[3510-16-P]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No.: PTO-P-2014-0023]

RIN 0651-AC96

Changes to Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (Office) is proposing changes to the rules of practice pertaining to the patent term adjustment provisions in view of the decision by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in Novartis AG v. Lee. The Federal Circuit confirmed in Novartis that any time consumed by continued examination is subtracted in determining the extent to which the period of application pendency exceeds three years, regardless when the continued

examination was initiated. The Federal Circuit, however, decided that the time consumed by continued examination does not include the time after a notice of allowance, unless the Office actually resumes examination of the application after allowance. The Office is proposing changes to the rules of practice to provide that the time consumed by continued examination does not include the time after a notice of allowance, unless the Office actually resumes examination of the application after allowance. The Office also is proposing changes to the rules of practice to provide that the submission of a request for continued examination after a notice of allowance has been mailed will constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and thus result in a reduction of any period of patent term adjustment.

DATES: COMMENT DEADLINE DATE: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: AC96.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, Office of the Deputy Commissioner for Patent Examination Policy.

Comments further may be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See 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 electronic mail message over the Internet because sharing comments with the public is more easily accomplished. Electronic comments submitted in plain text are preferred, but may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

Comments will be available for viewing via the Office's Internet Web site (http://www.uspto.gov). 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, Office of the Deputy Commissioner for Patent Examination Policy, at telephone number 571-272-7757.

SUPPLEMENTARY INFORMATION:

Executive Summary: Purpose: The Office is proposing changes to the rules of practice pertaining to the patent term adjustment provisions of 35 U.S.C. 154(b) in view of the decision by the Federal Circuit in Novartis, 740 F.3d 593 (Fed. Cir. 2014). The Federal Circuit confirmed in Novartis that any time consumed by continued examination under 35 U.S.C. 132(b) is subtracted in determining the extent to which the period defined in 35 U.S.C. 154(b)(1)(B) exceeds three years, regardless when the continued examination under 35 U.S.C. 132(b) was initiated. The Federal Circuit, however, decided that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance unless the Office actually resumes examination of the application after allowance.

Summary of Major Provisions: The Office is proposing changes to the rules of practice to provide that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance, unless the Office actually resumes examination of the application after allowance. The Office also is proposing changes to the rules of practice to provide that the submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed will constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and thus result in a reduction of any period of patent term adjustment under 35 U.S.C. 154(b)(1).

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

Background: In January 2014, the Federal Circuit issued a decision in Novartis pertaining to the patent term adjustment provisions of 35 U.S.C. 154(b), and specifically the impact of continued examination under 35 U.S.C. 132(b) on patent term adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B). The Federal Circuit confirmed in Novartis that any time consumed by continued examination under 35 U.S.C. 132(b) is subtracted in determining the extent to which the period defined in 35 U.S.C. 154(b)(1)(B) exceeds three years, regardless when the continued examination under 35 U.S.C. 132(b) was initiated. See 740 F.3d at 601 ("[t]he better reading of the language is that the patent term adjustment time should be calculated by determining the length of the time between application and patent issuance, then subtracting any continued examination time (and other time identified in (i), (ii), and (iii) of [35 U.S.C. 154](b)(1)(B)), and determining the extent to which the result exceeds three years"). The Federal Circuit, however, decided that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance unless the Office actually resumes examination of the application after allowance. See 740 F.3d at 602 ("[t]he common-sense understanding of 'time consumed by continued examination,' 35 U.S.C. 154(b)(1)(B)(i), is time up to allowance, but not later, unless examination on the merits resumes"). Therefore, the Office is proposing changes to the rules of practice to provide that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance, unless the Office actually resumes examination of the application after allowance.

The Office makes the patent term adjustment determination indicated in the patent by a computer program that uses the information recorded in the Office's Patent Application Locating and Monitoring (PALM) system (except when an applicant requests reconsideration pursuant to § 1.705). See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56370, 56380-81 (Sept. 18, 2000) (final rule). The decision in Novartis that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance unless the Office actually resumes examination of the application after allowance requires modifications of the Office's patent term adjustment program, and these modifications of the Office's patent term adjustment program have not yet been completed. The Office, however, calculates the patent term adjustment manually when an applicant requests reconsideration of a patent term adjustment determination pursuant to § 1.705. The Office is now deciding requests for reconsideration of a patent term adjustment filed pursuant to § 1.705 consistent with the Federal Circuit decision in Novartis.

The patent term adjustment statutory provision also includes the provision that "[t]he period of adjustment of the term of a patent under [35 U.S.C. 154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application," and that "[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." See 35 U.S.C. 154(b)(2)(C)(i) and (iii). Under the authority provided in 35

U.S.C. 154(b)(2)(C), the Office is proposing a rule of practice that establishes the submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed as constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. This rule of practice is proposed to ensure that an applicant does not obtain multiple periods of patent term adjustment under 35 U.S.C. 154(b)(1)(B) for the time after a notice of allowance under 35 U.S.C. 151 as a consequence of delaying issuance of the application by filing request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151.

Discussion of Specific Rules:

The following is a discussion of proposed amendments to title 37 of the Code of Federal Regulations, Part 1:

Section 1.703: Section 1.703(b)(1) is proposed to be amended to provide that the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of a notice of allowance under 35 U.S.C. 151, unless prosecution in the application is reopened. If prosecution in the application is reopened, the time consumed by continued examination of the application under 35 U.S.C. 132(b) also includes the number of days, if any, in the period or periods beginning on the date on

which a request for continued examination of the application under 35 U.S.C. 132(b) was filed or the date of mailing of an action under 35 U.S.C. 132, whichever occurs first, and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. 151. As discussed previously, this proposed amendment is consistent with the decision in Novartis that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance unless the Office actually resumes examination of the application after allowance.

Section 1.704: Section 1.704(c) is proposed to be amended to include a new provision that establishes the submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed as constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application, in which case the period of adjustment set forth in §1.703 shall be reduced by the number of days, if any, beginning on the date of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed. As discussed previously, this rule of practice is proposed to ensure that an applicant does not obtain multiple periods of patent term adjustment under 35 U.S.C. 154(b)(1)(B) for the time after a notice of allowance under 35 U.S.C. 151 as a consequence of delaying issuance of the application by filing request(s) for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151. The provisions of § 1.704(d) would not be applicable to this new provision as the information disclosure statement rules (§§ 1.97 and 1.98) provide for the submission of an information disclosure statement after a notice of allowance under 35

U.S.C. 151 has been mailed up until the issue fee is paid without the need for the filing of a request for continued examination under 35 U.S.C. 132(b) (§ 1.97(d)), and the Office has a program to allow for the submission of an information disclosure statement even after the payment of the issue fee (Quick Path Information Disclosure Statement (QPIDS) Pilot Program, 77 FR 27443 (May 10, 2012)).

Rulemaking Considerations:

A. Administrative Procedure Act: This rulemaking proposes to amend 37 CFR 1.703 to provide that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance has been mailed, unless the Office actually resumes examination of the application after allowance. This rulemaking also proposes to amend 37 CFR 1.704 to include a provision that establishes the submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed as constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. The proposed amendment to 37 CFR 1.703 to provide that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance has been mailed, unless the Office actually resumes examination of the application after allowance, simply implements the Federal Circuit's ruling on the provisions of 35 U.S.C. 154(b)(1)(B)(i) in Novartis. Therefore, the proposed amendment to 37 CFR 1.703 is simply a procedural and/or interpretive rule. See 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); 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), with respect to the proposed change to 37 CFR 1.703. 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)). The Office, however, is publishing all of these proposed changes (rather than only the proposed change to 37 CFR 1.704) for comment as it seeks the benefit of the public's views on the Office's proposed implementation of the Federal Circuit's interpretation of the provisions of 35 U.S.C. 154(b)(1)(B)(i) in Novartis.

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

The proposed changes to the patent term adjustment reduction provisions do not impose any additional requirements or fees on applicants. The proposed change to 37 CFR 1.703 simply implements the Federal Circuit's ruling on the provisions of 35 U.S.C. 154(b)(1)(B)(i) in Novartis and reflects how patent term adjustment is now calculated in response to a request for reconsideration of patent term adjustment. The proposed change to 37 CFR 1.704 specifies that the submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. This proposed change will not have a significant economic impact on a substantial number of small entities because applicants are not entitled to patent term adjustment for examination delays that result from an applicant's delay in prosecuting the application (35 U.S.C. 154(b)(2)(C)(i) and 37 CFR 1.704(a)) and because applicants may avoid any consequences from this provision simply by refraining from filing a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed.

For the foregoing reasons, the changes proposed in this notice 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 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. 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 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. 801–808), 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.

L. Unfunded Mandates Reform Act of 1995: The changes set forth in this notice 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 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. The rules of practice pertaining to patent term adjustment and extension have been reviewed and approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) under OMB control number 0651-0020. The changes proposed in this rulemaking would: (1) provide that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance, unless the Office actually resumes examination of the application after allowance; and (2) provide that the submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

This rulemaking does not add any additional requirements (including information collection requirements) or fees for patent applicants or patentees. Therefore, the Office is not resubmitting information collection packages to OMB for its review and approval because the changes in this rulemaking do not affect the information collection requirements associated with the information collections approved under OMB control number 0651-0020 or any other information collections.

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.

List of Subjects in 37 CFR Part 1

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

For the reasons set forth in the preamble, 37 CFR part 1 is proposed to be 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 1.703 is amended by revising paragraph (b)(1) to read as follows:

§ 1.703 Period of adjustment of patent term due to examination delay.

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(b) *** * ***

(1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of a notice of allowance under 35 U.S.C. 151, unless prosecution in the application is reopened, in which case the period of adjustment under § 1.702(b) also does not include the number of days, if any, in the period or periods beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed or the date of mailing of an action under 35 U.S.C. 132, whichever occurs first, and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. 151;

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2. Section 1.704 is amended by redesignating paragraphs (c)(12) and (13) as paragraphs (c)(13) and (14), respectively, and by adding a new paragraph (c)(12) to read as follows:

§1.704 Reduction of period of adjustment of patent term.

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(c) *** * ***

(12) Submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed, in which case the period of adjustment set forth in §1.703 shall be reduced by the number of days, if any, beginning on the date of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed;

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Dated: June 11, 2014.

Michelle K. Lee,
Deputy Under Secretary of Commerce for Intellectual Property and,
Deputy Director of the United States Patent and Trademark Office.

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