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Motion To Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board

A Proposed Rule by the [Patent and Trademark Office](#) on 03/04/2024

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DOCUMENT STATISTICS**ENHANCED CONTENT****Motion To Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board**PTO-P-2020-0060 (<https://www.regulations.gov/docket/PTO-P-2020-0060>)**ENHANCED CONTENT****PUBLISHED DOCUMENT****AGENCY:**

Patent Trial and Appeal Board, United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.**SUMMARY:**

The United States Patent and Trademark Office (Office or USPTO) proposes to update its rules governing amendment practice in trial proceedings under the Leahy-Smith America Invents Act (AIA) to make permanent certain provisions of the Office's motion to amend pilot program (MTA pilot program) and to revise the rules that allocate burdens of persuasion in connection with motions to amend (MTAs). The Office proposes to revise its rules of practice to provide for issuance of preliminary guidance in response to an MTA and to provide a patent owner with the option for filing one additional revised MTA. Further, the Office proposes to revise the rules to clarify that a preponderance of evidence standard applies to any new ground of unpatentability raised by the Board and to clarify that when exercising the discretion to grant or deny an MTA or to raise a new ground of unpatentability, the Board may consider all evidence of record in the proceeding, including evidence identified through a prior art search conducted by the Office at the Board's request and added to the record. These rules better ensure the Office's role of issuing robust and reliable patents, and the predictability and certainty of post-grant trial proceedings before the Board. These changes would apply to the existing consolidated set of rules relating to the Office trial practice for *inter partes* review (IPR), post-grant review (PGR), and derivation proceedings that implemented provisions of the AIA providing for trials before the Office.

DATES:

To ensure consideration, commenters must submit written comments on or before May 3, 2024.

ADDRESSES:

For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at <https://www.regulations.gov> (<https://www.regulations.gov>). To submit comments via the portal, enter docket number PTO-P-2020-0060 on the home page and select “search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this proposed rulemaking and select the “Comment” icon, complete the required fields, and enter or attach your comments.

Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal (<https://www.regulations.gov> (<https://www.regulations.gov>)) for additional instructions on providing comments via the portal. If the electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions regarding how to submit comments by mail or by hand delivery, based upon the public's ability to obtain access to USPTO facilities at the time.



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FOR FURTHER INFORMATION CONTACT:

Miriam L. Quinn, Acting Senior Lead Administrative Patent Judge; or Melissa Haapala, Vice Chief Administrative Patent Judge, at 571-272-9797, Miriam.Quinn@uspto.gov (<mailto:Miriam.Quinn@uspto.gov>) or Melissa.Haapala@uspto.gov (<mailto:Melissa.Haapala@uspto.gov>), respectively.

SUPPLEMENTARY INFORMATION:

Background

Development of the Proposed Rule

On September 16, 2011, the AIA was enacted into law (Pub. L. 112-29 (<https://www.govinfo.gov/link/plaw/112/public/29>), 125 Stat. 284 (2011)), and in 2012, the Office implemented rules to govern Office trial practice for AIA trials, including IPR, PGR, covered business method (CBM), and derivation proceedings pursuant to 35 U.S.C. 135 (<https://www.govinfo.gov/link/uscode/35/135>), 316 (<https://www.govinfo.gov/link/uscode/35/316>), and 326 (<https://www.govinfo.gov/link/uscode/35/326>) and AIA 18(d)(2). See 37 CFR part 42 (<https://www.ecfr.gov/current/title-37/part-42>); 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 (/citation/77-FR-48612) (August 14, 2012); Changes to Implement *Inter Partes* Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 FR 48680 (/citation/77-FR-48680) (August 14, 2012); Transitional Program for Covered Business Method Patents—Definitions of Covered Business Method Patent and Technological Invention, 77 FR 48734 (/citation/77-FR-48734) (August 14, 2012). Additionally, the Office published a Patent Trial Practice Guide (Practice Guide) for the rules 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 84 FR 64280 (/citation/84-FR-64280) (November 21,

2019); <https://www.uspto.gov/TrialPracticeGuideConsolidated> (<https://www.uspto.gov/TrialPracticeGuideConsolidated>). The Practice Guide provides a helpful overview of the Patent Trial and Appeal Board (PTAB or Board) process. See, e.g., Practice Guide at 5-8 (AIA trial process), 66-72 (motions to amend).

In 2018, the Office published a Request for Comments (RFC) on a proposed procedure for motions to amend filed in AIA proceedings before the PTAB. See RFC on MTA Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 83 FR 54319 (/citation/83-FR-54319) (October 29, 2018) (seeking public comments on a previously proposed procedure for MTAs, the Board's MTA practice generally, and the allocation of burdens of persuasion after *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc) (*Aqua Products*)) (2018 RFC). After considering the comments received in response, the Office implemented the MTA pilot program. See Notice Regarding a New Pilot Program Concerning MTA Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 FR 9497 (/citation/84-FR-9497) (March 15, 2019) (MTA pilot program notice). The MTA pilot program was extended through September 16, 2024. Extension of the Patent Trial and Appeal Board Motion to Amend Pilot Program, 87 FR 60134 (/citation/87-FR-60134) (October 4, 2022).

Preliminary Guidance and Revised Motions To Amend Under the MTA Pilot Program

The MTA pilot program provides a patent owner with two independent options when proposing substitute claims for challenged patent claims during an AIA trial proceeding. Under the first option in the MTA pilot program, if requested by a patent owner in its original MTA, the Board will issue preliminary, non-binding guidance. Under the second option, a patent owner may file, without needing Board authorization, a revised MTA as discussed further below.

The Board's preliminary guidance typically will come in the form of a short paper issued after a petitioner files its opposition to the MTA (or after the due date for a petitioner's opposition, if none is filed). The preliminary guidance provides, at a minimum, an initial discussion about whether there is a reasonable likelihood that the original MTA meets statutory and regulatory requirements for an MTA and whether the petitioner (or the record then before the Office, including any opposition to the MTA and accompanying evidence) establishes a reasonable likelihood that the substitute claims are unpatentable. See MTA pilot program notice, 84 FR 9500 (/citation/84-FR-9500).

Further, a patent owner may choose to file a revised MTA after receiving a petitioner's opposition to the original MTA or after receiving the Board's preliminary guidance (if requested). A revised MTA replaces the original MTA. If a patent owner chooses to file a revised MTA, the revised MTA must include one or more new proposed substitute claims in place of previously presented substitute claims, where each new proposed substitute claim presents a new claim amendment. The new claim amendments, as well as arguments and evidence, must be responsive to issues raised in the preliminary guidance (if requested) or in petitioner's opposition. Instead of filing a revised MTA, a patent owner may choose to file a reply to a petitioner's opposition to the MTA and/or the preliminary guidance (if requested). If preliminary guidance was issued at a patent owner's request, the patent owner may choose to take no action and wait for the petitioner's reply to the preliminary guidance and then file a sur-reply.

The MTA pilot program notice set forth typical timelines and due dates for the filing or issuance of MTA-related papers, depending on whether a patent owner takes advantage of neither, one, or both options under the program. See MTA pilot program notice, 84 FR 9506-9507 (/citation/84-FR-9506), Appendices 1A

(Patent Owner Reply Timeline) and 1B (Revised MTA Timeline). Where a revised MTA is filed, the Office issues a scheduling order that adjusts the deadline for oral hearing to accommodate the additional briefing on the MTA.

As described in the MTA pilot program notice and implemented by the Board, the preliminary guidance provides the Board's initial, preliminary views on the original MTA. With that in mind, the preliminary guidance will provide an initial discussion about whether the parties have shown a reasonable likelihood of meeting their respective burdens. See Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board. 85 FR 82923 (/citation/85-FR-82923) (December 21, 2020); 37 CFR 42.121(d) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d))), 42.221(d) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d))). In particular, the preliminary guidance will address whether there is a reasonable likelihood that the patent owner has shown that the MTA meets the statutory and regulatory requirements for an MTA. See 37 CFR 42.121(d)(1) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(1\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(1))), 42.221(d)(1) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(1\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(1))); see also 35 U.S.C. 316(d) (<https://www.govinfo.gov/link/uscode/35/316>), 326(d) (<https://www.govinfo.gov/link/uscode/35/326>); *Lectrosomics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, 2020 WL 407145, at *1 (precedential). The preliminary guidance will also provide an initial discussion about whether the petitioner (or the record then before the Office, including any opposition to the MTA and accompanying evidence) has established a reasonable likelihood that the proposed substitute claims are unpatentable. See 37 CFR 42.121(d)(2) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(2\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(2))), 42.221(d)(2) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(2\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(2))). The preliminary guidance may also address new grounds of unpatentability discretionarily raised by the Board, together with citations to the evidence of record supporting those new grounds. See 37 CFR 42.121(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(3))) and (4) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(4\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(4))), 42.221(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(3))) and (4) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(4\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(4))). In general, the Board's preliminary guidance will address the proposed substitute claims, in light of the amendments presented in those claims, in a patent owner's original MTA and will not address the patentability of the originally challenged claims.

Similar to an institution decision, preliminary guidance on an MTA during an AIA trial will not be binding on the Board. See *Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990, 1000 (Fed. Cir. 2023) (holding that the Board's decision to change its claim construction between its Preliminary Guidance and the final written decision (FWD) was not arbitrary and capricious □ and did not violate the Administrative Procedure Act). The Board's preliminary guidance is not a "decision" under 37 CFR 42.71(d) ([https://www.ecfr.gov/current/title-37/section-42.71#p-42.71\(d\)](https://www.ecfr.gov/current/title-37/section-42.71#p-42.71(d))), and thus parties may not file a request for rehearing or Director Review of the preliminary guidance. The parties will have the opportunity to respond to the preliminary guidance. For example, a patent owner may file a reply to a petitioner's opposition to the MTA or a revised MTA. The patent owner's reply may respond to the Board's preliminary guidance and/or to the petitioner's opposition to the MTA. If an opposition is not filed, but a preliminary guidance was requested, a patent owner's reply may respond only to the preliminary guidance. New evidence (including declarations) may be submitted with every paper in the MTA process, except with a sur-reply or in the special circumstance discussed below. Thus, a patent owner may file new evidence, including declarations, with its revised MTA or reply. See 84 FR 9500 (/citation/84-FR-9500) (stating further that when filing new declarations, parties are expected to make their declarants available for depositions promptly and to make their attorneys available to take and defend such depositions; any unavailability will not be a reason to adjust the schedule for briefing on an MTA

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or revised MTA absent extraordinary circumstances). The sur-reply also may respond to the preliminary guidance and is limited to responding to arguments made in the patent owner's reply brief, to commenting on reply declaration testimony, or pointing to cross-examination testimony.

In the special circumstance of a patent owner not filing either a reply or a revised MTA after receiving preliminary guidance from the Board, a petitioner may file a reply to the preliminary guidance, but such a reply may respond only to the preliminary guidance and may not be accompanied by new evidence. If a petitioner files a reply in this context, a patent owner may file a sur-reply, but that sur-reply may respond only to the petitioner's reply and may not be accompanied by new evidence.

If a patent owner files an MTA, the patent owner may, without prior authorization from the Board, file one revised MTA after receiving a petitioner's opposition or the Board's preliminary guidance (if requested). If the patent owner did not elect to receive preliminary guidance, the patent owner can still choose to file a revised MTA to address the petitioner's opposition to the original MTA.

Further, a revised MTA replaces the original MTA filed earlier in the proceeding. A patent owner may not incorporate by reference substitute claims or arguments presented in the original MTA into the revised MTA; all proposed substitute claims a patent owner wishes the Board to consider must be presented in the revised MTA.

A revised MTA is an additional MTA that is automatically authorized under 35 U.S.C. 316(d)(2) (<https://www.govinfo.gov/link/uscode/35/316>) and 326(d)(2) (<https://www.govinfo.gov/link/uscode/35/326>). The proposed revisions therefore distinguish between additional MTAs under 37 CFR 42.121(c) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(c\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(c))) and 42.221(c) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(c\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(c))), which require pre-authorization upon a showing of "good cause," and a revised MTA, which may be filed without prior authorization. Where the term "any motion to amend" is used, the proposed rule refers to an original, additional, or revised MTA.

A patent owner is not required to exercise either option under the MTA pilot program. Specifically, if a patent owner does not elect either to receive preliminary guidance on its original MTA or to file a revised MTA, the rules governing amendment of the patent are essentially unchanged from the practice prior to the MTA pilot program. See *Lectrosionics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, 2020 WL 407145, at *1 (PTAB January 24, 2020) (precedential).

The Office has tracked engagement with the MTA pilot program and published an updated study of the MTA pilot program, providing such data through March 31, 2023. See Patent Trial and Appeal Board Motion to Amend Study Installment 8, <https://www.uspto.gov/patents/ptab/motions-amend-study> (<https://www.uspto.gov/patents/ptab/motions-amend-study>) (last visited August 23, 2023) ("Study"). The Study shows that, of 2,832 trials that were instituted during the MTA pilot program, 9% (264) of instituted trials included a MTA (very close to the rate of MTAs filed before the MTA pilot program, 10% of all trials). Further, of the 264 instituted trials with an MTA, 88% (232) included a request for preliminary guidance, *i.e.*, the first of two MTA pilot program options. Still further, of those 232 trials with an MTA requesting preliminary guidance, 72% (168) filed either a Patent Owner Reply (41) or a Revised MTA (127), *i.e.*, the second of two MTA pilot program options. Additionally, during the MTA pilot program study period, 24% of

final determinations had at least one proposed substitute claim granted entry, as opposed to 14% of final determinations prior to the MTA pilot program. To-date, no final determination for an instituted proceeding has been extended beyond the one-year deadline based solely on the involvement of the MTA pilot program.

Allocation of Burdens of Persuasion and Scope of the Record in Motions To Amend

The Office, through notice and comment rulemaking, published a final rule that allocated burdens of persuasion in relation to motions to amend and the patentability of substitute claims. See 37 CFR 42.121(d) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d))), 42.221(d) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d))); Rules of Practice to Allocate the Burden of Persuasion on Motions to Amend in Trial Proceedings before the Patent Trial and Appeal Board, 85 FR 82936 (/citation/85-FR-82936) (December 21, 2020) (“the burden-allocation rules”).

These burden-allocation rules assign the burden of persuasion to the patent owner to show, by a preponderance of the evidence, that an MTA complies with certain statutory and regulatory requirements. 37 CFR 42.121(d)(1) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(1\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(1))), 42.221(d)(1) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(1\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(1))). These rules also assign the burden of persuasion to the petitioner to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable. 37 CFR 42.121(d)(2) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(2\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(2))), 42.221(d)(2) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(2\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(2))). Finally, these rules further specify that irrespective of those burdens, the Board may, in the “interests of justice” exercise its discretion to grant or deny an MTA, but “only for reasons supported by readily identifiable and persuasive evidence of record.” 37 CFR 42.121(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(3))), 42.221(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(3))); *Hunting Titan, Inc. v. DynaEnergetics Europe GmbH*, IPR2018-00600 (PTAB July 6, 2020) (Paper 67) (*Hunting Titan*).

Situations meeting the interests of justice standard 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.” 85 FR 82924 (/citation/85-FR-82924), 82927 (/citation/85-FR-82927) (citing *Hunting Titan*, Paper 67 at 12-13, 25-26). The rules further provide that in 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 MTA. *Id.* at 82927; see also 37 CFR 42.121(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(3))), 42.221(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(3))).

As noted in the final rule that allocated burdens of persuasion, “[i]n the vast majority of cases, the Board will consider only evidence a party introduces into the record of the proceeding.” 85 FR 82927 (/citation/85-FR-82927). Thus, “[i]n 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.” *Id.* at 82927-28. That said, the Board may consider, for example “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).” *Id.* at 82927. Likewise, “the Board may consider evidence that a district court can judicially notice under Federal Rule of Evidence 201.” *Id.*; see also 37 CFR 42.121(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(3))), 42.221(d)(3)

([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(3))) (“[T]he 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.”).

Subsequent to the issuance of the burden-allocation rules, the United States Court of Appeals for the Federal Circuit issued a precedential decision in *Hunting Titan, Inc., v. DynaEnergetics Europe GmbH*, 28 F.4th 1371 (Fed. Cir. 2022). The court confirmed that no court precedent has “established that the Board maintains an affirmative duty, without limitation or exception, to sua sponte raise patentability challenges to a proposed substitute claim.” *Id.* at 1381 (citations omitted). The court also stated that “confining the circumstances in which the Board should sua sponte raise patentability issues was not itself erroneous.” *Id.* The court, however, found it “problematic” that the USPTO confined the Board’s discretion to only rare circumstances. *Id.* It also noted that the USPTO’s “substantial reliance on the adversarial system . . . overlooks the basic purpose of [inter partes review] proceedings: to reexamine an earlier agency decision and ensure that patent monopolies are kept within their legitimate scope.” *Id.* (citations omitted); see *id.* at 1385 (concurring expressing concern that the burden-allocation rule’s requirement for “readily identifiable and persuasive evidence” may prevent the Board from raising grounds “even when no one is around to oppose a new patent monopoly grant.”).

Under the rules as currently written and under Federal Circuit case law, the Board retains discretion to raise, or to not raise, grounds of unpatentability with respect to proposed substitute claims. See *Nike, Inc. v. Adidas AG*, 955 F.3d 45, 53 (2020); *Hunting Titan*, 28 F.4th at 1381.

Consistent with the Board’s discretion to raise grounds of unpatentability, the MTA pilot program noted the Board’s discretion to solicit patent examiner assistance regarding the MTA when “petitioner cease[d] to participate altogether in an AIA trial in which the patent owner file[d] an MTA, and the Board nevertheless exercise[d] its discretion to proceed with the trial.” 84 FR 9502 (/citation/84-FR-9502). If solicited by the Board, the assistance could include the preparation of an advisory report that provides an initial discussion about whether an MTA meets certain statutory and regulatory requirements (*i.e.*, whether the amendment enlarges the scope of the claims of the patent or introduces new matter) and about the patentability of proposed substitute claims, for example, in light of prior art that was provided by the patent owner and/or obtained in prior art searches by the examiner. *Id.* As of issuance of this notice, the Board has not solicited examination assistance of this nature in exercising the Board’s discretion to raise or not to raise grounds of unpatentability. This proposed rule clarifies that the examination assistance to the Board may be effectuated by requesting that the Office conduct a prior art search. The proposed rule also clarifies that the Board’s request for the prior art search and the result of such a search by the Office will be made of record.

2023 RFC on MTA Pilot Program and Burden-Allocation Rules

After four years of experience with the MTA pilot program and development of Federal Circuit case law concerning burden allocation in the MTA context, the Office issued another Request for Comments to seeking feedback on the public’s experience with the program and the burden-allocation rules that apply to MTAs. See RFC Regarding MTA Pilot Program and Rules of Practice to Allocate Burdens of Persuasion on motions to Amend in Trial Proceedings Before the Patent Trial and Appeal Board, 88 FR 33063 (/citation/88-FR-33063) (May 23, 2023) (2023 RFC). The Office also sought feedback on when reexamination or reissue proceedings, also referred to as post-grant options, are better alternatives for patent owners seeking to amend claims. *Id.* at 33065-66. Further, the Office sought comments on whether the MTA pilot program should be modified and what barriers the Office could address to increase the effectiveness of MTA procedures. *Id.* at 33066.

The 2023 RFC also sought comments on the burden-allocation rules. In light of the Federal Circuit court's commentary on the current rules, as well as the Board's *Hunting Titan* decision, and given the Office's desire to support the integrity of the patent system and to issue robust and reliable patent rights, the Office sought public comments on whether the Board should more broadly use its discretion to raise sua sponte grounds in the MTA process. *Id.* Additionally, the Office sought public comments on whether, and under what circumstances, the Office should solicit patent examiner assistance regarding an MTA or conduct a prior art search in relation to proposed substitute claims. *Id.*

Furthermore, the Office recognized that if the Board exercises its discretion and raises its own grounds of unpatentability under the current rule, 37 CFR 42.121(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(3))), the burden-allocation rules do not specifically state where the burden of persuasion lies for Board-raised grounds. The Office sought public comments on whether the burden-allocation rules should be revised to clarify who bears the burden of persuasion for grounds of unpatentability raised by the Board under 37 CFR 42.121(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.121#p-42.121\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.121#p-42.121(d)(3))) or 42.221(d)(3) ([https://www.ecfr.gov/current/title-37/section-42.221#p-42.221\(d\)\(3\)](https://www.ecfr.gov/current/title-37/section-42.221#p-42.221(d)(3))). See 88 FR 33066 (/citation/88-FR-33066); see also *Nike, Inc. v. Adidas AG*, No. 2021-1903, 2022 WL 4002668, at *4-10 (Fed. Cir. September 1, 2022) (leaving open the question “whether, in an *inter partes* review, the petitioner or Board bears the burden of persuasion for an unpatentability ground raised sua sponte by the Board against proposed substitute claims”). The comments, and the rules proposed to address these comments and to enhance the Motions to Amend practice, are discussed below.

Revisions in This Proposed Rule

Response to Comments and Proposed Provisions on Preliminary Guidance and Revised Motions To Amend

The MTA pilot program has been generally well-received, and one or both pilot program options are exercised in the vast majority of MTAs. Commenters to the 2023 RFC noted specifically that the option to request preliminary guidance has been popular among those participating in MTAs and has been effective, guiding patent owners to revise their MTAs in many cases. Although some commenters noted that motions to amend in general may not be as useful as other alternatives for claim amendments, none of the commenters stated that the Office should discontinue the options of issuing preliminary guidance and allowing the filing of a revised MTA as currently implemented. Some commenters, however, indicated that the Office should consider providing more time for the MTA process. Commenters noted that parties may not have sufficient time after the preliminary guidance issues to address the preliminary guidance, secure expert testimony, and search for additional prior art. Proposals included having the Board hold a conference call to give parties an opportunity to offer a modified schedule.

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The Office appreciates the comments about the popularity and increased effectiveness of the MTA pilot program options, which are consistent with the Office's experience as supported by utilization data. In proceedings with MTAs filed under the pilot, at least 88% of patent owners have elected one or both pilot options (*i.e.*, a request for preliminary guidance, a revised MTA, or both). Based on its experience with the pilot program for the four-year period from its effective date in 2019, consideration of the formal feedback received in response to the 2023 RFC, as well as additional feedback received from a variety of stakeholders during the operation of the MTA pilot program itself, the Office proposes to formalize the options available to patent owners under the MTA pilot program. Accordingly, the Office now issues this proposed rule to implement the two options in the MTA pilot program: (1) requesting preliminary guidance and (2) filing, without pre-authorization, a revised MTA.

To address the concerns raised as to the ability of parties to have sufficient time to fully take advantage of the MTA procedure, the Office proposes rule language clarifying the Board may extend deadlines in the MTA timeline. Such extensions are not anticipated to be needed in most cases, because the Board's experience is that the default timelines have been sufficient to permit full and fair briefing in cases under the MTA pilot program. Thus, the Office will continue to apply the existing timelines by default as currently implemented under the MTA pilot program unless an extension is granted as discussed further below. See 84 FR 9506-9507 (/citation/84-FR-9506) (setting forth MTA pilot program timelines).

The AIA provides the Director the discretion to extend the deadlines for issuing a final written decision for good cause and by not more than 6 months. 35 U.S.C. 316 (<https://www.govinfo.gov/link/uscode/35/316>) (a)(11), 326 (a)(11). The Director's authority to extend the deadline of the final written decision has been delegated to the Chief Administrative Patent Judge. 37 CFR 42.100(c) ([https://www.ecfr.gov/current/title-37/section-42.100#p-42.100\(c\)](https://www.ecfr.gov/current/title-37/section-42.100#p-42.100(c))), 42.200(c) ([https://www.ecfr.gov/current/title-37/section-42.200#p-42.200\(c\)](https://www.ecfr.gov/current/title-37/section-42.200#p-42.200(c))). Thus, pursuant to 37 CFR 42.100(c) ([https://www.ecfr.gov/current/title-37/section-42.100#p-42.100\(c\)](https://www.ecfr.gov/current/title-37/section-42.100#p-42.100(c))) and 42.200(c) ([https://www.ecfr.gov/current/title-37/section-42.200#p-42.200\(c\)](https://www.ecfr.gov/current/title-37/section-42.200#p-42.200(c))), upon a showing of good cause, the Chief Administrative Patent Judge may extend the final written decision beyond the statutory deadline (one year from the date a trial is instituted) by up to six months, particularly, for example, if one or more circumstances are present in a proceeding, such as: (1) complex issues; (2) unavailability of the panel; or (3) need to accommodate additional papers (such as additional briefing or evaluate a requested examination search report). See *e.g.*, *Eden Park Illumination, Inc., v. S. Edward Neister*, IPR2022-00381, Paper 51 (August 4, 2023 PTAB) (determining as good cause the involvement of a revised MTA with new prior art, resulting in substantially compressed schedule, multiple postponements of the oral hearing due to scheduling conflicts, and additional briefing); *Hope Medical Enterprises, Inc. v. Fenec Pharmaceuticals Inc.*, IPR2022-00125, Paper 35 (April 18, 2023 PTAB) (determining as good cause the involvement of a revised MTA, resulting in a compressed schedule, with the revised claims subject to asserted grounds of unpatentability based on combination of at least four references); *Snap, Inc., v. Palo Alto Research Center Inc.*, IPR2021-00986, Paper 46 (November 7, 2022) (determining as good cause the substantial coordination of proceedings required by the Board due to multiple pending motions to amend).

As for deadlines that are not of a final written decision, typically, a panel of the Board determines whether to grant a good-cause extension under 37 CFR 42.5(c)(2) ([https://www.ecfr.gov/current/title-37/section-42.5#p-42.5\(c\)\(2\)](https://www.ecfr.gov/current/title-37/section-42.5#p-42.5(c)(2))) after request from and conference with the parties. In the context of the MTA timelines, the Board will continue to consider whether to grant extensions of those timelines as required by the Board's rules discussed above. In particular, the Board may determine at any time during the pendency of the case, but more specifically upon issuing the preliminary guidance or receiving a revised MTA, whether for good cause the particular circumstances raised by the parties to the proceeding warrant an extension of deadlines, including whether to extend the deadline for the final written decision, which can only be granted by the Chief Administrative Patent Judge under 37 CFR 42.100(c) ([https://www.ecfr.gov/current/title-37/section-42.100#p-42.100\(c\)](https://www.ecfr.gov/current/title-37/section-42.100#p-42.100(c))) and 42.200(c) ([https://www.ecfr.gov/current/title-37/section-42.200#p-42.200\(c\)](https://www.ecfr.gov/current/title-37/section-42.200#p-42.200(c))). When an extension is granted, the parties will be notified of the change in the due dates for the remainder of the deadlines and events in the proceeding.

Response to Comments on the Reissue and Reexamination Options

The 2023 RFC sought comments regarding whether reexamination and/or reissue proceedings are better options for patent owners seeking to amend claims in AIA proceedings as compared to the MTA pilot program. 88 FR 33065-66 (/citation/88-FR-33065). Although the majority of the comments supported use of the MTA pilot program, in response to this question some comments stated a preference to avoid the MTA

process altogether. As to the desirability of pursuing reissue or reexamination in connection with an AIA trial proceeding, a summary of the alternatives for seeking claim amendments before, during, and after a post-grant proceeding has been provided in a prior notice. Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding (April 2019), 84 FR 16654 (/citation/84-FR-16654) (April 22, 2019) (reissue and reexamination notice). The reissue and reexamination notice provides a summary of various pertinent practices regarding existing Office procedures that apply to reissue and reexamination, including after a petitioner files an AIA petition challenging claims of the same patent, after the Board institutes a trial, and after the Board issues a final written decision in an AIA trial proceeding. *Id.* at 16655-58. The notice also provides summary information about factors the Office currently considers when determining whether to stay or suspend a reissue proceeding, or stay a reexamination, that involves a patent involved in an AIA proceeding and when and whether to lift such a stay or suspension. *Id.* at 16656-58.

Some commenters stated that the usefulness of a reissue and reexamination is reduced given the likelihood of their stay during the post-grant proceeding, including through appeals of the final written decision at the Federal Circuit. In the event a party is considering the impact of a possible stay of the reissue and reexamination proceedings, the reissue and reexamination notice states that a stay of an ex parte reexamination may be lifted “notwithstanding a Federal Circuit appeal of a final written decision on the same patent.” *Id.* at 16658. The proposed rules do not change our current guidance in the reissue and reexamination notice.

Response to Comments and Proposed Provisions on Allocation of Burden and Evidence of Record for Proposed Amended Claims

Regarding the burden-allocation rules, commenters favored continuing the exercise of discretion by the Board to raise new grounds of unpatentability. Some favored the exercise of discretion more broadly, *i.e.*, for the Board to consider all prior art of record and conduct a prior art search in each case where an MTA is filed. Other commenters favored the Board considering the entirety of the record, but did not favor the Board conducting a prior art search, primarily because of the compressed case timelines.

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In recognition of these comments, and in view of Office experience, the Office proposes changes to the rules to address comments in favor of the Board's authority to consider the entirety of the art of record and to request examination assistance in an appropriate manner when justified by circumstances. The Office agrees that the burden-allocation rule should give the Board the ability to more broadly use its discretion to raise grounds of unpatentability and to consider all the prior art of record in the proceeding without limitation.

Further, consistent with current practice reflected in the MTA pilot program, the Office proposes rules clarifying that the Board may seek examination assistance in certain circumstances. 84 FR 9502 (/citation/84-FR-9502). For example, the Board has discretion to solicit examination assistance if the petitioner ceases to participate altogether in an AIA trial in which the patent owner files an MTA and the Board nevertheless exercises its discretion to proceed with the trial thereafter. *Id.* The Board may also solicit examination assistance when a petitioner continues to participate in the AIA trial but either does not oppose or has ceased to oppose an MTA. Examination assistance could include the preparation of an advisory report that provides an initial discussion of whether an MTA meets certain statutory and regulatory requirements (*i.e.*, whether the amendment enlarges the scope of the claims of the patent or introduces new matter), as well as the patentability of proposed substitute claims in light of prior art that was provided by the patent owner and/or obtained in prior art searches by the examiner. *Id.* The proposed rule confirms the Board's discretion to seek examination assistance by clarifying that the Office may conduct a prior art search at the Board's

request when no petitioner opposes or all petitioners cease to oppose an MTA. The proposed rule is intended to capture situations where no opposition is filed or an opposition is filed but other situations constitute a lack of opposition, such as the filing of an illusory opposition to the MTA or a petitioner filing that raises no prior art challenge. The proposed rule also clarifies that the Board may make of record any evidence identified through a prior art search undertaken at the Board's request. Additionally, the proposed rule provides that the Board's request and the prior art search report prepared by the Office at the request of the Board will be made of record.

The 2023 RFC also resulted in comments concerning the burden of persuasion on Board-raised grounds. One commenter proposed that the post-grant proceeding scheme should remain strictly adversarial, with the burden of persuasion on unpatentability issues remaining with petitioner at all times. Another commenter proposed that on Board-raised grounds, the Board has the “burden.” Other commenters noted that the statute is silent on this issue and that a patent owner must not bear this burden.

The Board is a neutral tribunal and the notion of burden allocation to the Board in determining whether to grant or deny an MTA is incongruent with the discharge of its adjudicatory functions. Notwithstanding this incongruity, the Office recognizes the need for clarity and consistency in the application of the Board's exercise of discretion in connection with raising new grounds of unpatentability for proposed claims presented in an MTA. The proposed rule clarifies that the Board determines unpatentability on the new ground by reference to the evidence of record or made of record and based on a preponderance of the evidence. Support for the Board's responsibility in this regard has been established in current precedent of the Board. *Lectrosomics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, 2020 WL 407145, at *1 (“The Board itself also may justify any finding of unpatentability by reference to evidence of record in the proceeding, for example, when a petitioner ceases to participate. . . . Thus, the Board determines whether substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record, including any opposition made by the petitioner.”).

Furthermore, the Office proposes to broaden the body of evidence that the Board may consider and make of record, to now include the entire evidence of record in the proceeding, without limitation, in accordance with *Nike, Inc. v. Adidas AG*, 955 F.3d at 54 (“[T]he Board may rely on prior art of record in considering the patentability of amended claims.”). By removing limitations of the “interests of justice” and of considering “only readily identifiable and persuasive” evidence and no longer relying solely on the adversarial system, the proposed rule alleviates the Federal Circuit's concern that the Board confined its discretion to only rare circumstances. See *Hunting Titan*, 28 F.4th at 1381 (noting that the USPTO's “substantial reliance on the adversarial system . . . overlooks the basic purpose of [inter partes review] proceedings: to reexamine an earlier agency decision and ensure ‘that patent monopolies are kept within their legitimate scope.’ ”); see also *id.* at 1385 (concurrence expressing concern that the burden-allocation rule's requirement for “readily identifiable and persuasive evidence” may prevent the Board from raising grounds “even when no one is around to oppose a new patent monopoly grant”).

The proposed rule moves away from the Board's precedential *Hunting Titan* decision. *Hunting Titan, Inc. v. DynaEnergetics Europe GmbH*, IPR2018-00600 (PTAB July 6, 2020) (Paper 67). That decision, criticized by the Federal Circuit, is at odds with the proposed broader authority of the Board to raise grounds sua sponte. Accordingly, the *Hunting Titan* decision shall be de-designated from precedential status upon the effective date of the final rule.

Discussion of Specific Rules

Sections 42.121 and 42.221

Sections 42.121(a) and 42.221(a) are proposed to be amended to refer to original motions to amend and to allow for requests for preliminary guidance on an original motion to amend.

Sections 42.121(b) and 42.221(b) are proposed to be amended to clarify that the regulation applies to any motion to amend and that support in the original disclosure must be included for each proposed substitute claim.

Sections 42.121(d) and 42.221(d) are proposed to be amended to provide that the Board may consider all evidence of record in the proceeding when exercising its discretion to grant or deny a motion to amend or raise a new ground of unpatentability in connection with a proposed substitute claim. The proposed amendment to each regulation further provides that the Board may consider, and may make of record, any evidence in a related proceeding before the Office and evidence that a district court can judicially notice. Each is also proposed to be amended to provide that the Board may, when no petitioner opposes or all petitioners cease to oppose the motion to amend, consider, and make of record, evidence identified through a prior art search conducted by the Office at the Board's request. The proposed provisions further require that when the Board exercises its discretion in connection with a motion to amend, the Board determine unpatentability on the new ground by reference to the □ evidence of record or made of record and based on a preponderance of the evidence. The proposed revisions also require that the Board's request for and the result of a prior art search conducted by the Office at the Board's request will be made of record.

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Sections 42.121(e) and 42.221(e) are proposed to be added to provide for an opportunity to request preliminary guidance, consistent with the MTA pilot program. Such guidance will not be binding on the Board, is not a “decision” under 37 CFR 42.71(d) ([https://www.ecfr.gov/current/title-37/section-42.71#p-42.71\(d\)](https://www.ecfr.gov/current/title-37/section-42.71#p-42.71(d))) and is not a final agency action. The proposed provision provides that a patent owner will be permitted to file a reply to the petitioner's opposition to the motion to amend, preliminary guidance (if requested and no opposition is filed), or a revised MTA as discussed in §§ 42.121(f) and 42.221(f). The reply or revised MTA may be accompanied by new evidence. Moreover, the proposed provision provides that, if a patent owner does not file either a reply or a revised MTA after receiving preliminary guidance from the Board, the petitioner may file a reply to the preliminary guidance, but such a reply may only respond to the preliminary guidance and may not be accompanied by new evidence. If the petitioner files a reply in this context, a patent owner may file a sur-reply, but that sur-reply may only respond to the petitioner's reply and may not be accompanied by new evidence.

Further, the proposed provision provides that the Board may, upon issuing the preliminary guidance, for good cause and on a case-by-case basis, determine whether to extend the final written decision more than one year from the date a trial is instituted in accordance with §§ 42.100(c) and 42.200(c) and whether to extend any remaining deadlines under § 42.5(c).

The proposed rule adds §§ 42.121(f) and 42.221(f) to provide for an opportunity for a patent owner to file one revised motion to amend, consistent with the MTA pilot program. Such a revised motion to amend must be responsive to issues raised in the preliminary guidance, or the petitioner's opposition to the motion to amend and include one or more new proposed substitute claims in place of previously presented substitute claims, where each new proposed substitute claim presents a new claim amendment. Any revised motion to amend replaces the original motion to amend in the proceeding.

Further, the Board may, upon receiving the revised motion to amend, for good cause and on a case-by-case basis, determine whether to extend the final written decision more than one year from the date a trial is instituted in accordance with §§ 42.100(c) and 42.200(c) and whether to extend any remaining deadlines under § 42.5(c).

Rulemaking Considerations

A. Administrative Procedure Act (APA)

This rulemaking proposes changes to the consolidated set of rules relating to Office trial practice for IPR, PGR, CBM, and derivation proceedings. The changes proposed in this rulemaking do not alter the substantive criteria of patentability. These changes involve rules of agency practice. See, e.g., 35 U.S.C. 316(a) (5) (<https://www.govinfo.gov/link/uscode/35/316>), as amended. The changes proposed by this rulemaking involve rules of agency practice and procedure, and/or interpretive rules, and do not require notice-and-comment rulemaking. See *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97, 101 (2015) (explaining that interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers” and do not require notice and comment when issued or amended); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (5 U.S.C. 553 (<https://www.govinfo.gov/link/uscode/5/553>), and thus 35 U.S.C. 2(b)(2)(B) (<https://www.govinfo.gov/link/uscode/35/2>), do not require notice-and-comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice”); and *JEM Broadcasting Co. v. F.C.C.*, 22 F.3d 320, 328 (D.C. Cir. 1994) (explaining that rules are not legislative because they do not “foreclose effective opportunity to make one’s case on the merits.”).

Nevertheless, the USPTO is publishing this proposed rule for comment to seek the benefit of the public’s views on the Office’s proposed regulatory changes.

B. Regulatory Flexibility Act

For the reasons set forth herein, the Senior Counsel for Legislative and Regulatory Affairs of the Office of General Law at the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes proposed in this rulemaking will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b) (<https://www.govinfo.gov/link/uscode/5/605>).

The changes proposed in this rulemaking would revise certain trial practice procedures before the Board. Specifically, the Office proposes to amend the rules of practice before the Board to reflect current Board practice, as set forth in various precedential and informative Board decisions, as well as the Office’s Trial Practice Guide. Specifically, the Office proposes to amend the rules of practice to make permanent certain provisions of the Office’s MTA pilot program. These changes are procedural in nature, and any requirements resulting from the proposed changes are of minimal or no additional burden to those practicing before the Board.

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

C. Executive Order 12866 (/executive-order/12866) (Regulatory Planning and Review)

This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (/executive-order/12866) (September 30, 1993), as amended by Executive Order 14094 (/executive-order/14094) (April 6, 2023).

D. Executive Order 13563 (/executive-order/13563) (Improving Regulation and Regulatory Review)

The Office has complied with Executive Order 13563 (/executive-order/13563) (January 18, 2011). Specifically, and as discussed above, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule 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.

E. Executive Order 13132 (/executive-order/13132) (Federalism)

This rulemaking pertains strictly to Federal agency procedures and does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (/executive-order/13132) (August 4, 1999).

F. Executive Order 13175 (/executive-order/13175) (Tribal Consultation)

This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (/executive-order/13175) (November 6, 2000).

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G. Executive Order 13211 (/executive-order/13211) (Energy Effects)

This rulemaking is not a significant energy action under Executive Order 13211 (/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 (/executive-order/13211) (May 18, 2001).

H. Executive Order 12988 (/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 (/executive-order/12988) (February 5, 1996).

I. Executive Order 13045 (/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 (/executive-order/13045) (April 21, 1997).

J. Executive Order 12630 (/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 (/executive-order/12630) (March 15, 1988).

K. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 (<https://www.govinfo.gov/link/uscode/5/801>) *et seq.*), prior to issuing any final rule, the USPTO 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 proposed rule 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) (<https://www.govinfo.gov/link/uscode/5/804>).

L. 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 (<https://www.govinfo.gov/link/uscode/2/1501>) *et seq.*

M. 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 (<https://www.govinfo.gov/link/uscode/42/4321>) *et seq.*

N. 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 (<https://www.govinfo.gov/link/uscode/15/272>)) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

O. Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3549 (<https://www.govinfo.gov/link/uscode/44/3501>)) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public.

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 (<https://www.govinfo.gov/link/uscode/44/3501>) *et seq.*), the paperwork and other information collection burdens discussed in this proposed rulemaking have already been approved under Office of Management and Budget (OMB) Control Number 0651-0069 (Patent Review and Derivations).

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 valid OMB control number.

List of Subjects in 37 CFR Part 42 (<https://www.ecfr.gov/current/title-37/part-42>)

- Administrative practice and procedure
- Inventions and patents
- Lawyers

For the reasons set forth in the preamble, the Office proposes to amend 37 CFR part 42 (<https://www.ecfr.gov/current/title-37/part-42>) as follows:

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

1. The authority citation for 37 CFR part 42 (<https://www.ecfr.gov/current/title-37/part-42>) continues to read as follows:

Authority: 35 U.S.C. 2(b)(2) (<https://www.govinfo.gov/link/uscode/35/2>), 6 (<https://www.govinfo.gov/link/uscode/35/6>), 21 (<https://www.govinfo.gov/link/uscode/35/21>), 23 (<https://www.govinfo.gov/link/uscode/35/23>), 41 (<https://www.govinfo.gov/link/uscode/35/41>), 135 (<https://www.govinfo.gov/link/uscode/35/135>), 311 (<https://www.govinfo.gov/link/uscode/35/311>), 312 (<https://www.govinfo.gov/link/uscode/35/312>), 316 (<https://www.govinfo.gov/link/uscode/35/316>), 321-326 (<https://www.govinfo.gov/link/uscode/35/321>); Pub. L. 112-29 (<https://www.govinfo.gov/link/plaw/112/public/29>), 125 Stat. 284; and Pub. L. 112-274 (<https://www.govinfo.gov/link/plaw/112/public/274>), 126 Stat. 2456.

2. Revise § 42.121 to read as follows:

§ **Amendment of the patent.**

(a) *Motion to amend*—(1) *Original motion to amend*. A patent owner may file one original motion to amend a patent, but only after conferring with the Board.

(i) *Due date*. Unless a due date is provided in a Board order, an original motion to amend must be filed no later than the filing of a patent owner response.

(ii) *Request for preliminary guidance*. If a patent owner wishes to receive preliminary guidance from the Board as discussed in paragraph (e) of this section, the original motion to amend must include the patent owner's request for that preliminary guidance.

(2) *Scope*. Any motion to amend may be denied where:

(i) The amendment does not respond to a ground of unpatentability involved in the trial; or

(ii) The amendment seeks to enlarge the scope of the claims of the patent or introduce new subject matter.

(3) *A reasonable number of substitute claims*. Any motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims. The presumption is that only one substitute claim will be needed to replace each challenged claim, and it may be rebutted by a demonstration of need.

(b) *Content.* Any motion to amend claims must include a claim listing, which claim listing may be contained in an appendix to the motion, show the changes clearly, and set forth:

(1) The support in the original disclosure of the patent for each proposed substitute claim; and

(2) The support in an earlier-filed disclosure for each claim for which the benefit of the filing date of the earlier-filed disclosure is sought.

(c) *Additional motion to amend.* Except as provided in paragraph (f) of this section, any additional motion to amend may not be filed without Board authorization. An additional motion to amend may be authorized when there is a good cause showing or a joint request of the petitioner and the patent owner to materially advance a settlement. In determining whether to authorize such an additional motion to amend, the Board will consider whether a petitioner has submitted supplemental information after the time period set for filing a motion to amend in paragraph (a)(1) (i) of this section.

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(d) *Burden of persuasion.* On any motion to amend:

(1) *Patent owner's burden.* 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) (<https://www.govinfo.gov/link/uscode/35/316>) and (3) of 35 U.S.C. 316(d) (<https://www.govinfo.gov/link/uscode/35/316>), as well as paragraphs (a)(2) and (3) and (b)(1) and (2) of this section;

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

(3) *Exercise of Board discretion.* Irrespective of paragraphs (d)(1) and (2) of this section, the Board may exercise its discretion to grant or deny a motion to amend or raise a new ground of unpatentability in connection with a proposed substitute claim. Where the Board exercises its discretion to raise a new ground of unpatentability in connection with a proposed substitute claim, the parties will have notice and an opportunity to respond. In the exercise of this discretion under this paragraph (d)(3) the Board may consider all evidence of record in the proceeding. The Board also may consider and make of record:

(i) Any evidence in a related proceeding before the Office and evidence that a district court can judicially notice; and

(ii) When no petitioner opposes or all petitioners cease to oppose a motion to amend, prior art identified through a prior art search conducted by the Office at the Board's request. The request for and the results of a prior art search conducted by the Office at the Board's request will be made of record.

(4) *Determination of unpatentability.* Where the Board exercises its discretion under paragraph (d)(3) of this section, the Board must determine unpatentability based on a preponderance of the evidence of record or made of record.

(e) *Preliminary guidance.* (1) In its original motion to amend, a patent owner may request that the Board provide preliminary guidance setting forth the Board's initial, preliminary views on the original motion to amend, including whether the parties have shown a reasonable likelihood of meeting their respective burdens of persuasion as set forth under paragraphs (d)(1) and (2) of this section and notice of any new ground of unpatentability discretionarily raised by the Board under paragraph (d)(3) of this section. The Board may, upon issuing the preliminary guidance, determine whether to extend the final written decision more than one year from the date a trial is instituted in accordance with § 42.100(c) and whether to extend any remaining deadlines under § 42.5(c)(2).

(2) Any preliminary guidance provided by the Board on an original motion to amend will not be binding on the Board in any subsequent decision in the proceeding, is not a “decision” under § 42.71(d) that may be the subject of a request for rehearing and is not a final agency action.

(3) In response to the Board's preliminary guidance, a patent owner may file a reply to the petitioner's opposition to the motion to amend, the preliminary guidance (if no opposition is filed), or a revised motion to amend as discussed in paragraph (f) of this section. The reply or revised motion to amend may be accompanied by new evidence. If a patent owner does not file either a reply or a revised motion to amend after receiving preliminary guidance from the Board, the petitioner may file a reply to the preliminary guidance, but such a reply may only respond to the preliminary guidance and may not be accompanied by new evidence. If the petitioner files a reply in this context, a patent owner may file a sur-reply, but that sur-reply may only respond to the petitioner's reply and may not be accompanied by new evidence.

(f) *Revised motion to amend.* (1) Irrespective of paragraph (c) of this section, a patent owner may, without prior authorization from the Board, file one revised motion to amend after receiving an opposition to the original motion to amend or after receiving the Board's preliminary guidance. The Board may, upon receiving the revised motion to amend, determine whether to extend the final written decision more than one year from the date a trial is instituted in accordance with § 42.100(c) and whether to extend any remaining deadlines under § 42.5(c)(2).

(2) A revised motion to amend must be responsive to issues raised in the preliminary guidance or in the petitioner's opposition to the motion to amend and must include one or more new proposed substitute claims in place of the previously presented substitute claims, where each new proposed substitute claim presents a new claim amendment.

(3) If a patent owner files a revised motion to amend, that revised motion to amend replaces the original motion to amend in the proceeding.

3. Revise § 42.221 to read as follows:

§ 42.221 **Amendment of the patent.**

(a) *Motion to amend* —(1) *Original motion to amend.* A patent owner may file one original motion to amend a patent, but only after conferring with the Board.

(i) *Due date.* Unless a due date is provided in a Board order, an original motion to amend must be filed no later than the filing of a patent owner response.

(ii) *Request for preliminary guidance.* If a patent owner wishes to receive preliminary guidance from the Board as discussed in paragraph (e) of this section, the original motion to amend must include the patent owner's request for that preliminary guidance.

(2) *Scope.* Any motion to amend may be denied where:

(i) The amendment does not respond to a ground of unpatentability involved in the trial; or

(ii) The amendment seeks to enlarge the scope of the claims of the patent or introduce new subject matter.

(3) *A reasonable number of substitute claims.* Any motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims. The presumption is that only one substitute claim will be needed to replace each challenged claim, and it may be rebutted by a demonstration of need.

(b) *Content.* Any motion to amend claims must include a claim listing, which claim listing may be contained in an appendix to the motion, show the changes clearly, and set forth:

(1) The support in the original disclosure of the patent for each proposed substitute claim; and

(2) The support in an earlier-filed disclosure for each claim for which the benefit of the filing date of the earlier-filed disclosure is sought.

(c) *Additional motion to amend.* Except as provided by paragraph (f) of this section, any additional motion to amend may not be filed without Board authorization. An additional motion to amend may be authorized when there is a good cause showing or a joint request of the petitioner and the patent owner to materially advance a settlement. In determining whether to authorize such an additional motion to amend, the Board will consider whether a petitioner has submitted supplemental information after the time period set for filing a motion to amend in paragraph (a)(1)(i) of this section.

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(d) *Burden of persuasion.* On any motion to amend:

(1) *Patent owner's burden.* 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) (<https://www.govinfo.gov/link/uscode/35/326>) and (3) of 35 U.S.C. 326(d) (<https://www.govinfo.gov/link/uscode/35/326>), as well as paragraphs (a)(2) and (3) and (b)(1) and (2) of this section;

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

(3) *Exercise of Board discretion.* Irrespective of paragraphs (d)(1) and (2) of this section, the Board may exercise its discretion to grant or deny a motion to amend or raise a new ground of unpatentability in connection with a proposed substitute claim. Where the Board exercises its discretion to raise a new ground of unpatentability in connection with a proposed substitute claim,

the parties will have notice and an opportunity to respond. In the exercise of discretion under this paragraph (d)(3), the Board may consider all evidence of record in the proceeding. The Board also may consider and may make of record:

(i) Any evidence in a related proceeding before the Office and evidence that a district court can judicially notice; and

(ii) When no petitioner opposes or all petitioners cease to oppose a motion to amend, prior art identified through a prior art search conducted by the Office at the Board's request. A request for and result of a prior art search conducted by the Office at the Board's request will be made of record.

(4) *Determination of unpatentability.* Where the Board exercises its discretion under paragraph (d)(3) of this section, the Board must determine unpatentability based on a preponderance of the evidence of record or made of record.

(e) *Preliminary guidance.* (1) In its original motion to amend, a patent owner may request that the Board provide preliminary guidance setting forth the Board's initial, preliminary views on the original motion to amend, including whether the parties have shown a reasonable likelihood of meeting their respective burdens of persuasion as set forth under paragraphs (d)(1) and (2) of this section and notice of any new ground of unpatentability discretionarily raised by the Board under paragraph (d)(3) of this section. The Board may, upon issuing the preliminary guidance, determine whether to extend the final written decision more than one year from the date a trial is instituted in accordance with § 42.200(c) and whether to extend any remaining deadlines under § 42.5(c)(2).

(2) Any preliminary guidance provided by the Board on an original motion to amend will not be binding on the Board in any subsequent decision in the proceeding, is not a "decision" under § 42.71(d) that may be the subject of a request for rehearing, and is not a final agency action.

(3) In response to the Board's preliminary guidance, a patent owner may file a reply to the petitioner's opposition to the motion to amend, preliminary guidance (no opposition is filed), or a revised motion to amend as discussed in paragraph (f) of this section. The reply or revised motion to amend may be accompanied by new evidence. If a patent owner does not file either a reply or a revised motion to amend after receiving preliminary guidance from the Board, the petitioner may file a reply to the preliminary guidance, but such a reply may only respond to the preliminary guidance and may not be accompanied by new evidence. If the petitioner files a reply in this context, a patent owner may file a sur-reply, but that sur-reply may only respond to the petitioner's reply and may not be accompanied by new evidence.

(f) *Revised motion to amend.* (1) Irrespective of paragraph (c) of this section, a patent owner may, without prior authorization from the Board, file one revised motion to amend after receiving an opposition to the original motion to amend or after receiving the Board's preliminary guidance. The Board may, upon receiving the revised motion to amend, determine whether to extend the final written decision more than one year from the date a trial is instituted in accordance with § 42.200(c) and whether to extend any remaining deadlines under § 42.5(c)(2).

(2) A revised motion to amend must be responsive to issues raised in the preliminary guidance, if requested, or in the petitioner's opposition to the motion to amend, and must include one or more new proposed substitute claims in place of the previously presented substitute claims, where each new proposed substitute claim presents a new claim amendment.

(3) If a patent owner files a revised motion to amend, that revised motion to amend replaces the original motion to amend in the proceeding.

Katherine K. Vidal,

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

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