

(NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a safety zone and thus, is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. Under figure 2–1, paragraph (34)(g), of the Instruction, an environmental analysis checklist supporting this determination and a Categorical Exclusion Determination will be available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C., 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T01–1037 to read as follows:

§ 165.T01–1037 Safety Zone: Eastport Breakwater Terminal, Eastport, Maine.

(a) *Location.* The following area is a safety zone: All navigable waters, from surface to bottom, within the following position(s) 44°54'26" N, 066°59'00" W, 44°54'25" N, 066°58'54" W, 44°54'19" N, 066°58'55" W, 44°54'19" N, 066°59'01" W, (NAD). Friar Roads, Eastport, Maine. All positions are approximate.

(b) *Enforcement period.* This rule will be enforced from 3:00 p.m. on December 11, 2014 to 11:59 p.m. January 30, 2017.

(c) *Notification.* Coast Guard Sector Northern New England will give actual notice to mariners for the purpose of enforcement of this temporary safety zone. Also, Sector Northern New England will notify the public to the greatest extent possible of any period in which the Coast Guard will suspend enforcement of this safety zone.

(d) *Regulations.* (1) The general regulations contained in § 165.23 apply.

(2) In accordance with the general regulations in § 165.23, entry into or

movement within this zone is prohibited unless authorized by the Captain of the Port or his designated representatives.

(3) The “designated representative” is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port to act on his behalf. The designated representative may be on board a Coast Guard vessel, or on board a federal, state, or local agency vessel that is authorized to act in support of the Coast Guard.

(4) Upon being hailed by a U.S. Coast Guard vessel or his designated representatives by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed.

(5) Vessel operators desiring to enter or operate within this safety zone shall contact the Captain of the Port or his designated representatives via VHF channel 16 to obtain permission to do so.

Dated: December 12, 2014.

B. S. Gilda,

Captain, U.S. Coast Guard, Captain of the Port, Northern New England.

[FR Doc. 2015–00184 Filed 1–8–15; 8:45 am]

BILLING CODE 9110–04–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: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is revising the rules of practice pertaining to patent term adjustment 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 of 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. Accordingly, the Office is revising 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 applicant files a request for continued examination after such allowance. The Office also is revising the rules of practice to provide that the submission of a request for continued examination after any 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. The Office is providing an exception to this patent term adjustment reduction provision for a request for continued examination filed solely to submit information cited in a patent office communication in a counterpart application that is submitted to the Office within thirty days of receipt of the patent office communication. Additionally, the Office is clarifying what papers may be submitted after a notice of allowance without the applicant being considered to have failed to engage in reasonable efforts to conclude processing or examination of the application.

DATES: *Effective date:* The changes to 37 CFR 1.703 in this final rule are effective on January 9, 2015, and the changes to 37 CFR 1.704 in this final rule are effective on March 10, 2015.

Applicability date: The changes to 37 CFR 1.703 in this final rule apply to any patent granted before, on, or after January 9, 2015. 37 CFR 1.704 as adopted in this final rule applies to all original applications (other than for a design patent) filed on or after May 29, 2000, and to patents issued on such applications, except that 37 CFR 1.704(c)(12) as adopted in this final rule applies only to applications in which a request for continued examination under 35 U.S.C. 132(b) and 37 CFR 1.114 is filed on or after March 10, 2015, and 37 CFR 1.704(c)(13) as adopted in this final rule applies only to patent applications filed under 35 U.S.C. 111 on or after December 18, 2013, and international patent applications in which the national stage commenced under 35 U.S.C. 371 on or after December 18, 2013.

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 revising 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 of 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. This final rule follows the Office's earlier proposal to change the rules of practice in view of the Federal Circuit's decision in *Novartis*. See *Changes to Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee*, 79 FR 34681 (June 18, 2014) (*Novartis* notice of proposed rulemaking).

Summary of Major Provisions: The Office is revising the rules of practice to provide that the time consumed by continued examination does not include the time after the mailing date of a notice of allowance, unless the applicant files a request for continued examination under 35 U.S.C. 132(b) after such allowance. The Office also is revising the rules of practice to provide that the submission of a request for continued examination after any 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. The Office is providing an exception to this patent term adjustment reduction provision for a request for continued examination filed solely to submit information cited in a patent office communication in a counterpart application that is submitted to the Office within thirty days of receipt of the patent office communication. Additionally, the Office is clarifying what papers may be submitted after a notice of allowance without the applicant being considered to have failed to engage in reasonable efforts to conclude processing or examination of the application.

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

Background: Section 532(a) of the Uruguay Round Agreements Act or

URAA (Pub. L. 103–465, 108 Stat. 4809 (1994)) amended 35 U.S.C. 154 to provide that the term of a patent ends on the date that is twenty years from the filing date of the application, or the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). The URAA also contained provisions, codified at 35 U.S.C. 154(b), for patent term extension due to certain examination delays. Under the patent term extension provisions of 35 U.S.C. 154(b) as amended by the URAA, an applicant is entitled to patent term extension for delays due to interference (which has since been replaced by derivation), secrecy order, or successful appellate review. See 35 U.S.C. 154(b) (1995). The Office implemented the patent term extension provisions of the URAA in a final rule published in April of 1995. See *Changes to Implement 20-Year Patent Term and Provisional Applications*, 60 FR 20195 (Apr. 25, 1995) (twenty-year patent term final rule).

The American Inventors Protection Act of 1999 or AIPA (Pub. L. 106–113, 113 Stat. 1501, 1501A–552 through 1501A–591 (1999)) further amended 35 U.S.C. 154(b) to include additional bases for patent term extension (characterized as “patent term adjustment” in the AIPA). Original utility and plant patents issuing from applications filed on or after May 29, 2000, may be eligible for patent term adjustment if issuance of the patent is delayed due to one or more of the enumerated administrative delays listed in 35 U.S.C. 154(b)(1). Specifically, under the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by the AIPA, an applicant is entitled to patent term adjustment for the following reasons: (1) If the Office fails to take certain actions during the examination and issue process within specified time frames (35 U.S.C. 154(b)(1)(A)); (2) if the Office fails to issue a patent within three years of the actual filing date of the application (35 U.S.C. 154(b)(1)(B)); and (3) for delays due to interference (and now derivation), secrecy order, or successful appellate review (35 U.S.C. 154(b)(1)(C)). See 35 U.S.C. 154(b)(1). The AIPA, however, sets forth a number of conditions and limitations on any patent term adjustment accrued under 35 U.S.C. 154(b)(1). Specifically, 35 U.S.C. 154(b)(2)(C) provides, in part, 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.” 35 U.S.C. 154(b)(2)(C)(i) and (iii). The Office implemented the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by the AIPA, including setting forth circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application, in a final rule published in September of 2000. See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR 56365 (Sept. 18, 2000) (AIPA patent term adjustment final rule).

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 of 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 revising 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 the mailing date of a notice of allowance, unless the

applicant files a request for continued examination after such 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 at 56381 (response to comment 25). 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 required a modification of the Office's patent term adjustment program. The modification of the Office's patent term adjustment program required by the decision in *Novartis* has now been completed, and the patent term adjustment determinations in patents issued on or after October 7, 2014 are consistent with the Federal Circuit decision in *Novartis* and this final rule. The Office calculates the patent term adjustment manually when an applicant requests reconsideration of a patent term adjustment determination pursuant to 37 CFR 1.705. The Office has been deciding requests for reconsideration of a patent term adjustment filed pursuant to 37 CFR 1.705 consistent with the Federal Circuit decision in *Novartis* since January 15, 2014 (the date the Federal Circuit issued its decision in *Novartis*).

Nothing in this final rule shall be construed as a waiver of: (1) The requirement of 37 CFR 1.705(b) that any request for reconsideration of the patent term adjustment indicated on the patent must be by way of an application for patent term adjustment filed no later than two months from the date the patent was granted (which two-month period may be extended under the provisions of 37 CFR 1.136(a)), and be accompanied by the items specified in 37 CFR 1.705(b)(1) and (b)(2); or (2) the requirement of 35 U.S.C. 154(b)(4) that an applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under 35 U.S.C. 154(b)(3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration under 35 U.S.C. 154(b)(3)(B)(ii). In other words, nothing in this final rule excuses patentees from having to meet the time limitations set forth in 37 CFR 1.705 or

35 U.S.C. 154(b)(4) in effect at the time of the patent's issuance in order to challenge any patent term adjustment under 37 CFR 1.702 *et seq.* regarding the issues addressed in this final rule.

As discussed previously, 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)(iii), the Office is revising the rules of practice to establish that the submission of a request for continued examination after any notice of allowance has been mailed constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. This provision has been adopted to ensure that an applicant does not obtain additional patent term adjustment under 35 U.S.C. 154(b)(1)(B) for the time after a notice of allowance has been mailed as a consequence of delaying issuance of the patent by filing a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance has been mailed.

Discussion of Specific Rules

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

Section 1.703: Section 1.703(b)(1) is 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 any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151. If a first request for continued examination is filed before a notice of allowance has been mailed and a second request for continued examination is filed after a notice of allowance has been mailed, the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days in the period beginning on the date on which the first request for continued examination was filed and ending on the date of mailing of the notice of allowance following the

first request for continued examination, plus the number of days in the period beginning on the date on which the second request for continued examination was filed and ending on the date of mailing of the notice of allowance following the second request for continued examination. If a second request for continued examination is filed without a notice of allowance having been mailed between the filing of the first and second requests for continued examination and a notice of allowance is mailed after the second request for continued examination, the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days in the period beginning on the date on which the first request for continued examination was filed and ending on the date of mailing of the notice of allowance.

Section 1.704: Section 1.704(c)(10) is amended to change "other paper" to "other paper, other than a request for continued examination in compliance with § 1.114," to clarify that the filing of a request for continued examination under 35 U.S.C. 132(b) in compliance with § 1.114 is treated under § 1.704(c)(12) rather than § 1.704(c)(10).

Section 1.704(c)(12) is amended to include a new provision that establishes the submission of a request for continued examination under 35 U.S.C. 132(b) after any 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 provision has been adopted to ensure that an applicant does not obtain additional patent term adjustment under 35 U.S.C. 154(b)(1)(B) for the time after a notice of allowance has been mailed as a consequence of delaying issuance of the patent by filing a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance has been mailed. Moreover, the filing of a request for continued examination after the mailing of a notice of allowance removes the application from the issue process, prevents the Office from issuing the patent, and requires the Office to determine if the submission affects the patentability of the application, which adds to the pendency of the application in which the request for continued examination is

filed (as well as other applications since examination resources must be diverted from other applications to the application in which the request for continued examination is filed).

Section 1.704(c)(13) is amended and § 1.704(c)(14) is added to include the provisions of §§ 1.704(c)(12) and (c)(13), respectively.

Section 1.704(d) is amended to also provide that a request for continued examination in compliance with § 1.114 with submission of only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under § 1.704(c)(12), if the request for continued examination under 35 U.S.C. 132(b) is accompanied by the statement provided for in § 1.704(d).

The Office has a pilot program that reduces the need for processing a request for continued examination with an information disclosure statement filed after payment of the issue fee in order for the information disclosure statement to be considered by the examiner. See *Quick Path Information Disclosure Statement (QPIDS) Pilot Program*, 77 FR 27443 (May 10, 2012). Applicants are encouraged to use the QPIDS program when submitting an information disclosure statement after payment of the issue fee, but an applicant may file a request for continued examination with an information disclosure statement and statement under § 1.704(d) without submitting the request for continued examination and information disclosure statement via the QPIDS program. An applicant submitting an information disclosure statement filed after payment of the issue fee via the QPIDS program should also include the statement under § 1.704(d) (if appropriate) with the conditional request for continued examination submitted in accordance with the QPIDS program.

Comments and Responses to Comments: The Office received eight written comments from intellectual property organizations, industry, a law firm, individual patent practitioners, and the general public in response to the *Novartis* notice of proposed rulemaking. The comments and the Office's responses to those comments follow:

Comment 1: Several comments suggest that “time consumed by continued examination of the application requested by the applicant under section 132(b)” under 35 U.S.C. 154(b)(1)(B)(i) does not include the date of mailing of a notice of allowance, citing *Novartis*, 740 F.3d at 601 *et seq.*

Response: The Federal Circuit decision in *Novartis* does not specifically state whether the date of mailing of a notice of allowance is considered part of the “time consumed by continued examination of the application requested by the applicant under section 132(b)” within the meaning of 35 U.S.C. 154(b)(1)(B)(i). The Federal Circuit decision in *Novartis* simply discusses the time period “before allowance” and the “time after allowance, until issuance.” See *Novartis*, 740 F.3d at 602 (“we reject the PTO’s view that the time after allowance, until issuance, is ‘time consumed by continued examination’” and “‘time consumed by continued examination’ . . . is time up to allowance, but not later”) (emphasis added). The mailing of the notice of allowance is the action which concludes examination of the application and closes prosecution of the application. See *id.* (“‘examination’ presumptively ends at allowance, when prosecution is closed and there is no further examination on the merits. . . .”) (emphasis added). Thus, it is appropriate to consider the “time consumed by continued examination of the application requested by the applicant under section 132(b)” as including the date of mailing of the notice of allowance in an application that has been allowed after the filing of a request for continued examination.

In addition, treating the period of “time consumed by continued examination of the application requested by the applicant under section 132(b)” as ending on the date on which a notice of allowance is mailed (rather than the day before the date on which a notice of allowance is mailed) is consistent with how the Office treats the date on which a patent issues for purposes of 35 U.S.C. 154(b)(1)(A)(iv) (four months to issue patent term adjustment provision) and 154(b)(1)(B) (the three-year pendency patent term adjustment provision). Specifically, the Office treats the four-month period in 35 U.S.C. 154(b)(1)(A)(iv) and the three-year period in 35 U.S.C. 154(b)(1)(B) as ending on the date the patent issues (rather than day before date the patent issues), even though the patent has been granted and is in force on the date the patent issues.

Comment 2: Several comments oppose the provision in proposed § 1.703(b)(1) that if prosecution in the application is reopened, the period under § 1.702(b) does not include the period between the reopening of prosecution and the date of mailing of a subsequent notice of allowance. The comments suggest that the period under

§ 1.702(b) should include any period of post-allowance examination unless the reopening of prosecution is in response to a request for continued examination, or at least that the period of adjustment under § 1.702(b) should include any period of post-allowance examination due to the Office *sua sponte* reopening prosecution.

Response: Section 1.703(b)(1) as adopted in this final rule provides 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 any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151. Thus, any period of examination after the mailing of a notice of allowance resulting from the filing of a subsequent request for continued examination would be considered “time consumed by continued examination,” but a period of examination after the mailing of a notice of allowance resulting from the Office *sua sponte* reopening prosecution would not be considered “time consumed by continued examination” (unless the applicant subsequently files a request for continued examination).

Comment 3: One comment suggests that there is no basis for treating a second or subsequent request for continued examination after a notice of allowance as “time consumed by continued examination of the application requested by the applicant under section 132(b),” arguing that the *Novartis* court did not consider second or third requests for continued examination to be continued examination. The comment alternatively suggests that a second or subsequent request for continued examination after a notice of allowance should not be treated as “time consumed by continued examination of the application requested by the applicant under section 132(b)” unless the request for continued examination results in the mailing of an Office action under 35 U.S.C. 132. One comment states that it is not clear why “time consumed by continued examination” is defined in such a way as to include non-contiguous periods of exclusion in certain circumstances where prosecution is reopened.

Response: 35 U.S.C. 154(b)(1)(B)(i) provides that the period under 35 U.S.C. 154(b)(1)(B) does not include “any time consumed by continued examination of the application requested by the applicant under section 132(b)” (emphasis added). There is no basis for

treating a second or subsequent request for continued examination differently than the first request for continued examination with respect to period between the filing of the request for continued examination and a notice of allowance being considered “time consumed by continued examination of the application requested by the applicant under section 132(b).” The Federal Circuit decision in *Novartis* did not state that this time “consumed by continued examination of the application” under 35 U.S.C. 154(b)(1)(B)(i) includes only the time consumed by a first request for continued examination, or includes the time consumed by a request for continued examination only if the Office issues an Office action under 35 U.S.C. 132.

Treating a second or subsequent request for continued examination as not being “time consumed by continued examination of the application requested by the applicant under section 132(b)” unless the Office issues an Office action under 35 U.S.C. 132 in response to the request for continued examination would not be consistent with the statutory framework of 35 U.S.C. 131, 132, and 151. 35 U.S.C. 131 provides for examination of patent applications, specifically stating that “[t]he Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.” 35 U.S.C. 131. Thus, examination has two possible outcomes: Namely, if “on such examination it appears that the applicant is entitled to a patent under the law,” the Office issues a notice of allowance under 35 U.S.C. 151; however, if “on such examination” it does not appear that the applicant is entitled to a patent under the law, the Office issues a notice (Office action) under 35 U.S.C. 132 specifying the reasons why it does not appear that the applicant is entitled to a patent under the law. *See* 35 U.S.C. 132(a) (“Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application”). Thus, the time period between a request for continued examination and a notice of allowance is “time consumed by continued

examination of the application requested by the applicant under section 132(b)” regardless of whether the Office issues an Office action under 35 U.S.C. 132.

Finally, § 1.703(b)(1) as adopted in this final rule does not “define” “time consumed by continued examination” as generally or necessarily including non-contiguous periods. The “time consumed by continued examination” as measured by § 1.703(b)(1) will include non-contiguous periods if the applicant files a request for continued examination after a notice of allowance is mailed because the “time consumed by continued examination” includes non-contiguous periods if the applicant files a request for continued examination after a notice of allowance is mailed.

Comment 4: One comment questions how an application will be treated when multiple consecutive notices of allowance (e.g., a notice of allowance and then a supplemental notice of allowance) are mailed.

Response: The Office issues a notice of allowability (PTOL–37) and a notice of allowance (PTOL–85) when an application is in condition for allowance. The Office rarely issues multiple consecutive notices of allowance (PTOL–85) (e.g., a notice of allowance and then a supplemental notice of allowance). In the rare situation in which the Office issues multiple consecutive notices of allowance (PTOL–85), the “time consumed by continued examination of the application requested by the applicant under section 132(b)” is the number of days, if any, in the period beginning on the date on which a request for continued examination was filed and ending on the date of mailing of the first notice of allowance (PTOL–85).

The Office does occasionally mail or issue multiple consecutive notices of allowability (PTOL–37) (e.g., a notice of allowability and then a supplemental notice of allowability). In these situations, the “time consumed by continued examination of the application requested by the applicant under section 132(b)” is the number of days, if any, in the period beginning on the date on which a request for continued examination was filed and ending on the date of mailing of the notice of allowance (PTOL–85), regardless of whether the notice of allowability (PTOL–37) and notice of allowance (PTOL–85) are mailed or issued on different days, and also regardless of whether the Office has issued multiple consecutive notices of allowability (PTOL–37).

Comment 5: Several comments oppose the provisions of proposed § 1.704(c)(12) stating that applicants must file a request for continued examination when they become aware of prior art after allowance that must be submitted to the Office to comply with § 1.56. The comments further state that applicants often cannot make the statement required by § 1.97(e), and that the QPIDS program is a pilot program and thus there is no certainty that it will continue. One comment further states that an applicant who may be able to make the statement required by § 1.704(d) does not necessarily have the option of filing an information disclosure statement after allowance without filing a request for continued examination, and suggests that the Office apply the “safe harbor” provision under § 1.704(d) to proposed § 1.704(c)(12). One comment suggests that the Office should make the QPIDS pilot program permanent, and one comment suggests that the Office should provide for the filing of an information disclosure statement after payment of the issue fee without the need for filing of a request for continued examination.

Response: As discussed previously, the mailing of a notice of allowance under 35 U.S.C. 151 concludes the examination process and starts the process of preparing the application for issuance as a patent. The AIPA patent term adjustment final rule defined the submission of an amendment under § 1.312 or other paper (which would include a request for continued examination) after a notice of allowance has been given or mailed as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application (codified in § 1.704(c)(10)) because the submission of amendments (or other papers) after an application is allowed causes substantial interference with the patent issue process. *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56373 (discussion of § 1.704(c)(10)). The filing of a request for continued examination after the mailing of a notice of allowance removes the application from the issue process, prevents the Office from issuing the patent, and requires the Office to determine if the submission affects the patentability of the application, which adds to the pendency of the application in which the request for continued examination is filed (as well as other applications since examination resources must be diverted from other applications to the application in which the request for

continued examination is filed). As further indicated in the AIPA patent term adjustment final rule, “[a]n applicant who is engaging in actions or inactions that prevent or interfere with the Office’s ability to process or examine an application cannot reasonably be characterized as ‘engag[ing] in reasonable efforts to conclude processing or examination of an application’ (35 U.S.C. 154(b)(2)(C)(i)).” See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56379 (response to comment 17). Therefore, the Office considers it appropriate to expressly define the filing of a request for continued examination after the mailing of any notice of allowance as a failure to engage in reasonable efforts to conclude processing or examination of an application. See 35 U.S.C. 154(b)(2)(C)(iii) (provides for the Office to 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).

Nevertheless, the AIPA patent term adjustment final rule also indicates that the Office considers it appropriate to permit applicants to submit information cited in a patent office communication in a counterpart application to the Office without a reduction in patent term adjustment if an information disclosure statement is submitted to the Office within thirty days (not three months) of the date the patent office communication was received by an individual designated in § 1.56(c). See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56385 (response to comment 36). Section 1.704(d) was thus adopted in the AIPA patent term adjustment final rule to permit applicants to file an information disclosure statement promptly without a reduction of patent term adjustment. See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56373 (discussion of § 1.704(d)). The Office is therefore revising § 1.704(d) in this final rule to provide that a request for continued examination in compliance with § 1.114 with no submission other than an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under § 1.704(c)(12), if the request for continued examination is accompanied by a statement in compliance with § 1.704(d).

With respect to the suggestions that the Office make the QPIDS pilot program permanent and provide for the filing of an information disclosure statement after payment of the issue fee without the need for filing of a request for continued examination, the Office is currently studying the results of the QPIDS pilot program and other mechanisms for considering information disclosure statements submitted after payment of the issue fee.

Comment 6: Several comments state that the provisions of proposed § 1.704(c)(12) should apply only when there is patent term adjustment under 35 U.S.C. 154(b)(1)(B) (under the “B” provision), and should not apply to patent term adjustment under 35 U.S.C. 154(b)(1)(A) or 154(b)(1)(C) (under the “A” or “C” provision). One comment states that 35 U.S.C. 154(b)(2)(C)(ii) applies only to patent term adjustment under 35 U.S.C. 154(b)(1)(B), and thus applicant delays that may be deducted from the total patent term adjustment are only those that occur at the same time that Office delays would otherwise be included in the calculation of patent term adjustment. The comment suggests that § 1.704(b) should be revised to indicate that patent term adjustment is not reduced by applicant delays arising after the filing of a request for continued examination, since 35 U.S.C. 154(b)(2)(C)(ii) applies only to patent term adjustment under 35 U.S.C. 154(b)(1)(B).

Response: The current provisions of § 1.704(b) were adopted in the AIPA patent term adjustment final rule. See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56370–71 and 56393 (discussion of § 1.704(b) and § 1.704(b)). The Office did not propose any amendment to § 1.704(b) in the *Novartis* notice of proposed rulemaking. 35 U.S.C. 154(b)(C)(ii) provides that, with respect to adjustments to patent term made under 35 U.S.C. 154(b)(1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request. 35 U.S.C. 154(b)(C)(iii), however, further provides that the Office 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. Thus, 35 U.S.C. 154(b)(2)(C)(ii) cannot be considered exhaustive of the circumstances for

which an applicant may be determined to have failed to engage in reasonable efforts to conclude processing or examination of an application. See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56381 (response to comment 28). Under the authority in 35 U.S.C. 154(b)(2)(C)(iii), § 1.704(b) as adopted in the AIPA patent term adjustment final rule established failure to respond to a notice from the Office making any rejection, objection, argument, or other request within three months as a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application with respect to patent term adjustment under §§ 1.702(a) through (e) (corresponding to the grounds for patent term adjustment under 35 U.S.C. 154(b)(1)(A) through (C)). See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56370 (discussion of § 1.704(b)).

35 U.S.C. 154(b) provides that the period of patent term adjustment 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.” See 35 U.S.C. 154(b)(2)(C)(i). 35 U.S.C. 154(b)(1)(C)(i) does not require the applicant’s action or inaction (that amounts to a failure to engage in reasonable efforts to conclude prosecution of the application) to have caused or contributed to patent term adjustment for the period of adjustment to be reduced due to such action or inaction. See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56379 (response to comment 18). The patent term adjustment provisions of 35 U.S.C. 154(b) create a balanced system allowing for patent term adjustment due to Office delays for a reasonably diligent applicant. *Id.* Since the public has an interest in the technology disclosed and covered by a patent being available to the public at the earliest possible date, it is appropriate to reduce patent term adjustment by any period of time during which applicant failed to engage in reasonable efforts to conclude prosecution of the application, regardless of whether the applicant’s actions or inactions caused or contributed to patent term adjustment. *Id.*

Comment 7: One comment opposes the provisions of proposed § 1.704(c)(12) stating that the proposed rule undermines the three-month statutory period applicant has to review the application and pay the issue fee, and is inconsistent with the “deduction

free” three-month response periods permitted in 35 U.S.C. 154(b)(2)(C)(ii).

Response: 35 U.S.C. 151 provides a three-month period for an applicant to pay the issue fee (or permit an application to become abandoned for failure to pay the issue fee). That applicants also use this three-month period for other purposes does not mean that the three-month period in 35 U.S.C. 151 is designed for those purposes. In addition, 35 U.S.C. 154(b)(2)(C)(ii) does not provide “deduction free” three-month response periods, but rather defines a failure to reply to any Office action or notice within three months as a *per se* failure to engage in reasonable efforts to conclude processing or examination of an application (subject to reinstatement under 35 U.S.C. 154(b)(3)(C)). *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56389 (response to comment 51). As discussed previously, 35 U.S.C. 154(b)(2)(C)(iii) authorizes (or requires) the Office to 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. In any event, a request for continued examination is not, strictly speaking, a “response” to a notice of allowance. *See* 35 U.S.C. 151 (“The notice [of allowance] shall specify a sum, constituting the issue fee and any required publication fee, which shall be paid within 3 months thereafter. . . . Upon payment of this sum, the patent may issue, but if payment is not timely made, the application shall be regarded as abandoned.”).

Comment 8: One comment opposing the provisions of proposed § 1.704(c)(12) states that proposed § 1.704(c)(12) is unnecessary as multiple requests for continued examination are filed in only a low percentage of applications, and that applicants have a “legal right” to file multiple requests for continued examination. The comment further states that proposed § 1.704(c)(12) is unwarranted as it treats requests for continued examination filed after allowance differently from requests for continued examination filed prior to allowance.

Response: Section 1.114 currently permits applicants to file multiple requests for continued examination and requests for continued examination after a notice of allowance has been mailed. *See Request for Continued Examination Practice and Changes to Provisional Application Practice*, 65 FR 50092, 50095–96 (Aug. 16, 2000) (comparing the request for continued examination practice as implemented in § 1.114 with

the transitional procedure in § 1.129(a)). There is, however, a distinction between permitting an applicant to take an action (or engage in an inaction) and treating that action or inaction as not being failure to engage in reasonable efforts to conclude processing or examination of an application. *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56379 (response to comment 17) (that conduct is permitted by the rules of practice does not imply that such conduct is not a failure to engage in reasonable efforts to conclude processing or examination of an application); *see also Changes to Implement the Patent Law Treaty*, 78 FR 62368, 62384–85 (Oct. 21, 2013) (revising patent term adjustment provisions to define delays newly permitted by the Patent Law Treaty and Patent Law Treaties Implementation Act of 2012 (Pub. L. 112–211, 126 Stat. 1527 (2012)) as a failure to engage in reasonable efforts to conclude processing or examination of an application). In addition, while multiple requests for continued examination are filed in a relatively low percentage of applications, even a low percentage of activity represents thousands of applications (and patents) in view of the number of applications filed in the Office each year. In any event, that only a few applicants engage in actions or inactions that are a failure to engage in reasonable efforts to conclude processing or examination of an application does not justify excusing such applicants from the patent term adjustment consequences of their actions or inactions.

Finally, requests for continued examination filed after allowance are treated differently from requests for continued examination filed prior to allowance because applications in which a notice of allowance has been mailed are ready to be issued as a patent (subject to the applicant paying the issue fee in a timely manner). As discussed previously, the filing of a request for continued examination after the mailing of a notice of allowance removes the application from the issue process and prevents the Office from issuing the patent, which adds to the pendency of the application as well as the pendency of other applications since examination resources must be diverted from other applications to the application in which the request for continued examination was filed after a notice of allowance was filed.

Comment 9: One comment opposing the provisions of proposed § 1.704(c)(12) states that requests for the Office to correct matters in a notice of

allowability (such as an error in the claims or the failure of the Office to provide an initialed copy of an information disclosure statement) or to respond to an amendment under § 1.312 before payment of the issue fee should not be held against applicant if applicant files a request for continued examination to have such addressed.

Response: A request for continued examination should never be filed simply to obtain correction of a notice of allowability or a response to an amendment under § 1.312. An applicant may simply call the examiner to obtain the correction (such as a supplemental notice of allowability correctly indicating the allowed claims or an initialed copy of an information disclosure statement) or a response to the amendment under § 1.312 (or call the supervisory patent examiner or technology center director if the call to the examiner is unavailing). Applicants should note that filing an amendment under § 1.312 is defined as a failure to engage in reasonable efforts to conclude prosecution of the application, and will result in a reduction of any patent term adjustment, under § 1.704(c)(10).

Comment 10: One comment opposing the provisions of proposed § 1.704(c)(12) states that the filing of a request for continued examination is already a “reduction” from any patent term adjustment under 35 U.S.C. 154(b)(1)(B) (the “B” provision) and would now be an additional reduction of patent term adjustment under § 1.704(c)(12).

Response: The provisions of 35 U.S.C. 154(b)(1)(B)(i) through (iii) are not a “reduction” of patent term adjustment. Rather, 35 U.S.C. 154(b)(1)(B)(i) through (iii) simply define periods that are not included in determining whether and by how much the pendency of an application has exceeded the three-year period specified in 35 U.S.C. 154(b)(1)(B). Under §§ 1.703 and 1.704 as adopted in this final rule, if a request for continued examination is filed after any notice of allowance was mailed, any patent term adjustment would be reduced by the number of days in the period starting on the day after the date of mailing of the notice of allowance and ending on the date the request for continued examination was filed as provided in § 1.704(c)(12), and the period between the date the request for continued examination was filed and the date of mailing of the subsequent notice of allowance would not be included in determining whether and by how much the pendency of an application has exceeded the three-year period specified in 35 U.S.C. 154(b)(1)(B).

Comment 11: One comment opposing the provisions of proposed § 1.704(c)(12) states that proposed § 1.704 is unclear as to how it would work if a request for continued examination is filed after payment of the issue fee.

Response: If a request for continued examination is filed after payment of the issue fee, any patent term adjustment would be reduced by the number of days in the period starting on the day after the date of mailing of the notice of allowance and ending on the date the request for continued examination was filed.

35 U.S.C. 154(b)(1)(A)(iv) provides that, subject to the limitations under 35 U.S.C. 154(b)(2), if the issue of an original patent is delayed due to the failure of the Office to issue a patent within four months after the date on which the issue fee was paid under 35 U.S.C. 151 and all outstanding requirements were satisfied, the term of the patent shall be extended one day for each day after the date on which the issue fee was paid and all outstanding requirements were satisfied until the patent is issued. Thus, the period of adjustment under 35 U.S.C.

154(b)(1)(A)(iv), if any, is ascertained by looking back from the issue date to the most recent time at which the issue fee or another requirement was outstanding, determining the succeeding date on which the issue fee was paid and all outstanding requirements were satisfied, and measuring the number of days, if any, in the period beginning on the day after the date that is four months after such date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued. Where prosecution in an application is reopened after a notice of allowance (before or after payment of the issue fee), either by the Office *sua sponte* or as the result of an applicant filing a request for continued examination, the date on which the issue fee was paid and all outstanding requirements were satisfied is the date on which the Issue Fee Transmittal Form (PTOL-85(b)) from the ultimate notice of allowance under 35 U.S.C. 151 is returned to the Office (or a later date if there remain additional outstanding requirements, such as payment of any additional fees owed or required drawings to be submitted). See Manual of Patent Examining Procedure (MPEP) 2731. The mailing of a notice of allowance by the Office subsequent to the reopening of prosecution is the Office's indication that the application is (again) in condition to be issued as a patent, and the applicant's return of the Issue Fee Transmittal Form (PTOL-

85(b)) is the applicant's indication or confirmation that the applicant wants any previously paid issue fee to be applied as the issue fee for the patent. See MPEP 1306 ("[i]f an issue fee has previously been paid in the application as reflected in the Notice of Allowance, the return of Part B (Fee(s) Transmittal form) will be considered a request to reapply the previously paid issue fee toward the issue fee that is now due"). Thus, if prosecution in an application is reopened after a notice of allowance as the result of an applicant filing a request for continued examination, the date on which the issue fee was paid and all outstanding requirements were satisfied is the date on which the Issue Fee Transmittal Form (PTOL-85(b)) from the ultimate notice of allowance under 35 U.S.C. 151 is returned to the Office (or a later date if there remain additional outstanding requirements, such as payment of any additional fees owed or required drawings to be submitted). Applicants should note that § 1.114 does not permit an applicant to file a request for continued examination under 35 U.S.C. 132(b) after the date the issue fee is paid as a matter of right. See § 1.114(a)(1).

Comment 12: One comment states that the date of mailing of a notice of allowance should not be included in § 1.704(c)(12) if it is excluded in § 1.703(b)(1).

Response: Section 1.704(c)(12) as adopted in this final rule provides that the period of reduction begins on the "day after the date" of mailing of a notice of allowance under 35 U.S.C. 151.

Comment 13: One comment questions whether the proposed change to § 1.703 and § 1.704 will be "retroactive," how existing petitions are being treated under *Novartis*, and whether there will be any interim procedure to request recalculation under *Novartis*. Several comments suggest that the proposed change to § 1.704 should only be applied prospectively if it is adopted.

Response: The changes to § 1.703 in this final rule apply to any patent granted before, on, or after January 9, 2015. However, nothing in this final rule excuses or supersedes the timing requirements set forth in § 1.705 regarding requests for reconsideration of patent term adjustment for patents granted before, on, or after January 9, 2015. The Office has been deciding requests for reconsideration of a patent term adjustment timely filed pursuant to § 1.705 consistent with the Federal Circuit decision in *Novartis* since January 15, 2014 (the date the Federal Circuit issued its decision in *Novartis*).

As discussed in the final rule to implement the patent term adjustment provisions of the Leahy-Smith America Invents Act Technical Corrections Act (Pub. L. 112-274, 126 Stat. 2456 (2013)), because of the change to the time period for requesting reconsideration of a patent term adjustment determination adopted in that final rule, the Office is not adopting *ad hoc* procedures for requesting a patent term adjustment recalculation specifically directed to the Federal Circuit decision in *Novartis*. See *Revisions to Implement the Patent Term Adjustment Provisions of the Leahy-Smith America Invents Act Technical Corrections Act*, 79 FR 27755, 27759 (May 15, 2014) (discussion of Federal Circuit decision in *Novartis*).

The changes to 37 CFR 1.704 in this final rule apply only to applications in which a request for continued examination after a notice of allowance is filed on or after March 10, 2015.

Comment 14: One comment states that the Office should amend § 1.704(d) to provide a way to submit an information disclosure statement without any reduction of patent term adjustment when the failure to submit the information disclosure statement within the thirty-day time period provided in § 1.704 was unintentional.

Response: That a delay is "unintentional" may be an appropriate standard for the revival of an abandoned application (35 U.S.C. 27) or acceptance of a delayed maintenance fee (35 U.S.C. 41(c)), it is not an appropriate standard for the reinstatement of reduced patent term adjustment. See § 1.703(c)(2) (defining abandonment of an application as a failure to engage in reasonable efforts to conclude processing or examination of an application notwithstanding that an application may be revived if the delay is shown to have been unintentional). Patent term adjustment reduced under 35 U.S.C. 154(b)(2)(C) may be reinstated only if the applicant makes a showing that, "in spite of all due care," the applicant was unable to respond within the three-month period set forth in 35 U.S.C. 154(b)(2)(C). See 35 U.S.C. 154(b)(3)(C). The "in spite of all due care" standard in 35 U.S.C. 154(b) is significantly more stringent than the "unintentional" delay standard of 35 U.S.C. 27 and 41(c). See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56389 (response to comment 51) (discussing the "in spite of all due care" standard of 35 U.S.C. 154(b)(3)(C)). Thus, reinstatement of reduced patent term adjustment solely on the basis of "unintentional" delay would not be appropriate.

Comment 15: One comment questions whether the filing of a request for continued examination was also considered a failure under § 1.703(c)(10).

Response: The Office has, as a matter of practice, not treated the filing of a request for continued examination as a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application under § 1.703(c)(10). The Office is revising § 1.703(c)(10) in this final rule to add “other than a request for continued examination in compliance with § 1.114,” to clarify that the filing of a request for continued examination under 35 U.S.C. 132(b) in compliance with § 1.114 is treated under § 1.704(c)(12) rather than § 1.704(c)(10).

Comment 16: One comment opposing the provisions of proposed § 1.704(c)(12) states that the Federal Circuit decision in *Novartis* does not permit the Office to treat applicant actions after a notice of allowance as a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application unless the action results in the resumption of examination. The comment requests that the Office clarify what applicant actions after a notice of allowance constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

Response: The regulations setting out the circumstances that are considered a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application in § 1.704 are authorized by 35 U.S.C. 154(b)(2)(C)(iii). *See* 35 U.S.C. 154(b)(2)(C)(iii) (“The 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”). The provisions of 35 U.S.C. 154(b)(2)(C) and § 1.704(c) were not at issue in *Novartis*. Rather, the provisions of 35 U.S.C. 154(b)(1)(B) and § 1.703(b) were at issue in *Novartis*. The Federal Circuit in *Novartis* held that the period between the mailing of a notice of allowance and the issue of the patent was not “time consumed by continued examination of the application requested by the applicant under section 132(b)” under 35 U.S.C. 154(b)(1)(B)(i), unless action is taken to actually resume examination after allowance. *Novartis*, 740 F.3d at 602. That an action (or inaction) by the applicant after the allowance of an application does not result in examination, and is thus not “time

consumed by continued examination of the application requested by the applicant under section 132(b)” under 35 U.S.C. 154(b)(1)(B)(i), does not imply that an action (or inaction) by the applicant after the allowance of an application cannot be defined in § 1.704 as a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application under the authority provided in 35 U.S.C. 154(b)(2)(C)(iii).

Section 1.704(c)(10), as adopted in the AIPA patent term adjustment final rule, provides that the circumstances constituting a “failure to engage in reasonable efforts to conclude processing or examination of an application” include submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of: (1) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or (2) four months.

All new patent applications are now scanned into the Office’s Image File Wrapper (IFW) system, and all processing and examination of these applications is conducted using electronic images instead of the paper source documents. This process permits multiple employees to view the IFW file of an application concurrently, which has reduced processing delays in patent issuance for certain papers filed after the mailing of the notice of allowance. In view of the changes that have been brought about by the electronic filing and processing of patent applications, the Office is clarifying what papers may be submitted after a notice of allowance without the applicant being considered to have failed to engage in reasonable efforts to conclude processing or examination of the application under § 1.704(c)(10). Specifically, the submission of the following papers after a notice of allowance will not be considered a failure to engage in reasonable efforts to conclude processing or examination of the application under § 1.704(c)(10): (1) An Issue Fee(s) Transmittal (PTOL-85B); (2) a power of attorney; (3) a power to inspect; (4) a change of address; (5) a change of entity status (micro, small, non-small); (6) a response to the examiner’s reasons for allowance or a request to correct an error or omission in the “Notice of Allowance” or “Notice of Allowability”; (7) status letters; (8) requests for a refund; (9) an inventor’s

oath or declaration; (10) an information disclosure statement with a statement in compliance with § 1.704(d); (11) the resubmission by applicant of unlocatable paper(s) previously filed in the application (§ 1.251); (12) a request for acknowledgment of an information disclosure statement in compliance with §§ 1.97 and 1.98, provided that the applicant had requested that the examiner acknowledge the information disclosure statement prior to the notice of allowance, or the request for acknowledgement was applicant’s first opportunity to request that the examiner acknowledge the information disclosure statement; (13) comments on the substance of an interview where the applicant-initiated interview resulted in a notice of allowance; and (14) letters related to government interests (e.g., those between NASA and the Office).

The Office previously indicated that three types of these papers (written status inquiries, requests for refund, an inventor’s oath or declaration) were a type of after-allowance submission that would be considered a failure to engage in reasonable efforts to conclude processing and examination of the application. *See Clarification of 37 CFR 1.704(c)(10) □ Reduction of Patent Term Adjustment For Certain Types of Papers After a Notice of Allowance has been Mailed*, 1247 Off. Gaz. Pat. Office 111 (June 26, 2001); *see also* MPEP section 2732. The Office no longer considers submission of a written (or other type of) status inquiry, request for refund, or an inventor’s oath or declaration to be a failure to engage in reasonable efforts to conclude processing and examination of the application under § 1.704(c)(10) due to the changes that have been brought about by the electronic filing and processing of patent applications.

The Office reminds applicants that the submission of other types of papers after a notice of allowance has been given or mailed constitutes a “failure 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 lesser of: (1) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or (2) four months. *See* § 1.703(c)(10). An exemplary listing of such papers includes: (1) An amendment under § 1.312; (2) a paper containing a claim for priority or benefit or request to correct priority or benefit information (e.g., a new or supplemental application data sheet filed to correct foreign or

domestic benefit information); (3) a request for a corrected filing receipt; (4) a certified copy of a priority document; (5) drawings; (6) a letter relating to biologic deposits; (7) a request to change or correct inventorship; and (8) an information disclosure statement not accompanied by a statement in compliance with § 1.704(d).

Rulemaking Considerations

A. Administrative Procedure Act: The amendments to 37 CFR 1.703 in this rulemaking 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 applicant files a request for continued examination after such allowance, simply implements the Federal Circuit's ruling on the provisions of 35 U.S.C. 154(b)(1)(B)(i) 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 has been mailed, unless the Office actually resumes examination of the application after allowance. Therefore, the amendment to 37 CFR 1.703 eliminates any inconsistency with the Federal Circuit's determination and is simply a procedural and/or interpretive rule. See *Bachow Commc'ns Inc. v. FCC*, 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 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, published the change to 37 CFR 1.703 for comment as it sought the benefit of the public's views on the Office's implementation of the Federal Circuit's interpretation of the provisions of 35 U.S.C. 154(b)(1)(B)(i) in *Novartis*. Similarly, the change to 37 CFR 1.703, as a procedural and/or interpretive rule,

is not subject to the requirement of 5 U.S.C. 553(d) and any delayed effective date.

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

The changes to the patent term adjustment provisions do not impose any additional requirements or fees on applicants. The 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. The change to 37 CFR 1.704 specifies that the submission of a request for continued examination under 35 U.S.C. 132(b) after any 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 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. The Office received no public comment on this Regulatory Flexibility Act certification, or any of the sections under the Rulemaking Considerations, in the *Novartis* notice of proposed rulemaking. For the foregoing reasons, the changes adopted in this final rule 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 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 *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 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 any 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 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.

* * * * *

(b) * * *

(1) The number of days, if any, in the period beginning on the date on which any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151;

* * * * *

■ 3. Section 1.704 is amended by revising paragraphs (c)(10), (12), and (13) and (d)(1) and adding paragraph (c)(14) to read as follows:

§ 1.704 Reduction of period of adjustment of patent term.

* * * * *

(c) * * *

(10) Submission of an amendment under § 1.312 or other paper, other than

a request for continued examination in compliance with § 1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or

(ii) Four months;

* * * * *

(12) Submission of a request for continued examination under 35 U.S.C. 132(b) after any 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 day after 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;

(13) Failure to provide an application in condition for examination as defined in paragraph (f) of this section within eight months from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international 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 day after the date that is eight months from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application and ending on the date the application is in condition for examination as defined in paragraph (f) of this section; and

(14) Further prosecution via a continuing application, in which case the period of adjustment set forth in § 1.703 shall not include any period that is prior to the actual filing date of the application that resulted in the patent.

(d)(1) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section, and a request for continued examination in compliance with § 1.114 with no submission other than an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in

reasonable efforts to conclude prosecution (processing or examination) of the application under paragraph (c)(12) of this section, if the paper or request for continued examination is accompanied by a statement that each item of information contained in the information disclosure statement:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

* * * * *

Dated: December 17, 2014.

Michelle K. Lee,

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

[FR Doc. 2015-00061 Filed 1-8-15; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 17 and 71

RIN 2900-AN94

Caregivers Program

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts, with changes, the interim final rule concerning VA's Program of Comprehensive Assistance for Family Caregivers. VA administers this program to provide certain medical, travel, training, and financial benefits to caregivers of certain veterans and servicemembers who were seriously injured during service on or after September 11, 2001. Also addressed in this rulemaking is the Program of General Caregiver Support Services that provides support services to caregivers of veterans from all eras who are enrolled in the VA health care system. Specifically, changes in this final rule include a requirement that Veterans be notified in writing should a Family Caregiver request revocation (to no longer be a Family Caregiver), an extension of the application timeframe

from 30 days to 45 days for a Family Caregiver, and a change in the stipend calculation to ensure that Primary Family Caregivers do not experience unexpected decreases in stipend amounts from year to year.

DATES: *Effective Date:* This rule is effective on January 9, 2015.

FOR FURTHER INFORMATION CONTACT: Michael Kilmer, Chief Consultant, Veterans Health Administration, 810 Vermont Avenue, Washington, DC 20420, 202-461-6780. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose of the Final Rule

This final rule continues to implement title I of the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111-163, which was signed into law on May 5, 2010. VA has been administering the benefits program under this law continuously since May 5, 2011, under an interim final rule published in the **Federal Register** (76 FR 26148) as well as part 71 of title 38, Code of Federal Regulations (CFR). The purpose of the benefits program under this law is to provide certain medical, travel, training, and financial benefits to caregivers of certain veterans and servicemembers who were seriously injured in the line of duty on or after September 11, 2001. Among other things, title I of the law established 38 U.S.C. 1720G, which requires VA to "establish a program of comprehensive assistance for family caregivers of eligible veterans," as well as a program of "general caregiver support services" for caregivers of "veterans who are enrolled in the health care system established under [38 U.S.C. 1705(a)] (including caregivers who do not reside with such veterans)." 38 U.S.C. 1720G(a), (b).

II. Major Provisions

VA distinguishes between three types of caregivers based on the requirements of the law: Primary Family Caregivers, Secondary Family Caregivers, and General Caregivers. A Primary Family Caregiver is an individual designated as a "primary provider of personal care services" for the eligible veteran under 38 U.S.C. 1720G(a)(7)(A), who the veteran specifies on the joint application and is approved by VA as the primary provider of personal care services for the veteran. A Secondary Family Caregiver is an individual approved as a "provider of personal care services" for the eligible veteran under 38 U.S.C. 1720G(a)(6)(B), and generally serves as a back-up to the Primary

Family Caregiver. General Caregivers are "caregivers of covered veterans" under the program in 38 U.S.C. 1720G(b), and provide personal care services to covered veterans, but do not meet the criteria for designation or approval as a Primary or Secondary Family Caregiver.

In general, caregivers receive the following benefits and services:

- General Caregivers—Education and training on caring for an enrolled Veteran; use of telehealth technologies; counseling and other services under § 71.50; and respite care.

- Secondary Family Caregivers—All benefits and services available to General Caregivers; monitoring; veteran-specific instruction and training; beneficiary travel under 38 CFR part 70; ongoing technical support; and counseling.

- Primary Family Caregivers—All benefits and services available to both General Caregivers and Secondary Family Caregivers; monthly caregiver stipend; respite care available for at least 30 days per year, and may exceed 30 days per year if clinically appropriate and if requested by the Primary Family Caregiver; and health care coverage (if they are eligible).

Some of these benefits are delivered directly to veterans, such as monitoring the quality of the care provided by caregivers to ensure that the veteran is able to live in a residential setting without unnecessary deterioration of his or her disability, and safe from potential abuse or neglect. Other benefits are delivered directly to the veteran's caregiver, such as a stipend or enrollment in the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), which provides health coverage for certain Primary Family Caregivers. The fact that caregiver benefits are offered and delivered to both the veteran and his or her caregiver makes the benefits significantly different from virtually all other benefits programs offered through the Veterans Health Administration.

III. Costs and Benefits

Summary of Costs of the Caregiver Program for FY2015 Through FY2017

In developing the Regulatory Impact Analysis (RIA) for this final rule, VA did consider different alternative approaches on how best to regulate the statutory provisions of the law. More specifically, VA changed the formula and methodology to compute the caregiver stipend rate from the interim final rule. Individuals designated as the eligible Veteran's primary family caregiver are eligible to receive a monthly stipend from VA as an