510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2021-0038]

RIN 0651-AD56

2021 Increase of the Annual Limit on Accepted Requests for Track One Prioritized Examination

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

ACTION: Interim rule.

SUMMARY: The Leahy-Smith America Invents Act (America Invents Act) includes provisions for prioritized examination of patent applications that have been implemented by the United States Patent and Trademark Office (USPTO or Office) in previous rulemakings. The America Invents Act provides that the Office may not accept more than 10,000 requests for prioritization in any fiscal year (October 1 to September 30) until regulations setting another limit are prescribed. The Office published an interim rule in 2019 expanding the availability of prioritized examination by increasing the limit on the number of prioritized examination requests that may be accepted in a fiscal year to 12,000. The current interim rule further expands the availability of prioritized examination by increasing the limit on the number of prioritized examination requests that may be accepted in a fiscal year to 15,000.

DATES: *Effective Date:* **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Applicability Date: The limit of 15,000 requests for prioritized examination accepted per year is applicable for fiscal year 2021.

Comment Deadline Date: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, enter docket number PTO-P-2021-0038 on the homepage and click "Search." The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click on the "Comment Now!" icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal website (www.regulations.gov) for additional instructions on providing comments via the portal. If electronic submission of 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: Kery Fries, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-7757; or Parikha Mehta, Legal Advisor, Office of Patent Legal Administration, at 571-272-3248.

SUPPLEMENTARY INFORMATION:

Executive Summary: *Purpose:* This interim rule expands prioritized examination (Track One) practice to increase the number of applications that may be accepted for prioritized examination in a fiscal year to 15,000.

Summary of Major Provisions: The prioritized examination provisions (37 CFR 1.102(e)) currently provide that a request for prioritized examination may be filed with an

original utility or plant nonprovisional application under 35 U.S.C. 111(a). The America Invents Act provides that the Office may not accept more than 10,000 requests for prioritization in any fiscal year until regulations setting another limit are prescribed. The Office published an interim rule in 2019 expanding the availability of prioritized examination by increasing the limit on the number of prioritized examination requests that may be accepted in a fiscal year to 12,000. The current interim rule further expands the availability of prioritized examination by increasing the limit on the number of prioritized examination requests that may be accepted in a fiscal year to 15,000.

Background: Section 11(h) of the America Invents Act provides for prioritized examination of an application. *See* Pub. L. 112-29, 125 Stat. 284, 324 (2011). Section 11(h)(1)(B)(i) of the America Invents Act also provides that the Office may, by regulation, prescribe conditions for the acceptance of a request for prioritized examination, and section 11(h)(1)(B)(iii) provides that "[t]he Director may not accept in any fiscal year more than 10,000 requests for prioritization until regulations are prescribed under this subparagraph setting another limit." *Id*.

The Office implemented the prioritized examination provision of the America Invents Act for applications on filing in a final rule published on September 23, 2011. *See* Changes to Implement the Prioritized Examination Track (Track I) of the Enhanced Examination Timing Control Procedures Under the Leahy-Smith America Invents Act, 76 FR 59050 (Sept. 23, 2011) (codified in 37 CFR 1.102(e)). Following its implementation, the Office improved its processes for carrying out prioritized examination and expanded the scope of prioritized examination in view of those improvements. First, the Office implemented prioritized examination for pending applications after the filing of a proper request for continued examination under 35 U.S.C. 132(b) and 37 CFR 1.114. *See* Changes to Implement the Prioritized Examination for Requests for Continued Examination, 76 FR 78566 (Dec. 19, 2011).

Next, the prioritized examination procedures further expanded to permit the delayed submission of certain filing requirements while maintaining the Office's ability to timely examine the patent application. *See* Changes to Permit Delayed Submission of Certain Requirements for Prioritized Examination, 79 FR 12386 (Mar. 5, 2014).

The number of requests for prioritized examination has been increasing steadily over the years. The Office published an interim rule in 2019 expanding the availability of prioritized examination by increasing the limit on the number of prioritized examination requests that may be accepted in a fiscal year from 10,000 to 12,000. *See* Increase of the Annual Limit on Accepted Requests for Track I Prioritized Examination, 84 FR 45907 (Sept. 3, 2019). The current interim rule further expands the availability of prioritized examination by increasing the limit on the number of prioritized examination requests that may be accepted in a fiscal year to 15,000. Through continued monitoring of the implementation of the Track One program, the Office has determined that the program may be further expanded to permit more applications to undergo prioritized examination while maintaining the ability to timely examine all prioritized applications. Quality metrics used by the Office continue to reveal no loss in examination quality for applications given prioritized examination. In addition, the number of applications accepted for prioritized examination will remain a small fraction of the patent examinations completed in a fiscal year (the Office examines approximately 640,000 applications and requests for continued examination in total per fiscal year). Accordingly, the Office is further expanding the availability of prioritized examination by increasing the limit on the number of prioritized examination requests that may be accepted in a fiscal year to 15,000, beginning in fiscal year 2021 (October 1, 2020, through September 30, 2021) and continuing every fiscal year thereafter until further notice.

Discussion of Specific Rules

The following is a discussion of the amendments to 37 CFR part 1.

Section 1.102: Section 1.102(e) is revised to increase the limit on the total number of requests for prioritized examination that may be accepted (granted) in any fiscal year from 12,000 to 15,000.

Rulemaking Considerations:

A. Administrative Procedure Act: This interim rule revises the procedures that apply to applications for which an applicant has requested Track One prioritized examination. The changes in this interim rule do not change the substantive criteria of patentability. Therefore, the changes in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See JEM Broad. Co.* v. *F.C.C.*, 22 F.3d 320, 326 (D.C. Cir. 1994) ("[T]he 'critical feature' of the procedural exception [in 5 U.S.C. 553(b)(A)] 'is that it covers agency actions that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency.'" (quoting *Batterton* v. *Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980))); *see also Bachow Commc'ns Inc.* v. *F.C.C.*, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); *Inova Alexandria Hosp.* v. *Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims). 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 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)(A)). In addition, the

changes in this interim rule may be made immediately effective because this interim rule is not a substantive rule under 35 U.S.C. 553(d).

Moreover, the Office, pursuant to authority at 5 U.S.C. 553(b)(B), finds good cause to adopt the changes in this interim rule without prior notice and an opportunity for public comment, as such procedures would be contrary to the public interest. Delay in the promulgation of this interim rule to provide prior notice and comment procedures would cause harm to those applicants who desire to file a request for Track One prioritized examination with a new application or request for continued examination. Immediate implementation of the changes in this interim rule is in the public interest because: (1) the public does not need time to conform its conduct, as the changes in this interim rule do not add any additional requirement for requesting prioritized examination of an application; and (2) those applicants who would otherwise be ineligible for prioritized examination will benefit from the immediate implementation of the changes in this interim rule. *See Nat'l Customs Brokers & Forwarders Ass'n of Am., Inc.* v. *United States*, 59 F.3d 1219, 1223-24 (Fed. Cir. 1995). In addition, pursuant to authority at 5 U.S.C. 553(d)(3), the Office finds good cause to adopt the changes in this interim rule without the 30-day delay in effectiveness as such delay would be contrary to the public interest. Immediate implementation of the changes in this interim rule is in the public interest because: (1) the public does not need time to conform its conduct, as the changes in this interim rule do not add any additional requirement for requesting prioritized examination of an application; and (2) those applicants who would otherwise be ineligible for prioritized examination will benefit from the immediate implementation of the changes in this interim rule.

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a regulatory

flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) is required. *See* 5 U.S.C. 603.

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).

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 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 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 effect 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 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 expected to result in 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 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This interim rule does not involve information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3549). An applicant who wishes to participate in the prioritized examination program must submit a certification and request to participate in the program, preferably by using Form PTO/AIA/424. However, OMB has determined that, under 5 CFR 1320.3(h), Form PTO/AIA/424 does not collect "information" within the meaning of the

Paperwork Reduction Act of 1995. Therefore, this rulemaking does not impose any additional collection requirements under the Paperwork Reduction Act that are subject to further review by OMB.

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 1

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

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

PART 1 - RULES OF PRACTICE IN PATENT CASES

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

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

2. Section 1.102 is amended by revising paragraph (e) introductory text to read as follows:

§ 1.102 Advancement of examination.

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(e) A request for prioritized examination under this paragraph (e) must comply with the requirements of this paragraph (e) and be accompanied by the prioritized examination fee set forth in § 1.17(c), the processing fee set forth in § 1.17(i), and if not already paid, the publication fee set forth in § 1.18(d). An application for which prioritized examination has been requested may not contain or be amended to contain more than four independent claims, more than thirty total claims, or any multiple

dependent claim. Prioritized examination under this paragraph (e) will not be accorded to international applications that have not entered the national stage under 35 U.S.C. 371, design applications, reissue applications, provisional applications, or reexamination proceedings. A request for prioritized examination must also comply with the requirements of paragraph (e)(1) or (2) of this section. No more than 15,000 requests for such prioritized examination will be accepted in any fiscal year.

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Andrew Hirshfeld,
Commissioner for Patents,
Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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