

earnings and profits under section 1248(d)(1) and (d)(6), except that those exclusions will apply with respect to the earnings and profits of a foreign corporation that are attributable to:

\* \* \* \* \*

(d) \* \* \*

(5) *Basis adjustments under section 367(b)*. With respect to stock of a foreign corporation that is exchanged in a transaction subject to section 367(b), the portion of the basis increase provided by § 1.367(b)-2(e)(3)(ii) by reason of paragraph (c)(3)(ii) of this section is made solely for purposes of section 1411.

\* \* \* \* \*

(i) \* \* \* Paragraph (c)(3) of this section, to the extent it references regulations issued under section 367(b), and paragraph (d)(5) of this section, apply to transactions completed on or after October 5, 2023 and to any transactions treated as completed before October 5, 2023 as a result of an entity classification election made under § 301.7701-3 of this chapter that is filed on or after October 5, 2023.

**Douglas W. O'Donnell,**

*Deputy Commissioner for Services and Enforcement.*

[FR Doc. 2023-22061 Filed 10-5-23; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

#### 37 CFR Part 43

[Docket No. PTO-P-2023-0012]

RIN 0651-AD68

### Rules Governing Pre-Issuance Internal Circulation and Review of Decisions Within the Patent Trial and Appeal Board

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The United States Patent and Trademark Office (“USPTO” or “Office”) proposes regulations to govern the pre-issuance circulation and review of decisions within the Patent Trial and Appeal Board (“PTAB” or “Board”). The Office proposes these provisions to refine the current interim process in light of stakeholder feedback received in response to a Request for Comments (RFC). This proposed rule promotes the efficient delivery of reliable intellectual property rights by promoting consistent, clear, and open decision-making processes at the PTAB.

**DATES:** Comments must be received by December 5, 2023 to ensure consideration.

**ADDRESSES:** Comments must be submitted through the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov). To submit comments via the portal, one should enter docket number PTO-P-2023-0012 on the homepage and select “search.” The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this notice and select the “comment” icon, complete the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe® portable document format (PDF) 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 for additional instructions on providing comments via the portal. If electronic submission of, or access to, comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

#### FOR FURTHER INFORMATION CONTACT:

Melissa A. Haapala, Vice Chief Administrative Patent Judge, or Stacy B. Margolies, Lead Administrative Patent Judge, 571-272-9797.

#### SUPPLEMENTARY INFORMATION:

##### Executive Summary

*Purpose:* This proposed rule would codify processes and standards to govern the internal pre-issuance circulation and review of decisions within the PTAB.

Since May of 2022, the USPTO has been using an interim process for PTAB decision circulation and internal PTAB review to promote consistent, clear, and open decision-making processes at the USPTO. The processes were put in place to support a consistent and clear approach to substantive areas of patent law and PTAB-specific procedures, while maintaining open decision-making processes. The USPTO subsequently issued an RFC seeking public input on these processes. After reviewing feedback received from the public in response to the RFC, the USPTO now seeks to formalize its processes for circulation and review of decisions within the PTAB through notice-and-comment rulemaking.

This proposed rule provides that the USPTO Director, Deputy Director, and Commissioners for Patents and Trademarks are not involved, directly or indirectly, in the decision making of panels of the PTAB prior to issuance of a decision by the panel. In addition, no employee of the Office external to the Board, nor any member of PTAB management, is involved, directly or indirectly, in panel decision-making unless a panel member has requested their input. The adoption of any feedback received by the panel is entirely optional and solely within the discretion of the panel.

This proposed rule also sets forth that, if the Office establishes procedures governing the internal circulation and review of decisions prior to issuance to one or more designated members of the Board, no management judge shall participate in any such review, either directly or indirectly. The adoption of any feedback received pursuant to such review is entirely optional and solely within the discretion of the panel.

Finally, this proposed rule provides that decisions of the Board are expected to comport with applicable statutes, regulations, binding case law, and written agency or Board policy or guidance, and that there is no unwritten agency or Board policy or guidance that is binding on any panel of the Board.

#### Background

On September 16, 2011, the America Invents Act (AIA) was enacted into law (Pub. L. 112-29, 125 Stat. 284 (2011)). The AIA established the PTAB, which is made up of administrative patent judges (APJs) and four statutory members, namely the USPTO Director, the USPTO Deputy Director, the USPTO Commissioner for Patents, and the USPTO Commissioner for Trademarks. 35 U.S.C. 6(a). The PTAB hears and decides ex parte appeals of adverse decisions by examiners in applications for patents; appeals of adverse decisions by examiners in reexamination proceedings; and proceedings under the AIA, including inter partes reviews, post grant reviews, covered business method (CBM) patent reviews,<sup>1</sup> and derivation proceedings, in panels of at least three members. 35 U.S.C. 6(b), (c). Under the statute, the Director designates the members of each panel. 35 U.S.C. 6(c). The Director has delegated that authority to the Chief

<sup>1</sup> Under section 18 of the AIA, the transitional program for post-grant review of CBM patents sunset on September 16, 2020. AIA 18(a). Although the program has sunset, existing CBM proceedings, based on petitions filed before September 16, 2020, remain pending on appeal at the Federal Circuit Court of Appeals.

Judge of the Board. See PTAB Standard Operating Procedure 1 (SOP1), Assignment of Judges to Panels, <https://www.uspto.gov/sites/default/files/documents/SOP%201%20R15%20FINAL.pdf>.

#### *Interim Process and CJP*

The Office recognizes that it is important that the PTAB maintain a consistent and clear approach to substantive areas of patent law and PTAB-specific procedures, while maintaining open decision-making processes. Since May 2022, the USPTO has been using an interim process for PTAB decision circulation and internal PTAB review. See “Interim process for PTAB decision circulation and internal PTAB review,” available at <https://www.uspto.gov/interim-process-ptab-decision-circulation-and-internal-ptab-review>. That interim process has now been replaced by a new Standard Operating Procedure (SOP4), issued concurrently with this Notice of Proposed Rulemaking. The process set forth in SOP4 is substantially similar to the interim process, except for the change described below to the Circulation Judge Pool (CJP) review. SOP4 further sets forth additional details requested by stakeholders.

Under the prior interim process, certain categories of PTAB decisions were required to be circulated to a pool of non-management APJs (the Circulation Judge Pool, also known as CJP) prior to issuance. These decisions included all AIA institution decisions; AIA final written decisions; AIA decisions on rehearing; inter partes reexamination appeal decisions; designated categories of ex parte appeal, ex parte reexamination appeal, and reissue appeal decisions; and all Board decisions (including AIA and ex parte appeal decisions) following a remand from the Federal Circuit. Judges could, at their option, circulate other types of decisions for CJP review. In response to stakeholder feedback, under the process set forth in SOP4, circulation to CJP is now optional.

The CJP comprises a representative group of non-management APJs who collectively have technical/scientific backgrounds and legal experience representative of the PTAB judges as a whole. The CJP was modeled after both the Federal Circuit’s previous circulation to the Senior Technical Assistant and the Federal Circuit’s 10-day circulation process for precedential decisions. See United States Court of Appeals for the Federal Circuit, Internal Operating Procedures, Redlined Copy, 18 (Mar. 1, 2022), available at [\[RulesProceduresAndForms/InternalOperatingProcedures/IOPs-Redline-03012022.pdf\]\(https://cafc.uscourts.gov/wp-content/uploads/RulesProceduresAndForms/InternalOperatingProcedures/IOPs-Redline-03012022.pdf\) \(describing the previous circulation to the Senior Technical Assistant\); and United States Court of Appeals for the Federal Circuit, Internal Operating Procedures, 10.5 \(Mar. 1, 2022\), available at <https://cafc.uscourts.gov/wp-content/uploads/RulesProceduresAndForms/InternalOperatingProcedures/IOPs-03012022.pdf> \(describing the 10-day circulation process for precedential decisions\).](https://cafc.uscourts.gov/wp-content/uploads/</a></p></div><div data-bbox=)

The CJP’s role is to provide the panel with information regarding potential conflicts or inconsistencies with relevant authority, including PTAB precedential decisions, Director guidance memoranda, and other written agency or Board policies or guidance. The CJP also provides the panel with information regarding potential inconsistencies with informative or routine PTAB decisions and suggestions for improved readability and stylistic consistency. The panel has the final authority and responsibility for the content of a decision and determines when and how to incorporate feedback from the CJP. The APJs are required to apply pertinent statutes, binding case law, and written policy or guidance issued by the Director or the Director’s delegate that is applicable to PTAB proceedings. All policies or guidance applicable to PTAB proceedings that the APJs are required to apply are written.

The CJP may have periodic meetings with PTAB Executive Management (*i.e.*, PTAB Chief Judge, Deputy Chief Judge, Vice Chief Judges, Senior Lead Judges, and those acting in any of the foregoing positions) to discuss issued panel decisions and general areas for potential policy clarification. PTAB Executive Management may discuss these issues or issued decisions that have issued with the Director for the purposes of (i) considering whether to issue new or updated policies or guidance, for example, through regulation, precedential or informative decisions, and/or a Director guidance memorandum; and (ii) considering sua sponte (on the Director’s own initiative) Director Review of a decision.

Under the interim process, any panel member, at their sole discretion, could also optionally consult with one or more members of PTAB management (*i.e.*, PTAB Executive Management and Lead Judges) regarding a decision prior to issuance. If consulted, PTAB management could provide information regarding the consistent application of USPTO policy, applicable statutes and regulations, and binding case law. Adoption of any suggestions provided

by PTAB management based on such consultation was optional. Unless consulted by a panel member, PTAB management did not make suggestions to the panel regarding the substance of any pre-issuance decision, either directly or indirectly through the CJP.

The interim PTAB decision circulation and internal review processes promoted decisional consistency and open decision-making processes by reinforcing that the adoption of all CJP and requested PTAB management feedback is optional, that members of PTAB management did not provide feedback on decisions prior to issuance unless they are a panel member or a panel member requests such feedback, and that the PTAB panel had the final authority and responsibility for the content of a decision. Additionally, the processes provided a mechanism by which the Director could be made aware of decisions to consider for sua sponte Director Review, and of areas to consider for issuing new, or modified, USPTO policy to promote the efficient delivery of reliable intellectual property rights.

Furthermore, under both the interim process and SOP4, all consultations are covered by conflict of interest policies. If a member of the CJP or management has a conflict of interest, they are required to notify the other members of their respective team and recuse themselves from any discussion or analysis of that decision. In determining whether a conflict of interest exists, the USPTO follows the guidance set forth in the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635 and will consult with the Department of Commerce Ethics Law and Programs Office, as necessary, to resolve any questions pertaining to conflicts of interest.

#### *Request for Comments*

On July 20, 2022, the USPTO issued an RFC on Director Review, Precedential Opinion Panel Review, and Internal Circulation and Review of Patent Trial and Appeal Board Decisions (RFC), to obtain public feedback on the interim PTAB decision circulation and internal review processes. See 87 FR 43249–52. The USPTO received over 4,300 comments from a wide range of stakeholders, including individuals, associations, and companies, on all aspects of the RFC including specific responses to question 13 (which asked if any changes should be made to the interim PTAB decision circulation and review process) and question 14 (which asked what other considerations should be taken into

account with respect to the interim PTAB decision circulation and internal review process).

Several commenters emphasized the need for judicial independence and review processes that reduce influence by USPTO senior management on PTAB panels. Other commenters emphasized the value of transparency in the PTAB's processes and requested that further details on the CJP be made public. One representative commenter stated that, even when the CJP reviews a decision prior to issuance, it should not discuss the decision with PTAB management until the decision is issued by the panel. Another commenter believed that the value of the CJP may be outweighed by concerns with undue pre-issuance influence by the Director and suggested abandoning the CJP procedure in favor of entrusting the APJs and the Director Review process with maintaining consistency and quality of PTAB decisions.

#### *Proposed Provisions Governing Pre-Issuance Internal Circulation and Review*

In view of the comments and the USPTO's further experience with AIA proceedings, the USPTO undertakes this rulemaking to make policy changes to the processes and standards that govern the internal pre-issuance circulation and review of decisions within the PTAB. This rulemaking is consistent with comments received from stakeholders expressing a preference that key policy changes be made and formalized through rulemaking. This proposed rule seeks to promote consistent, clear, and open decision-making processes while protecting judicial independence and increasing transparency of USPTO processes. For example, this proposed rule would prohibit PTAB management review of decisions prior to issuance by the panel (absent a request by a panel member, at the panel member's sole discretion). The proposed rule also provides that, if the Office establishes procedures governing the internal circulation and review of decisions prior to issuance (such as CJP review), no management judge shall participate directly or indirectly in any such review. Adopting the suggestion of stakeholders, this proposed rule further specifies that the group of reviewing non-management judges (e.g., CJP members) would be prohibited from discussing any reviewed decision with PTAB management prior to issuance.

In response to public feedback requesting additional information on the processes, the USPTO has provided further details regarding the internal circulation process and the structure of

the reviewing body of non-management judges (currently embodied by the CJP) by issuing a Standard Operating Procedure (SOP4) concurrently with the publication of this NPRM. The processes set forth in the SOP4 replace the former interim process for PTAB decision circulation described above. The Office may consider further refinements or modifications to the SOP4 in view of the comments received from the public in response to this NPRM.

The USPTO proposes to add part 43, which provides for new regulations governing the pre-issuance circulation and review of decisions within the PTAB. A section-by-section discussion of the new provisions is as follows:

*Section 43.1:* Proposed § 43.1 would set forth general policy considerations for Part 43 and define the scope of the rules.

*Section 43.2:* Proposed § 43.2 would set forth definitions for terms used in Part 43.

The proposed definition of *Board* would refer to the Patent Trial and Appeal Board.

The proposed definition of *decision* would refer to any decision, order, opinion, or other written work product intended for entry into the record of a Board proceeding.

The proposed definition of *Director* would refer to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office or an individual serving as Acting Director or performing the functions and duties of the Director.

The proposed definition of *Deputy Director* would refer to the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office or an individual serving as Acting Deputy Director.

The proposed definitions of *Commissioner for Patents* and *Commissioner for Trademarks* would be the positions defined in 35 U.S.C. 3(b)(2) or an individual acting in the capacity of one of those positions.

The proposed definition of *issuance* would refer to the entry of a decision into the record of a Board proceeding.

The proposed definition of *Management Judge* would encompass the Chief Administrative Patent Judge, the Deputy Chief Administrative Patent Judge, a Vice Chief Administrative Patent Judge, a Senior Lead Administrative Patent Judge, and/or a Lead Administrative Patent Judge, including individuals who serve in these positions in an acting capacity. The definition is also intended to capture any other Administrative Patent

Judge who, as part of their duties, supervises the work of other Administrative Patent Judges or is responsible for reviewing the performance of other Administrative Patent Judges.

The proposed definition of *panel* would refer to the members of the Board assigned to a proceeding pursuant to the Board's Standard Operating Procedure 1.

The proposed definition of *proceeding* would refer to an appeal or contested case under Part 41 or trial proceeding under Part 42.

*Section 43.3:* Proposed § 43.3 would specify that the Director of the USPTO and other high-level officers are not involved in panel decisions prior to their issuance, either directly or indirectly. The provision ensures the judicial independence of Board panels by insulating panel decision-making from the policy-setting functions of Office leadership.

Proposed § 43.3(a) would prohibit the Director, Deputy Director, Commissioner for Patents, and Commissioner for Trademarks from communicating, directly or indirectly, with any member of a panel regarding a decision, prior to issuance of that decision by the panel.

Proposed § 43.3(b) would provide that paragraph (a) would not apply to any proceeding in which the named individual is a member of the panel and would also specify that when sitting as a member of a panel, the individual is a coequal member of the panel.

Proposed § 43.3(c) would clarify that nothing in § 43.3 shall prevent the Director or their delegate from communicating with a panel as to resource needs or the procedural status of any proceeding. This provision is intended to permit Office leadership to engage in communications of a purely administrative or logistical nature that are necessary to ensure the effective and efficient administration of the Office. Communications with a panel attempting to influence or direct the outcome or reasoning of any decision would not be permitted under this provision.

Proposed § 43.3(d) would specifically delegate to the Chief Administrative Patent Judge the Director's power to designate and re-designate panels of the Board under 35 U.S.C. 6(c). The proposed rule would also prohibit the Director from directing or otherwise influencing the paneling or repaneling of any proceeding prior to issuance of the panel decision. The proposed rule permits the Director to issue generally applicable paneling guidance to be applied to proceedings before the Board,

and to direct the repaneling of a proceeding according to that generally applicable guidance when the Director is reviewing or rehearing an issued panel decision.

*Section 43.4:* Proposed § 43.4 would govern involvement by Board management or Office employees outside the Board in the review and circulation of decisions prior to issuance. The provision ensures judicial independence of Board panels while permitting a panel member to request management input on issues when desired.

Proposed § 43.4(a) would prohibit any Management Judge or employee of the Office external to the Board from initiating communication, directly or through intermediaries, with any member of a panel regarding a decision, prior to issuance of that decision.

Proposed § 43.4(b) would provide an exception to paragraph (a) in the event a member of the panel requests input from a Management Judge prior to issuance of the decision. The proposed rule clarifies that requesting input is optional and the decision to request input is solely within the discretion of an individual panel member.

Proposed § 43.4(c) would specify that it is within the panel's sole discretion to adopt any edits, suggestions, or feedback provided by a Management Judge in response to a request for input, and the panel has the final authority and responsibility for the content of a decision.

Proposed § 43.4(d) would provide that paragraph (a) would not apply to a Management Judge who is a member of the panel and would specify that when sitting as a member of a panel, a Management Judge is a coequal member of the panel and exercises no review authority over the decision.

Proposed § 43.4(e) would clarify that nothing in § 43.4 shall prevent a Management Judge from communicating with a panel as to resource needs or the procedural status of any proceeding. This provision is intended to permit Board management to engage in communications of a purely administrative or logistical nature that are necessary to ensure the effective and efficient administration of the Board. Communications with a panel attempting to influence or direct the outcome or reasoning of any decision would not be permitted under this provision.

*Section 43.5:* Proposed § 43.5 would govern procedures for circulation of decisions to, and review of decisions by, a designated group of non-Management Judges if the Office sets forth procedures for such circulation. The provision

promotes consistent, clear, and open decision-making by permitting peer review of decisions prior to issuance, while respecting the judicial independence of panels by providing that all feedback from such review is optional and at the panel's sole discretion to adopt.

Proposed § 43.5(a) would provide that no Management Judge shall participate in any such circulation and review procedures. The proposed rule further provides that if a decision is circulated to non-Management Judges for review prior to issuance, the reviewing judges will not discuss the substance of the circulated decision with a Management Judge prior to issuance by the panel, except with a Management Judge who is a member of the panel.

Proposed § 43.5(b) would specify that any edits, suggestions, or feedback provided, following circulation and review to a non-Management Judge, are optional and in the sole discretion of a panel to accept. The proposed rule also states that the panel has final authority and responsibility for the content of a decision and determines whether and how to incorporate any feedback provided.

*Section 43.6:* Proposed § 43.6 would provide that all decisions of the Board are expected to comport with all applicable statutes, regulations, binding case law, and written agency policy or guidance applicable to Board proceedings. This proposed provision would also specifically state that there is no unwritten agency or Board policy or guidance that is binding on any panel of the Board. The proposed provision would further require that all written policy or guidance binding on panels of the Board shall be made public.

#### Rulemaking Considerations

*A. Administrative Procedure Act:* The changes proposed by this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. See *Perez v. Mortg. Bankers Ass'n*, 135 S.Ct. 1199, 1204 (2015) (Interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers.” (citation and internal quotation marks omitted)); *Nat’l Org. of Veterans’ Advocates, Inc. v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Rule that clarifies interpretation of a statute is interpretive.).

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) or any other law. See *Perez*, 135 S.Ct. 1199, 1206 (Notice-and-comment procedures are required neither when an agency “issue[s] an initial

interpretive rule” nor “when it amends or repeals that interpretive rule.”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 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”) (quoting 5 U.S.C. 553(b)(3)(A)).

The Office, nevertheless, is publishing this proposed rule for comment to seek the benefit of the public’s views on the Office’s proposed changes as set forth herein.

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

The changes in this notice of proposed rulemaking are to set forth expressly the rules governing the circulation and review of decisions of the Board prior to issuance by a panel. The changes do not create additional procedures or requirements or impose any additional compliance measures on any party, nor do these changes cause any party to incur additional cost. Therefore, any requirements resulting from these proposed changes are of minimal or no additional burden to those practicing before the Board.

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

*C. Executive Order 12866 (Regulatory Planning and Review):* This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993), 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 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rules; (2) tailored the rules to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the

public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

*E. Executive Order 13132*

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

*F. Executive Order 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 (Nov. 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 (Feb. 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 (Apr. 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 (Mar. 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.*), 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 notice of proposed rulemaking are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not a “major rule” as defined in 5 U.S.C. 804(2).

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

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

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

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

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

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

*P. E-Government Act Compliance*: The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

**List of Subjects in 37 CFR Part 43**

Administrative practice and procedure.

For the reasons set forth in the preamble, the USPTO proposes to amend title 37 as follows:

- 1. Add part 43 to read as follows:

**PART 43— DECISION CIRCULATION AND REVIEW WITHIN THE PATENT TRIAL AND APPEAL BOARD**

Sec.

- 43.1 Policy.
- 43.2 Definitions.
- 43.3 No Pre-Issuance Director Involvement in Board Decisions.
- 43.4 Limited Pre-Issuance Management Involvement in Decisions.
- 43.5 Review of Decisions by Non-Management Judges.
- 43.6 Controlling Legal Authority; No Unwritten or Non-Public Binding Policy or Guidance.

**Authority**: 35 U.S.C. 2(b)(2), 6, 134, 135, 311, 316, 321, and 326; Pub. L. 112–29, 125 Stat. 284; and Pub. L. 112–274, 126 Stat. 2456.

**§ 43.1 Policy.**

*Scope*. This Part sets forth procedures for the pre-issuance circulation and review within the Patent Trial and Appeal Board of draft panel decisions rendered in proceedings pending under Parts 41 and 42 of this chapter and sets forth the controlling legal authority, policy, and guidance applicable to the decisions of the Board.

**§ 43.2 Definitions.**

The following definitions apply to this part:

*Board* means the Patent Trial and Appeal Board.

*Decision* means any decision, order, opinion, or other written work product intended for entry into the record of a Board proceeding.

*Director* means the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, or an individual serving as Acting Director or performing the functions and duties of the Director.

*Deputy Director* means the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office, or an individual serving as Acting Deputy Director.

*Commissioner for Patents* and *Commissioner for Trademarks* mean the positions defined in 35 U.S.C. 3(b)(2), or an individual acting in the capacity of one of those positions.

*Issuance* means the entry of a decision into the record of a Board proceeding.

*Management Judge* means the Chief Administrative Patent Judge, the Deputy Chief Administrative Patent Judge, a Vice Chief Administrative Patent Judge, a Senior Lead Administrative Patent Judge, a Lead Administrative Patent Judge, including individuals who serve in these positions in an acting capacity, or any other Administrative Patent Judge who, as part of their duties, supervises the work of other Administrative Patent Judges or is responsible for reviewing the performance of other Administrative Patent Judges.

*Panel* means the members of the Board assigned to a proceeding pursuant to the Board's Standard Operating Procedure 1.

*Proceeding* means an appeal or contested case under Part 41, or trial proceeding under Part 42.

#### **§ 43.3 No Pre-Issuance Director Involvement in Panel Decisions.**

(a) Prior to issuance of a decision by the panel, the Director, Deputy Director, Commissioner for Patents, and Commissioner for Trademarks shall not communicate, directly or through intermediaries, with any member of the panel regarding the decision.

(b) The prohibition of paragraph (a) shall not apply to any proceeding in which the individual is a member of the panel. When sitting as a member of a panel, the Director or other individual listed in paragraph (a) is a coequal member of the panel and exercises no review authority over the proceeding prior to the issuance of the panel's decision on the merits.

(c) Nothing in this section shall prevent the Director or delegate from communicating with a panel as to resource needs or the procedural status of any proceeding pending before the Board.

(d) The Chief Administrative Patent Judge or delegates of the Chief Administrative Patent Judge shall designate panels of the Board on behalf of the Director. The Director may issue generally applicable paneling guidance to be applied to proceedings before the

Board. The Director shall not direct or otherwise influence the paneling or repaneling of any specific proceeding prior to issuance of the panel decision. When reviewing or rehearing an issued panel decision, the Director may direct the repaneling of the proceeding in a manner consistent with PTAB paneling guidance, through an Order entered into the record.

#### **§ 43.4 Limited Pre-Issuance Management Involvement in Decisions.**

(a) Except as requested pursuant to paragraph (b) or permitted under paragraph (d) or (e), prior to issuance of a decision by the panel, no Management Judge or employee of the Office external to the Board shall initiate communication, directly or through intermediaries, with any member of a panel regarding a decision.

(b) Any individual panel member may request that one or more Management Judges provide input on a decision prior to issuance. The choice to request input is optional and solely within the discretion of an individual panel member.

(c) It is within the sole discretion of the panel to adopt any edits, suggestions, or feedback provided to the panel by a Management Judge as part of a review requested under paragraph (b). The panel has final authority and responsibility for the content of a decision and determines whether and how to incorporate any feedback requested under paragraph (b).

(d) The prohibition of paragraph (a) shall not apply to any Management Judge who is a member of the panel. When sitting as a member of a panel, a Management Judge is a coequal member of the panel and exercises no review authority over the proceeding prior to the issuance of the panel's decision on the merits.

(e) Nothing in this section shall prevent a Management Judge from communicating with a panel as to resource needs or the procedural status of any case pending before the Board.

#### **§ 43.5 Review of Decisions by Non-Management Judges.**

If the Office establishes procedures governing the internal circulation and review of decisions prior to issuance to one or more designated members of the Board:

(a) No Management Judge shall participate directly or indirectly in any such review and the reviewing non-Management judges shall not discuss the substance of any circulated decision with a Management Judge prior to issuance of the decision, except with a

Management Judge who is a member of the panel; and

(b) Any edits, suggestions, or feedback provided to the panel pursuant to such circulation and review are optional and in the sole discretion of the panel to accept. The panel has final authority and responsibility for the content of a decision and determines whether and how to incorporate any feedback provided.

#### **§ 43.6 Controlling Legal Authority; No Unwritten or Non-Public Binding Policy or Guidance.**

Notwithstanding any other provision of this Part, all decisions of the Board are expected to comport with all applicable statutes, regulations, binding case law, and written agency policy and guidance applicable to Board proceedings. There shall be no unwritten agency or Board policy or guidance that is binding on any panel of the Board. All written policy and guidance binding on panels of the Board shall be made public.

**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**

### **42 CFR Part 93**

**RIN 0937-AA12**

#### **Public Health Service Policies on Research Misconduct**

**AGENCY:** U.S. Department of Health and Human Services (HHS).

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** In this Notice of Proposed Rulemaking (NPRM), the Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI) proposes to revise the Public Health Service (PHS) Policies on Research Misconduct. The proposed revisions are based on the experience ORI and institutions have gained with the regulation since it was released in 2005. This NPRM seeks comment from individuals, institutional officials, organizations, institutions, research funding agencies, and other members of the public on the proposed revisions and how to improve the clarity of substantive and non-substantive.