

rain date scheduled on September 22, 2024.

J.J. Schock,

Commander, U.S. Coast Guard, Acting
Captain of the Port Sector Boston.

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2020–0060]

RIN 0651–AD50

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

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

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office or USPTO) modifies its rules of practice 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). These rules provide a patent owner with the option of issuance of preliminary guidance in response to an MTA and the option of filing one additional revised MTA. Further, these rules clarify that a preponderance of evidence standard applies to any new ground of unpatentability raised by the Board, and 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. The rules further provide that the Board may consider information identified in response to a Board-initiated request for examination assistance, and that the results of that assistance will be added to the record. The 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 rules relate 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: This rule is effective October 18, 2024.

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 or Melissa.Haapala@uspto.gov, respectively.

SUPPLEMENTARY INFORMATION:

Background

Development of the Final Rule

On September 16, 2011, the AIA was enacted into law (Pub. L. 112–29, 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, 316, and 326 and AIA 18(d)(2). See 37 CFR 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 (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 (August 14, 2012); Transitional Program for Covered Business Method Patents—Definitions of Covered Business Method Patent and Technological Invention, 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 (November 21, 2019); <https://www.uspto.gov/TrialPracticeGuide> *Consolidated*. 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 2019, the Office implemented a pilot program (MTA Pilot Program) for motions to amend filed in AIA proceedings before the PTAB. 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 (March 15, 2019) (MTA pilot program notice). The MTA Pilot Program addressed 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*)). 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 (October 29, 2018) (2018 RFC). 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 (October 4, 2022).

In 2020, 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), 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 (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), 42.221(d)(1). The burden-allocation 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), 42.221(d)(2).

Finally, the burden-allocation 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), 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 were stated to 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, 82927 (citing *Hunting Titan*, Paper 67 at 12–13, 25–26). The burden-allocation 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), 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. 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), 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 (concurrency 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.”).

2023 Request for Comments 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 a Request for Comments to seek feedback on the public’s experience with the program and the burden-allocation rules that apply to MTAs. See Request for Comments Regarding MTA Pilot Program and Rules of Practice to Allocate the Burdens of Persuasion on Motions to Amend in Trial Proceedings Before the Patent Trial and Appeal Board, 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), 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) or 42.221(d)(3). See 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”).

2024 Notice of Proposed Rulemaking

On March 4, 2024, the Office published a notice of proposed rulemaking concerning Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 89 FR 15531 (“2024 NPRM”). The Office proposed 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 proposed to revise the rules to clarify that a preponderance of the 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. The comment period for the 2024 NPRM closed on May 3, 2024, and the Office received six public comments on the proposed rules.

Proposed Rule: Comments and Responses

The Office received six public comments to the 2024 NPRM none of which opposed the proposal to make permanent the MTA pilot program options. Some commenters, however, stated that the Office should consider additional proposals. These additional proposals include: (1) expressly allowing extensions of time for the final written decision and for filing MTA-related briefs, (2) revising the proposed rules to allow petitioner to file a sur-reply, and (3) clarifying the manner in which patent owner identifies written description support for the proposed substitute claims. Some commenters also recommended expanding the proposed rules on discretion to request examination assistance such that the Board would exercise this discretion in every case with a motion to amend. Finally, one commenter expressed concerns with the proposed rules that revise the Board’s limits on the discretion to raise grounds of unpatentability *sua sponte*. These comments, along with other stated ideas and concerns, are addressed more specifically below.

Extensions of Time for Issuing Final Written Decision and Other Deadlines

A comment expressed support for an automatic extension of the deadline for issuing a final written decision in proceedings in which a motion to amend has been filed. A second comment raised the concern that any automatic extension of time might not be necessary in all cases and that there could be a potential for abuse of the motion to amend process if extensions were automatic. Another comment suggested that additional procedures, such as a Board-initiated conference call upon issuance of preliminary guidance, could provide an opportunity for a party to request an extension of time for the final written decision.

The Office appreciates the comments and the concern with scheduling when a motion to amend is filed. After careful review of the comments, the Office does not adopt any changes to the proposed rules. The proposed rules do not modify the current procedures by which an extension may be granted, as discussed above, and an extension of the final written decision deadline may be granted by the Chief Administrative Patent Judge for good cause, and the deadline may be extended by not more than six months. These procedures allow for a case-by-case determination of whether an extension should be granted. In the Board's experience, most cases do not require an extension. With respect to automatic scheduling of a conference call upon issuance of preliminary guidance, the rules provide for an initial conference call upon the filing of a motion to amend at which a discussion of the schedule can occur, and panels of the Board generally honor any request by a party for a further conference call. See 37 CFR 42.121(a), 42.221(a).

With respect to the limitations on timing for post grant review proceedings with motions to amend, we acknowledge a comment suggesting that reexamination or reissue proceedings may be better options for pursuing claim amendments if substantial changes that may require additional time are contemplated. See Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding (April 2019), 84 FR 16654 (April 22, 2019).

Petitioner Sur-Reply

A commenter expressed concern with the proposed rule as it relates to the preliminary guidance provided by the Board on an original motion to amend. In particular, the commenter noted that

the proposed rule is silent as to whether the petitioner has an opportunity to file a sur-reply to address the Board's preliminary guidance or any new evidence that may accompany the patent owner's reply filed in response to the Board's preliminary guidance. The commenter noted that the proposed rule allows the petitioner to file a reply to the Board's guidance only if the patent owner does not file a reply or revised motion to amend. The commenter urged the Office that the petitioner should be provided, expressly, with a sur-reply in order to afford due process to the petitioner.

The Office appreciates the comment and agrees that the rule should expressly provide for a petitioner sur-reply. The final rule states that the petitioner may file a sur-reply that is limited to responding to the preliminary guidance and/or arguments made in the patent owner's reply brief. Further, although the sur-reply may not be accompanied by new evidence, it may comment on any new evidence filed with the reply and/or point to cross-examination testimony of a reply witness, if relevant to the arguments made in the reply brief.

Moreover, if a patent owner does not file 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 only respond 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 only respond to the petitioner's reply and may not be accompanied by new evidence.

Written-Description Support

A commenter raised a concern that proposed provisions in 37 CFR 42.121(b) and 42.221(b), which relate to the content of a motion to amend, contain a possible ambiguity regarding whether the required support in the original disclosure or earlier-filed disclosure must be set forth in the motion to amend or should be set forth as part of the claim listing.

The Office appreciates the comment. To improve clarity, this final rule amends those sections to state that the written description support for a proposed substitute claim must be set forth in the motion to amend, as opposed to the claim listing. This is consistent with current practice and the precedential decision in *Lectrosomics*: “[t]he written description support must be set forth in the motion to amend itself, not the claim listing.” *Lectrosomics, Inc. v. Zaxcom, Inc.*,

IPR2018–01129, 2019 WL 1118864, at *3 (precedential).

Examination Assistance

The majority of commenters support the proposed rule's provision permitting the Board to request examination assistance from patent examiners when considering claim amendments. A commenter noted, however, that opinions vary on whether, and to what extent, the Board should request assistance to conduct a prior art search. Two commenters suggested that such assistance not be limited to situations in which no petitioner opposes, or all petitioners cease to oppose a motion to amend. These commenters highlighted the expertise of examiners in identifying prior art as reasons to expand the situations for which assistance may be requested. These commenters also expressed concern that Board panels may hesitate to use the proposed rule's full extent, because identifying a petitioner's filing as “illusory opposition” appears to imply that the petitioner is not acting in good faith, and such a standard may be difficult to assess. These commenters suggested that the benefit of ensuring that substitute claims are patentable would justify the relatively few additional prior art searches per year. A third commenter also agreed that having an examiner's search report for each MTA would alleviate concerns with the Office issuing “unexamined” claims, finding such technical assistance to be of value to the panel in evaluating the parties' patentability arguments, although appreciating that such assistance may be perceived as a disincentive to filing motions to amend.

Another commenter suggested that amended claims undergo review prior to a decision being made by the Board only in circumstances where the adversarial system fails to provide the Board with arguments for the unpatentability of the proposed substitute claims, and that both parties be afforded the opportunity to respond. A further commenter disagreed that the Board should be pressured to come up with rejections even when the adversarial process has not failed. That further commenter suggested that encouraging the Board to dig deeply into the records of other proceedings would disadvantage patent owners seeking to save patentable claim scope. That further commenter suggested that language be added to make clear that intervention is neither needed nor expected in a typical proceeding.

The Office appreciates the robust discussion of the variety of viewpoints expressed in the comments. After

careful consideration, the Office does not adopt the suggestions to rely solely on the adversarial nature of the proceeding to determine when to request examination assistance. Rather, the Office revises the proposed rule to take into account the comments expressing concern about the narrow circumstances under which examination assistance would be requested. The final rule now states that a lack of opposition would be considered one of the reasons sufficient for the Board to seek examination assistance. As such, the final rule also encompasses the situation in which the Board determines that a deficient prior art challenge in an opposition warrants a search for additional prior art. The ability of the Board to seek examination assistance when warranted, including a prior art search, for amended claims preserves the Office's goal of ensuring that it adequately evaluates the patentability of claims before issuance. The final rule's clarification of appropriate situations for seeking examination assistance is designed to help panels identify when such examination assistance would further the Office's goal. The final rule also accounts for the adversarial motion to amend process that suffices for the vast majority of cases filed to-date. The examination assistance typically would be appropriate in situations that are not duplicative of reasonable efforts expended by the petitioner, such as when an opposition lacks a prior art challenge or when there is no opposition, thus ensuring that the resources of the Office and the patent owner are not expended unnecessarily. Further because it relies on a determination that a deficient prior art challenge warrants a search for additional prior art, the Board would not need to address or inquire about the intent behind an opposition or bad faith efforts of a petitioner. As in the proposed rule, the final rule provides that when the Board requests examination assistance, that the request, as well as the results of the examination assistance will be made of record. The fact that the Board possesses, but has never used, its discretionary authority to request examination assistance reflects the Board's careful exercise of this authority to date. Based upon the comments and the Board's experience, the final rule fairly balances the interests of patent owners who desire to amend claims during an AIA proceeding and the Office's role in maintaining the integrity of the patent system by ensuring the issuance of robust and reliable patents.

Discretion To Raise Grounds Sua Sponte

A commenter expressed concerns with the proposed revisions to the rule on the Board's discretion to raise grounds of unpatentability *sua sponte*. In particular, the commenter stated that the proposed changes would broaden the Board's discretion to raise grounds to an uncertain degree, even in cases where zealous advocacy against an amendment is present. The commenter urged the Office to revise the proposed changes to the Board's exercise of discretion to restrain its frequency and clarify that the Board's actions in this regard would neither be needed nor expected in "run-of-the-mine proceedings." This commenter also urged that the Board consider retaining the prior rule's limitation to considering "only readily identifiable and persuasive evidence in a related proceeding before the Office." Other commenters expressed support for the proposed rules that give the Board the ability to more broadly exercise its discretion to raise *sua sponte* grounds of unpatentability and to ensure that the parties are given the opportunity to respond to those grounds. The commenters noted that the Office's current rules, which rely solely on the adversarial process, are at odds with current Federal Circuit case law and undermine the Office's role of ensuring that newly issued claims are patentable.

The Office appreciates the comments. After careful review of the comments made and in light of the careful balance of the various viewpoints on this issue and in alignment with the Office's goals of ensuring the issuance of robust and reliable patents, the Office does not adopt the suggestion to limit the exercise of discretion to raise grounds *sua sponte*, nor to retain the limit that only "readily identifiable and persuasive evidence" may be relied upon. The rule allows the Board to retain discretion to raise grounds of unpatentability with respect to proposed substitute claims in accordance with Federal Circuit precedent. See *Nike, Inc. v. Adidas AG*, 955 F.3d 45, 53 (2020); *Hunting Titan*, 28 F.4th at 1381. Additionally, the commenter's proposed limitations on the Board's exercise of discretion in this regard are similar to those criticized by the Federal Circuit in *Hunting Titan*. 28 F.4th at 1381, 1385. Consequently, as noted further below, the Board's *Hunting Titan* decision, which places limitations on the Board's exercise of discretion to raise grounds, is de-designated from precedential status as of the effective date of this final rule.

See PTAB Standard Operating Procedure 2 (Revision 10), Publication of Decisions and Designation or De-Designation of Decisions as Precedential or Informative, Part IV (SOP2) available at <https://www.uspto.gov/sites/default/files/documents/SOP2%20R10%20FINAL.pdf>.

The Office notes that although the adversarial nature of the proceedings provides, in the majority of proceedings, the safeguards of a robust evaluation of proposed substitute claims, there may be situations in which, despite such advocacy, the Board will be able to identify or will be aware of additional reasons the proposed substitute claims may not be granted. It is better for the Office to maintain the integrity of the patent system by ensuring that where the Board determines *sua sponte* new reasons why a proposed substitute claim should not be granted, that in accordance with due process, the parties are notified of grounds of unpatentability not raised by the opposition and that the parties are given an opportunity to respond. The final rule provides that such notice may be included in the preliminary guidance if one is requested but does not place limitations on such a notice to be provided in other papers or at a different stage of the proceeding, such as after receiving a revised motion to amend. 37 CFR 42.121(e), 42.221(e).

Upon careful consideration of the public comments, the Office adopts the provisions in the proposed rule with minor changes for additional clarity and consistency.

Preliminary Guidance and Revised Motions To Amend

The final rule, which implements the procedure set forth in the Motion to Amend Pilot Program, provides a patent owner with two options when proposing substitute claims for challenged patent claims during an AIA trial proceeding. First, if requested by a patent owner in its original MTA, the Board will issue preliminary, non-binding guidance. 37 CFR 42.121(e), 42.221(e). Second, a patent owner may file, without needing Board authorization, a revised MTA. 37 CFR 42.121(f), 42.221(f). These options are discussed further below.

Preliminary Guidance

The Board's preliminary guidance, if requested, typically will come in the form of a short paper issued after a petitioner has filed its opposition to the MTA (or after the due date for a petitioner's opposition, if none is filed). According to the MTA pilot program, 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.

Under the amended rules, preliminary guidance will provide the Board's initial, preliminary views on the original MTA. 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 (December 21, 2020); 37 CFR 42.121(d)(1) and (2), 42.221(d)(1) and (2). 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), 42.221(d)(1); see also 35 U.S.C. 316(d), 326(d); *Lectrosomics, Inc. v. Zaxcom, Inc.*, IPR2018–01129, 2019 WL 1118864, at *2 (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), 42.221(d)(2). The preliminary guidance may also address any 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) and (4), 42.221(d)(3) and (4). In general, the Board's preliminary guidance will address the proposed substitute claims in a patent owner's original MTA in light of the amendments presented in those claims and will not address the patentability of the originally challenged claims.

Preliminary guidance on an MTA during an AIA trial does not bind 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 was not arbitrary and capricious and did not violate the Administrative Procedure Act (APA)). The Board's preliminary guidance is not a "decision" under 37 CFR 42.71(d),

and thus parties may not file a request for rehearing or a request for 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 and/or the preliminary guidance or may file a revised MTA. If an opposition is filed and preliminary guidance was requested, 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 preliminary guidance was requested, a patent owner's reply may only respond 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 where a patent owner does not file either a reply or a revised MTA after receiving preliminary guidance from the Board as discussed below. Thus, a patent owner may file new evidence, including declarations, with its revised MTA or reply. See 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 or revised MTA absent extraordinary circumstances). The petitioner may file a sur-reply that is limited to responding to the preliminary guidance and/or arguments made in the patent owner's reply brief. Although the sur-reply may not be accompanied by new evidence, it may comment on any new evidence filed with the reply and/or point to cross-examination testimony of a reply witness, if relevant to the arguments made in the reply brief.

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 only respond 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 limited to responding to the petitioner's reply, and the sur-reply may not be accompanied by new evidence.

Revised MTA

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). As

stated in the rule, a patent owner may file either a reply *or* a revised motion to amend, but not both. That is, 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.

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. Particularly, the revised MTA may include new arguments and/or evidence as to why the revised MTA meets statutory and regulatory requirements for an MTA, as well as arguments and evidence relevant to the patentability of the new proposed substitute claims. 84 FR 9501. Because 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) and 326(d)(2). The revisions therefore distinguish between additional MTAs under 37 CFR 42.121(c) and 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 final rule refers to an original, additional, or revised MTA.

A patent owner is not required to request preliminary guidance or file a revised motion to amend. 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 *Lectrosomics, Inc. v. Zaxcom, Inc.*, IPR2018–01129, 2019 WL 1118864 (PTAB January 24, 2020) (precedential).

MTA Timeline and Extensions of Time

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 one, both, or neither of the options under the

program. See MTA pilot program notice, 84 FR 9506–9507, 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 additional briefing on the 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 amends the rules to clarify that the Board may determine whether to request the Chief Administrative Patent Judge extend the final written decision deadline. The rules have also been amended to clarify that the Board may determine whether to extend deadlines in the MTA timeline pursuant to 37 CFR 42.5(c)(2). 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 (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 six months. 35 U.S.C. 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), 42.200(c). Thus, pursuant to 37 CFR 42.100(c) and 42.200(c), upon a showing of good cause, the Chief Administrative Patent Judge may extend the final written decision deadline beyond the statutory deadline (*i.e.*, one year from the date a trial is instituted) by up to six months. For example, good cause may be present 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 a requested examination assistance). 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 a substantially compressed schedule, multiple postponements of the oral hearing due to scheduling conflicts, and additional briefing); *Hope Medical Enterprises, Inc. v. Fennec 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 a 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 for 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) 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. 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.

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

Under the rules prior to this final rule 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.

In the final rule, the body of evidence that the Board may consider and make of record now includes 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 prior rules, such as the “interests of justice” standard and the requirement for “readily identifiable and persuasive” evidence, the final 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 (concurrency 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 final rule broadens the Board's authority to sua sponte raise grounds of unpatentability with respect to proposed substitute claims and provides for notification of those grounds to be given to the parties, typically in, but not limited to, preliminary guidance. 37 CFR 42.121(d)(3) and (4), 42.221(d)(3) and (4).

The final rule therefore departs 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 discretion of the Board to raise grounds sua sponte. Accordingly, the *Hunting Titan* decision is de-designated from precedential status as of the effective date of this final rule. See (SOP2).

Examination Assistance

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. If solicited by the Board, the assistance could include the preparation of an advisory report that: (1) provides an initial discussion about whether an MTA meets certain statutory and regulatory requirements (*e.g.*, whether the amendment enlarges the scope of the claims of the patent or introduces new matter) and/or (2) provides an initial discussion about the patentability of proposed substitute claims, for example, in light of prior art that was identified by the parties in their submissions and/or obtained in prior art searches by the examiner. *Id.* As of issuance of this final rule, the Board has not exercised its discretion to solicit examination assistance.

The final rule provides that the Board may request such examination assistance consistent with current practice reflected in the MTA pilot program. 37 CFR 42.121(d)(3)(ii), 42.221(d)(3)(ii); 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. 84 FR 9502. 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 as outlined above. *Id.*

The final rule thus confirms the Board's discretion to seek examination assistance at any time after any motion to amend has been filed if no petitioner opposes or all petitioners cease to oppose the MTA. The final rule also ensures that the Board retains the discretion to request examination assistance when the opposition is deficient such that a search for additional prior art is warranted. The final rule also clarifies that the Board may make of record information identified in response to the Board-initiated request for examination assistance. Additionally, the final rule provides that the Board's request for examination assistance and the results of that assistance will be made of record.

Changes From Proposed Rule

In light of the received comments, this final rule makes the revisions to the 2024 NPRM as follows.

Sections 42.121(b) and 42.221(b) have been revised further to clarify that the motion itself (not the claim listing) must set forth the support in the original disclosure of the patent for each proposed substitute claim and 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.

Sections 42.121(d)(3)(ii) and 42.221(d)(3)(ii) have been revised further to state that the Board also may consider and make of record information identified in response to a Board-initiated request for examination assistance. These sections are revised further to expressly state that Board may request the examination assistance at any time after any motion to amend has been filed if no petitioner opposes or all petitioners cease to oppose the motion to amend, or if the Board determines that a deficient prior art challenge in an opposition to a motion to amend warrants a search for additional prior art. Further, the revised rules state that the Board's request for examination

assistance and the results of such assistance will be made of record.

Sections 42.121(e)(3) and 42.221(e)(3) have been revised further to clarify that in response to the preliminary guidance, a patent owner may file a reply that responds to the petitioner's opposition to the motion to amend and/or the preliminary guidance. The patent owner may file a revised motion to amend instead of a reply, as discussed in §§ 42.121(f) and 42.221(f). These sections are also revised further to expressly provide for petitioner's filing of a sur-reply that is limited to responding to the preliminary guidance and/or arguments made in the patent owner's reply brief. Further, the revised rule specifies that the sur-reply may not be accompanied by new evidence, but may comment on any new evidence filed with the reply and/or point to cross-examination testimony of a reply witness, if relevant to the arguments made in the reply brief.

New §§ 42.121(e)(4) and 42.221(e)(4) are a renumbering of unchanged provisions previously included in §§ 42.121(e)(3) and 42.221(e)(3).

Discussion of Specific Rules

Sections 42.121 and 42.221

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

Sections 42.121(d) and 42.221(d) are 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. These sections are further amended to provide that the Board may consider, and may make of record, any evidence in a related proceeding before the Office as well as evidence that a district court can judicially notice. These sections are also amended to provide that the Board may request examination assistance at any time after any motion to amend has been filed, if no petitioner opposes or all petitioners cease to oppose the motion to amend, or if the Board determines that a deficient prior art challenge in an opposition to a motion to amend warrants a search for additional prior art. These sections are further amended

to state that information identified in response to the Board-initiated request for examination assistance may be considered and made of record, and that the request and the results of the examination assistance will also be made of record. The sections further state that when the Board exercises discretion to raise a new ground in connection with a motion to amend, the Board will determine patentability on the new ground by reference to the evidence of record or made of record and based on a preponderance of the evidence. These sections do not alter the current rules on burden of persuasions of parties to the proceeding.

Sections 42.121(e) and 42.221(e) are 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), and is not a final agency action. The added sections permit a patent owner to file a reply to the petitioner's opposition to the motion to amend and/or the preliminary guidance (if requested), 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. Further, the petitioner may file a sur-reply that is limited to responding to the preliminary guidance and/or arguments made in the patent owner's reply brief. The sur-reply may not be accompanied by new evidence but may comment on any new evidence filed with the reply and/or point to cross-examination testimony of a reply witness, if relevant to the arguments made in the reply brief. Moreover, the added sections provide 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 added sections provide that the Board may, upon issuing the preliminary guidance, for good cause and on a case-by-case basis, determine whether to request the Chief Administrative Patent Judge to extend the final written decision deadline 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 final rule adds §§ 42.121(f) and 42.221(f) to provide 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 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. 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, on a case-by-case basis, determine whether to request the Chief Administrative Patent Judge to extend the final written decision deadline 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 makes changes to the consolidated set of rules relating to Office trial practice for IPR, PGR, and derivation proceedings. The changes 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), as amended. The changes in 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, and thus 35 U.S.C. 2(b)(2)(B), 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 has chosen to seek public comment before implementing the rule to benefit from the public’s input.

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 in this rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

This rule revises 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 amends 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 in this rulemaking will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review)

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

D. Executive Order 13563 (Improving Regulation and Regulatory Review)

The Office has complied with 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 (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 (August 4, 1999).

F. 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 (November 6, 2000).

G. 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).

H. 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 (February 5, 1996).

I. 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 (April 21, 1997).

J. 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 (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 *et seq.*), the USPTO will submit a report containing the final rule and other required information to

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

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 *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 *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) 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) 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 *et seq.*), the paperwork and other information collection burdens discussed in this 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

Administrative practice and procedure, Inventions and patents, Lawyers.

For the reasons set forth in the preamble, the Office amends 37 CFR part 42 as follows:

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

- 1. The authority citation for part 42 continues to read as follows:

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

- 2. Revise § 42.121 to read as follows:

§ 42.121 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 the motion must 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.

(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) and (3) of 35 U.S.C. 316(d), 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) Information identified in response to a Board-initiated examination assistance. The Board may request the examination assistance at any time after any motion to amend has been filed if no petitioner opposes or all petitioners

cease to oppose the motion to amend, or if the Board determines that a deficient prior art challenge in an opposition to the motion to amend warrants a search for additional prior art. The Board's request for examination assistance and the results of such assistance 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.

(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 request the Chief Administrative Patent Judge to extend the final written decision deadline 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 or Director Review, and is not a final agency action.

(3) In response to the Board's preliminary guidance, a patent owner may file a reply that responds to the petitioner's opposition to the motion to amend and/or the preliminary guidance, 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. The petitioner may file a sur-reply that is limited to responding to the preliminary guidance and/or arguments made in the patent owner's reply brief. The sur-reply may not be accompanied by new evidence, but may comment on any new evidence filed with the reply and/or point to cross-examination testimony of a reply witness, if relevant to the arguments made in the reply brief.

(4) 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 request the Chief Administrative Patent Judge to extend the final written decision deadline 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 the motion must 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.

(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) and (3) of 35 U.S.C. 326(d), 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) Information identified in response to a Board-initiated examination assistance. The Board may request the examination assistance at any time after any motion to amend has been filed if no petitioner opposes or all petitioners cease to oppose the motion to amend, or if the Board determines that a deficient prior art challenge in an opposition to the motion to amend warrants a search for additional prior art. The Board's request for examination assistance and the results of such assistance 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.

(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 request the Chief Administrative Patent Judge extend the final written decision deadline 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 or Director Review, and is not a final agency action.

(3) In response to the Board's preliminary guidance, a patent owner may file a reply that responds to the petitioner's opposition to the motion to amend and/or the preliminary guidance, 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. The petitioner may file a sur-reply that is limited to responding to the preliminary guidance and/or arguments made in the patent owner's reply brief. The sur-reply may not be accompanied by new evidence, but may comment on any new evidence filed with the reply and/or point to cross-examination testimony of a reply witness, if relevant to the arguments made in the reply brief.

(4) 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 request the Chief Administrative Patent Judge to extend the final written decision deadline 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 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1007

Performance Standards for Medicaid Fraud Control Units

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Notice of final revised performance standards.

SUMMARY: This document sets forth OIG guidance regarding standards OIG will apply in assessing the performance of Medicaid Fraud Control Units (MFCUs or Units). Based on its experience in overseeing MFCUs, and after consultation with key stakeholders, OIG is revising the standards. These standards replace and supersede standards published on June 1, 2012.

DATES: Effective Date: These standards are effective upon publication.

FOR FURTHER INFORMATION CONTACT: Susan Burbach, OIG Office of Evaluation and Inspections, 202-731-8516, susan.burbach@oig.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The mission of MFCUs is to investigate and prosecute (or refer for prosecution): (1) fraud committed by Medicaid providers, (2) fraud in the administration of the Medicaid program, and (3) patient abuse or neglect of residents in health care facilities and board and care facilities and of Medicaid enrollees in noninstitutional or other settings. MFCUs receive most of their funding from the Federal Government, and each MFCU operates as "a single, identifiable entity of State government." Each of the 50 States has a MFCU, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. Except for four States, each MFCU is organized as part of the State Attorney General's office.

HHS-OIG has been delegated authority under sections 1903(q) and 1903(a)(6) of the Social Security Act (the Act) to certify and annually recertify Units as eligible for Federal financial participation (FFP), and to reimburse States for costs incurred in operating a MFCU. Through the certification and recertification process, OIG ensures that the Units meet the requirements for FFP set forth in section 1903(q) of the Act and in Federal regulations found at 42 CFR part 1007. As part of this process, OIG applies a series of performance standards, as required by section