



**3510-16-P**

**DEPARTMENT OF COMMERCE**

**Patent and Trademark Office**

**37 CFR Part 1**

**[Docket No. PTO-P-2019-0020]**

**RIN 0651-AD39**

**Increase of the Annual Limit on Accepted Requests for Track I 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, which 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 are prescribed setting another limit. This interim rule 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 from 10,000 to 12,000.

**DATES:** Effective Date: [Insert date of publication in the FEDERAL REGISTER].

Applicability Date: The limit of 12,000 granted requests for prioritized examination per year becomes effective for fiscal year 2019.

Comment Deadline Date: Written comments must be received on or before [Insert date 60 days after publication in the FEDERAL REGISTER].

**ADDRESSES:** Comments should be sent by e-mail addressed to:

AD39.comments@uspto.gov. Comments also may be submitted by postal mail addressed to: Mail Stop Comments--Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, marked to the attention of Kery Fries, Senior Legal Advisor, Office of Patent Legal Administration.

Comments further may be sent via the Federal eRulemaking Portal. Visit the Federal eRulemaking Portal Web site (<http://www.regulations.gov>) for additional instructions on providing comments via the Federal eRulemaking Portal.

Although comments may be submitted by postal mail, the Office prefers to receive comments by e-mail. E-mailed comments are preferred to be submitted in plain text, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted by e-mail or via the Federal eRulemaking Portal should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

The comments will be available for viewing via the Office's Internet Web site (<https://www.uspto.gov/patent/laws-and-regulations/comments-public-response-specific-requests-uspto>). 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.

**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 I”) practice to increase the number of applications that may be accorded prioritized examination in a fiscal year.

*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 are prescribed setting another limit. This interim rule increases the limit on the number of prioritized examination requests that may be accepted in a fiscal year from 10,000 to 12,000.

*Costs and Benefits:* This rulemaking is not economically significant under Executive Order 12866 (Sept. 30, 1993).

**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 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 (referred to as “Track I”) 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 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 increased steadily over the last few years to the point that the Office will reach the limit of 10,000 requests for prioritized examination that may be accepted (granted) in any fiscal year if the limit is not increased. Through continued monitoring of the implementation of the Track I 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 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 650,000 applications and requests for continued examination in total per fiscal year). Accordingly, the Office is 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, beginning in fiscal year 2019 (October 1, 2018, through September 30, 2019) and continuing every fiscal year thereafter until further notice.

### **Discussion of Specific Rules**

The following is a discussion of the amendments to title 37 of the Code of Federal Regulations, 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 10,000 to 12,000.

### **Rulemaking Considerations:**

*A. Administrative Procedure Act:* This interim rule revises the procedures that apply to applications for which an applicant has requested Track I 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), does 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 I 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)(1), the changes in this interim rule may be made immediately effective because they relieve restrictions in the requirements for requesting prioritized examination of an application.

***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 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 13771 (Reducing Regulation and Controlling Regulatory Costs):** This rulemaking is not an Executive Order 13771 (Jan. 30, 2017) regulatory action because the rulemaking is not significant under Executive Order 12866 (Sept. 30, 1993).

***F. 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).

***G. 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).

***H. 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).

***I. Executive Order 13783 (Promoting Energy Independence and Economic Growth):*** This rulemaking does not potentially burden the development or use of domestically produced energy resources, with particular attention to oil, natural gas, coal, and nuclear energy resources under Executive Order 13783 (Mar. 28, 2017).

***J. Executive Order 13772 (Core Principles for Regulating the United States Financial System):*** This rulemaking does not involve regulation of the United States financial system under Executive Order 13772 (Feb. 3, 2017).

***K. 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).

***L. 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).

***M. 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).

***N. Congressional Review Act:*** Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801–808), the United States Patent and Trademark Office will submit a report containing any final rule resulting from this rulemaking and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office.

***O. 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 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.*

***P. 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.*

***Q. 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.

***R. Paperwork Reduction Act:*** 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 involves information

collection requirements which 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 prioritized examination program, preferably by using Form PTO/AIA/424. 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. This rulemaking does not impose any additional collection requirements under the Paperwork Reduction Act which are subject to further review by OMB.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

**List of Subjects in 37 CFR Part 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 the introductory text of paragraph (e) to read as follows:

**§ 1.102 Advancement of examination.**

\* \* \* \* \*

(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 12,000 requests for such prioritized examination will be accepted in any fiscal year.

\* \* \* \* \*

Dated: August 27, 2019.

**Andrei Iancu,**

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

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