonable number of substitute claims and

that the amendments do not broaden the scope of the claims. *Id.* at 4-5. The 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.” As discussed in more detail below, the proposed rules herein allocate the burden of persuasion regarding the patentability of proposed substitute claims in a motion to amend as set forth in *Lectrosonics* and *Western Digital*.

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 54325.¹

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).^{2,3}

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

¹ The October 2018 Request for Comments was published before *Western Digital* was superseded by *Lectrosonics*, and thus refers 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, are equally pertinent to the current Board precedent of *Lectrosonics*.

² 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 recently 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).

³ 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 recently addressed those comments and questions separately in a “Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding (April 2019).” 84 FR 16654 (Apr. 22, 2019).

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.

The Office appreciates the public input provided in response to the Request for Comments and has reviewed the individual responses thoroughly. 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 *Lectrosonics*), and in the interest of providing greater clarity, certainty, and predictability to parties participating in trial proceedings before the Board, the Office now issues proposed rules allocating the burden of persuasion. The rules would specify that the burden of persuasion as to patentability of substitute claims proposed in a motion to amend is on the petitioner. In addition, the rules would specify 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).

Irrespective of the burdens of persuasion discussed above, however, the rules also would specify 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. 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, based on the entirety of the evidence made of record in the proceeding. The Office anticipates that the Board will exercise this discretion only in rare circumstances. Any evidence relied on to support a determination regarding patentability will be made of record in the proceeding by the parties or the Board.

For instance, 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 or establish every requirement in its briefing. The Office expects that the Board will do so only in circumstances where there is easily identified and persuasive evidence that the motion complies with the statutory and regulatory requirements, and only where the petitioner has been afforded the opportunity to respond to that evidence. The Board will rely on evidence of record when making such a determination.

Furthermore, as supported by the majority of the comments received in response to Question 16, under the proposed rules, the Board may exercise its discretion to reach a determination regarding patentability in instances where a petitioner does not oppose the amendment or does not meet its burden of persuasion in relation to any proposed substitute claim. The proposed rules limit such instances to those in which the interests of justice warrant the Board reaching a determination regarding patentability. Such

instances may include, for example, situations where the petitioner has ceased to participate in the proceeding altogether (for example, as a result of settlement) or where the petitioner remains in the proceeding but does not oppose the motion to amend.

The interests of justice also may, for example, support the Board exercising its discretion to deny a motion to amend when the petitioner opposes the motion to amend and has failed to meet the burden of persuasion, but where there is easily identified and persuasive evidence of unpatentability in the record. In such situations, the proposed rules would grant the Board discretion regarding whether to make any determination of unpatentability that is supported by the evidence of record, even if the ground of unpatentability has not been advanced by the petitioner. The Office expects that the Board will do so only in rare circumstances, and only where the patent owner has been afforded the opportunity to respond to that evidence and related grounds of unpatentability. Ordinarily, 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.

Discussion of Specific Rules

The USPTO proposes to amend 37 CFR part 42 as follows:

Section 42.121: § 42.121 is proposed to be amended by adding a new subsection (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 subsection (d) also states that in cases where 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 for any reason supported by the evidence of record.

Section 42.221: § 42.221 is proposed to be amended by adding a new subsection (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 subsection (d) also states that in cases where 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 for any reason supported by the evidence of record.

Rulemaking Considerations

A. Regulatory Flexibility Act: For the reasons set forth 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 notice of proposed rulemaking would not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

The changes set forth in this notice of proposed rulemaking are 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 proposed changes are of minimal or no additional burden to those practicing before the Board.

For the foregoing reasons, the proposed changes in this notice of proposed rulemaking would not have a significant economic impact on a substantial number of small entities.

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 on-line 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 proposed rule is not expected to be an Executive Order 13771 (Jan. 30, 2017) regulatory action because this proposed rule 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 this rulemaking 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 notice of proposed rulemaking are not expected to result in an annual effect on the economy of 100 million dollars 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 notice of proposed 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 dollars (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 dollars (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: 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: 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 which involve the use of technical standards.

N. Paperwork Reduction Act: 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 proposed 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.

For the reasons set forth in the preamble, the Office proposes to amend part 42 of title 37 as follows:

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), (3), (b)(1), and (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 for any reason supported by the evidence of record.

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), (3), (b)(1), and (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 for any reason supported by the evidence of record.

Dated: October 10, 2019.

Andrei Iancu,

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

