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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2019-0019]

RIN 0651-AD38

Patent Term Adjustment Reductions in View of the Federal Circuit Decision in

Supernus Pharm., Inc. v. Iancu

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

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (USPTO or 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 *Supernus Pharm., Inc. v. Iancu* (*Supernus*). The Federal Circuit in *Supernus* held that a reduction of patent term adjustment must be equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application. The USPTO is revising the provisions pertaining to reduction of patent term adjustment for alignment with the Federal Circuit decision in *Supernus*.

DATES: *Effective date:* This final rule is effective on [Insert date 30 days after the date of publication in the FEDERAL REGISTER].

Applicability date: The changes in this final rule apply to original utility and plant patents issuing from applications filed on or after May 29, 2000, in which a notice of allowance

was mailed on or after [Insert date 30 days after the date of publication in the FEDERAL REGISTER].

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 USPTO 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 *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351 (Fed. Cir. 2019). The Federal Circuit in *Supernus* held that a reduction of patent term adjustment under 35 U.S.C. 154(b)(2)(C) must be equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application. The regulations pertaining to a reduction of patent term adjustment due to a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application are set forth in 37 CFR 1.704. Several provisions in 37 CFR 1.704 (i.e., 37 CFR 1.704(c)(2), (3), (6), (9), and (10)) specify a period of reduction corresponding to the consequences to the USPTO of the applicant's failure to engage in reasonable efforts to conclude prosecution, rather than "the period from the beginning to the end of the applicant's failure to engage in reasonable efforts to conclude prosecution," as provided for in *Supernus*. 913 F.3d at 1359. Therefore, the USPTO is revising these provisions of 37 CFR 1.704 for consistency with the Federal Circuit's decision in *Supernus*.

Summary of Major Provisions: This rulemaking pertains to the patent term adjustment regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and resulting reduction of any patent term adjustment (37 CFR 1.704). This rulemaking specifically revises the period of reduction of patent term adjustment in the provisions of 37 CFR 1.704 pertaining to deferral of issuance of a patent (37 CFR 1.704(c)(2)), abandonment of an application (37 CFR 1.704(c)(3)), submission of a preliminary amendment (37 CFR 1.704(c)(6)), submission of papers after a decision by the Patent Trial and Appeal Board or by a Federal court (37 CFR 1.704(c)(9)), and submission of papers after a notice of allowance under 35 U.S.C. 151 (37 CFR 1.704(c)(10)) to specify a period of reduction corresponding to “the period from the beginning to the end of the applicant’s failure to engage in reasonable efforts to conclude prosecution” (rather than corresponding to the consequences to the USPTO of the applicant’s failure to engage in reasonable efforts to conclude prosecution) for consistency with the Federal Circuit’s decision in *Supernus*. 913 F.3d at 1359. This rulemaking also revises 37 CFR 1.704(c)(10) to exclude after-allowance amendments or other after-allowance papers that are “expressly requested by the Office” from the after-allowance amendments or other after-allowance papers that will result in a reduction of patent term adjustment under 37 CFR 1.704(c)(10).

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 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 (termed “patent term adjustment” in the AIPA). Generally, 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 USPTO fails to take certain actions during the examination and issue process within specified time frames (35 U.S.C. 154(b)(1)(A)) (known as “A” delays); (2) if the USPTO fails to issue a patent within three years of the actual filing date of the application (35 U.S.C. 154(b)(1)(B)) (known as “B” delays); and (3) for delays due to interference (and now derivation), secrecy order, or successful appellate review (35 U.S.C. 154(b)(1)(C)) (known as “C” delays). *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). *See* 35 U.S.C. 154(b)(2). 35 U.S.C. 154(b)(2)(C) sets forth one such limitation, providing, 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 USPTO implemented the AIPA patent term adjustment provisions of 35 U.S.C. 154(b), including setting forth circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and resulting in a reduction of any patent term adjustment, 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). The regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and resulting reduction of any patent term adjustment are set forth in 37 CFR 1.704.

In January 2019, the Federal Circuit issued a decision in *Supernus* pertaining to the patent term adjustment provisions of 35 U.S.C. 154(b)(2)(C). The Federal Circuit confirmed that 37 CFR 1.704(c)(8) “‘is a reasonable interpretation of the [patent term adjustment] statute’ insofar as it includes ‘not only applicant conduct or behavior that result in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred.’” *Supernus*, 913 F.3d at 1356 (quoting *Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1349-50 (Fed. Cir. 2015)). The Federal Circuit, however, held that the USPTO may not reduce patent term adjustment by a period that

exceeds the “time during which the applicant failed to engage in reasonable efforts” to conclude prosecution, specifically stating that “[o]n the basis of the plain language of [35 U.S.C. 154(b)(2)(C)(i),] ... the [USPTO] may not count as applicant delay a period of time during which there was no action that the applicant could take to conclude prosecution of the patent.” *Id.* at 1358. The Federal Circuit specifically stated that:

Thus, the statutory period of PTA reduction must be the same number of days as the period from the beginning to the end of the applicant’s failure to engage in reasonable efforts to conclude prosecution. PTA cannot be reduced by a period of time during which there is no identifiable effort in which the applicant could have engaged to conclude prosecution because such time would not be “equal to” and would instead exceed the time during which an applicant failed to engage in reasonable efforts.

Id. at 1359.

37 CFR 1.704(c)(1) through (c)(14) set forth: (1) the exemplary circumstances prescribed by the USPTO “that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application” pursuant to 35 U.S.C.

154(b)(2)(C)(iii); and (2) the resulting period of reduction of any patent term adjustment.

The Federal Circuit decision in *Supernus* involved a reduction to patent term adjustment under the provisions of 37 CFR 1.704(c)(8). The period of reduction of patent term

adjustment in 37 CFR 1.704(c)(8) is as follows: “the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the

supplemental reply or other such paper was filed.” 37 CFR 1.704(c)(8). This period

corresponds to “the period from the beginning to the end of the applicant’s failure to

engage in reasonable efforts to conclude prosecution,” except in the rare situation in

which such period includes “a period of time during which there is no identifiable effort

in which the applicant could have engaged to conclude prosecution.” *Supernus*, 913 F.3d at 1359. The USPTO published a notice in May of 2019 setting out its implementation of *Supernus* with respect to the provisions of 37 CFR 1.704(c)(8) and other provisions of 37 CFR 1.704(c) that may include “a period of time during which there is no identifiable effort in which the applicant could have engaged to conclude prosecution.” *See Patent Term Adjustment Procedures in View of the Federal Circuit Decision in Supernus Pharm., Inc. v. Iancu*, 84 FR 20343 (May 9, 2019).

While the Federal Circuit decision in *Supernus* involved 37 CFR 1.704(c)(8), there are several provisions in 37 CFR 1.704(c)(1) through (c)(14) whose period of reduction corresponds to or includes the consequences to the USPTO of the applicant’s failure to engage in reasonable efforts to conclude prosecution, rather than “the period from the beginning to the end of the applicant’s failure to engage in reasonable efforts to conclude prosecution.” *Supernus*, 913 F.3d at 1359. Therefore, the USPTO is revising the periods of reduction of patent term adjustment in 37 CFR 1.704(c) for consistency with the Federal Circuit’s decision in *Supernus*. The USPTO is also revising 37 CFR 1.704(c)(10) to exclude after-allowance amendments or other after-allowance papers that are “expressly requested by the Office” from the after-allowance amendments or other after-allowance papers that will result in a reduction of patent term adjustment under 37 CFR 1.704(c)(10).

Discussion of Specific Rules

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

Section 1.704(c)(2) is amended to change “the date the patent was issued” to “the earlier of the date a request to terminate the deferral was filed or the date the patent was issued.” The period of reduction of patent term adjustment in § 1.704(c)(2) is now as follows: “the number of days, if any, beginning on the date a request for deferral of issuance of a patent under § 1.314 was filed and ending on the earlier of the date a request to terminate the deferral was filed or the date the patent was issued.”

Section 1.704(c)(3) is amended to change “the earlier of: (i) The date of mailing of the decision reviving the application or accepting late payment of the issue fee; or (ii) The date that is four months after the date the grantable petition to revive the application or accept late payment of the issue fee was filed” to “the date the grantable petition to revive the application or accept late payment of the issue fee was filed.” The period of reduction of patent term adjustment in § 1.704(c)(3) is now as follows: “the number of days, if any, beginning on the date of abandonment or the day after the date the issue fee was due and ending on the date the grantable petition to revive the application or accept late payment of the issue fee was filed.”

Section 1.704(c)(6) is amended to change “the lesser of: (i) The number of days, if any, beginning on the day after the mailing date of the original Office action or notice of allowance and ending on the date of mailing of the supplemental Office action or notice of allowance; or (ii) Four months” to “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 preliminary amendment or other preliminary paper was filed.” This eight-month period corresponds to the eight-month period in § 1.704(c)(13) for placing an application in condition for examination. *See Changes to Implement the Patent Law Treaty*, 78 FR 62367, 62385 (Oct. 21, 2013) (an application is expected to be in condition for examination no later than eight months from its filing date (or date of commencement of the national stage in an international application)). The period of reduction of patent term adjustment in § 1.704(c)(6) is now as follows: “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 preliminary amendment or other preliminary paper was filed.”

Section 1.704(c)(9) is amended to change “the lesser of: (i) The number of days, if any, beginning on the day after the mailing date of the original Office action or notice of allowance and ending on the mailing date of the supplemental Office action or notice of allowance; or (ii) Four months” to “the number of days, if any, beginning on the day after the date of the decision by the Patent Trial and Appeal Board or by a Federal court and ending on date the amendment or other paper was filed.” The period of reduction of patent term adjustment in § 1.704(c)(9) is now as follows: “the number of days, if any, beginning on the day after the date of the decision by the Patent Trial and Appeal Board or by a Federal court and ending on date the amendment or other paper was filed.”

Section 1.704(c)(10) is amended to change “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” to “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 amendment under § 1.312 or other paper was filed.” The period of reduction of patent term adjustment in § 1.704(c)(10) is now as follows: “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 amendment under § 1.312 or other paper was filed.”

Section 1.704(c)(10) is also amended to exclude “an amendment under § 1.312 or other paper expressly requested by the Office” from the amendments under § 1.312 or other papers filed after a notice of allowance that will result in a reduction of patent term adjustment under § 1.704(c)(10). Thus, an amendment under § 1.312 or other paper not expressly requested by the USPTO (i.e., a “voluntary” amendment under § 1.312 or other paper) after the notice of allowance will result in a reduction of patent term adjustment under § 1.704(c)(10). An amendment under § 1.312 or other paper going beyond what was requested by the USPTO (i.e., including material not expressly requested by the USPTO in addition to what was requested by the USPTO) would not be considered “an amendment under § 1.312 or other paper expressly requested by the Office” under § 1.704(c)(10). In addition, the phrase “expressly requested by the Office” requires a specific request in an Office action or notice, or in an Examiner’s Interview Summary (PTOL-413), for the amendment under § 1.312 or other paper. For example, generic

language in an Office action or notice, such as a statement in a notice of allowability containing an examiner's amendment indicating that if the changes and/or additions are unacceptable to applicant, an amendment may be filed as provided by § 1.312 (section 1302.04 of the Manual of Patent Examining Procedure (MPEP)), is not a basis for considering an amendment under § 1.312 to be "expressly requested by the Office" within the meaning of § 1.704(c)(10) as adopted in this final rule. Similarly, the provisions of §§ 1.56, 1.97, and 1.98 are not a basis for considering an information disclosure statement including information that has come to the attention of the applicant after a notice of allowance has been given or mailed to be a paper "expressly requested by the Office" within the meaning of § 1.704(c)(10). An information disclosure statement in compliance with §§ 1.97 and 1.98, however, will not be considered a failure to engage in reasonable efforts to conclude prosecution of the application under § 1.704(c)(10) (or § 1.704(c)(6), (8), or (9) if the information disclosure statement is accompanied by a statement under § 1.704(d)). Finally, an amendment under § 1.312 or other paper expressly requested by the USPTO not filed within three months from the date of mailing or transmission of the USPTO communication notifying the applicant of such request will result in a reduction of patent term adjustment under § 1.704(b).

Section 1.704(c) is also amended to change "mailing date" to "date of mailing" throughout for consistency with the other regulations pertaining to AIPA patent term adjustment (§§ 1.702 through 1.705) and URAA patent term extension (§ 1.701). The USPTO has been issuing Office actions and notices through the Electronic Office Action Program since June of 2009 for patent applicants choosing this form of notification. *See Electronic Office Action*, 1343 *Off. Gaz. Pat. Office* 45 (June 2, 2009). The term "date of

mailing” as used in the regulations pertaining to AIPA patent term adjustment and URAA patent term extension means the mailroom/notification date indicated on the form PTOL-90 accompanying the Office action or notice communication. *See Electronic Office Action*, 1343 *Off. Gaz. Pat. Office* at 46 (“The mailroom/notification date will also be considered the date of mailing of the correspondence for all other purposes (e.g., [§§] 1.71(g)(2), 1.97(b), 1.701 through 1.705)”).

Applicability of the Changes in This Final Rule

The AIPA patent term adjustment provisions apply to original utility and plant patents issuing from applications filed on or after May 29, 2000 (applications and patents eligible for patent term adjustment). The changes in this final rule apply to all applications and patents eligible for patent term adjustment in which a notice of allowance was mailed on or after [Insert date 30 days after the date of publication in the FEDERAL REGISTER]. The USPTO makes the patent term adjustment determination indicated in the patent by a computer program that uses the information recorded in the USPTO’s Patent Application Locating and Monitoring (PALM) system (except when an applicant requests reconsideration pursuant to § 1.705(b)). *See* 65 FR at 56381 (response to comment 25). The USPTO is in the process of modifying its patent term adjustment program to implement the changes in this final rule. The USPTO calculates the patent term adjustment manually when an applicant requests reconsideration of a patent term adjustment determination pursuant to § 1.705(b) (the fee required for a reconsideration of a patent term adjustment determination pursuant to § 1.705(b) partially covers the USPTO’s cost of performing a manual patent term adjustment determination). The

USPTO will decide any timely request for reconsideration in compliance with § 1.705(b) of a patent term adjustment determination in applications and patents eligible for patent term adjustment in which a notice of allowance was mailed on or after [Insert date 30 days after the date of publication in the FEDERAL REGISTER], consistent with the changes in this final rule.

While the USPTO has adopted *ad hoc* procedures for seeking reconsideration of the patent term adjustment determination in the past when there have been changes to the interpretation of the provisions of 35 U.S.C. 154(b) as a result of court decisions, these *ad hoc* procedures were adopted because former 35 U.S.C. 154(b)(4) provided a time period for seeking judicial review that was not related to the filing of a request for reconsideration of the USPTO's patent term adjustment determination or the date of the USPTO's decision on any request for reconsideration of the USPTO's patent term adjustment determination. *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). As § 1.705(b) now provides that its two-month time period may be extended under the provisions of § 1.136(a) (permitting an applicant to request reconsideration of the patent term adjustment indicated on the patent as late as seven months after the date the patent was granted), the USPTO is not adopting an *ad hoc* procedure for requesting a patent term adjustment recalculation directed to the changes in this final rule. The USPTO will decide any timely request for reconsideration in compliance with § 1.705(b) of a patent term adjustment determination in applications and patents eligible for patent term adjustment in which a notice of allowance was mailed

before [Insert date 30 days after the date of publication in the FEDERAL REGISTER], consistent with the changes in this final rule, if requested by the patentee.

Comments and Responses to Comments

The USPTO published a notice proposing changes to the rules of practice pertaining to patent term adjustment in view of the decision by the Federal Circuit in *Supernus*. See *Patent Term Adjustment Reductions in View of the Federal Circuit Decision in Supernus Pharm., Inc. v. Iancu*, 84 FR 53090 (Oct. 4, 2019). In response to the notice of proposed rulemaking, the USPTO received seven comments from three submitters, more particularly, from an intellectual property organization, a healthcare company, and an individual patent practitioner. The comments were supportive of the proposed changes to § 1.704(c) but included specific suggestions and questions. The comments and the USPTO's responses thereto follow:

Comment (1): One comment suggests that the USPTO confirm that the patent term reduction under § 1.704(c)(3) does not apply where a notice of abandonment has been withdrawn by the USPTO, either *sua sponte* or as the result of a petition.

Response: Section 1.704(c)(3) addresses the situation in which an abandoned application has been revived (§ 1.137), whereas § 1.704(c)(4) addresses the situation in which a holding of abandonment is withdrawn, and § 1.704(c)(4) has not been amended in this final rule. Section 1.704(c)(4) continues to provide that the failure to file a petition to withdraw the holding of abandonment or to revive an application within two months from the date of mailing of a notice of abandonment will result in the period of adjustment set forth in § 1.703 being reduced by “the number of days, if any, beginning

on the day after the date two months from the date of mailing of a notice of abandonment and ending on the date a petition to withdraw the holding of abandonment or to revive the application was filed.”

Comment (2): One comment seeks clarification whether the USPTO would extend the eight-month period to respond to the next business day if the eight-month period ends on a Saturday, Sunday, or Federal holiday under proposed § 1.704(c)(6).

Response: Under 35 U.S.C. 21(b), “[w]hen the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a Federal holiday within the District of Columbia, the action may be taken, or fee paid, on the next succeeding secular or business day.” Accordingly, any reduction under § 1.704(c)(6), as adopted in this final rule, would begin on the day after the next succeeding secular or business day in this situation. For example, if an application was filed on May 18, 2019, and the USPTO mailed an Office action on February 28, 2020, but the applicant had filed a preliminary amendment on February 17, 2020, that required a supplemental Office action addressing the preliminary amendment, the eight-month period would end on Tuesday January 21, 2020, under § 1.704(c)(6), as adopted in this final rule, because January 18 and 19, 2020, were weekend days and January 20, 2020, was a Federal holiday. Thus, the period of reduction under § 1.704(c)(6), as adopted in this final rule, would begin on Wednesday, January 22, 2020 (i.e., Wednesday, January 22, 2020, would be “day one”), and end on February 17, 2020.

Comment (3): One comment requests clarification whether an applicant could avoid a reduction of patent term adjustment under § 1.704(c)(6) for the submission of a

preliminary amendment or other paper by having the examiner expressly request that the applicant submit the preliminary amendment or other paper.

Response: Section 1.706(c)(6) does not contain a provision for preliminary amendments or other papers expressly requested by the examiner (like § 1.704(c)(8)). Section 1.704(c)(6), however, does not result in a reduction of patent term adjustment unless the preliminary amendment or other preliminary paper: (1) is submitted less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151; and (2) requires the mailing of a supplemental Office action or notice of allowance. A preliminary amendment or other paper expressly requested by the examiner should not require the mailing of a supplemental Office action or notice of allowance.

Comment (4): One comment suggests that the USPTO do a further study of the impact to § 1.704(c)(6).

Response: The eight-month period in § 1.704(c)(6), as adopted in this final rule, is consistent with the eight-month period in § 1.704(c)(13), which is the time period at which an application is expected to be in condition for examination. *See* 78 FR at 62385. The USPTO's first action pendency has been decreasing in recent years, and the USPTO expects that trend to continue. The USPTO will monitor the impact that delays in placing an application in condition for examination have on first action pendency and will adjust the time periods in § 1.704(c)(6) and (c)(13) as appropriate.

Comment (5): Several comments request clarification regarding § 1.704(c)(10) and the submission of drawings and other papers in response to a notice received from the USPTO. The comments suggest that the USPTO should make a distinction as to

whether the papers are being voluntarily submitted or are being submitted in response to an Office action or notice from the USPTO.

Response: Section 1.704(c)(10), as adopted in this final rule, excludes “an amendment under § 1.312 or other paper expressly requested by the Office” from the amendments under § 1.312 or other papers filed after a notice of allowance that will result in a reduction of patent term adjustment. Thus, only an amendment under § 1.312 or other paper not expressly requested by the USPTO (i.e., a “voluntary” amendment under § 1.312 or other paper) after the notice of allowance will result in a reduction of patent term adjustment under § 1.704(c)(10), as adopted in this final rule. An amendment under § 1.312 or other paper expressly requested by the USPTO filed more than three months from the date of mailing or transmission of the USPTO communication notifying the applicant of such request, however, will result in a reduction of patent term adjustment under § 1.704(b). Thus, an amendment under § 1.312 or other paper expressly requested by the USPTO submitted within three months of the date of mailing or transmission of the Office action or notice requiring such an amendment under § 1.312 or other paper will not result in a reduction of patent term adjustment.

Comment (6): One comment asks whether the proposed change to § 1.704(c)(10) affects the list of other papers not considered to be a failure to engage in unreasonable efforts under this provision.

Response: The USPTO has previously indicated that the submission of the following papers after a notice of allowance will **not** result in a reduction of patent term adjustment under § 1.704(c)(10): (1) Fee(s) Transmittal (PTOL-85B); (2) power of attorney; (3) power to inspect; (4) change of address; (5) change of entity status

(micro/small/not small entity status); (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 the 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 the 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 USPTO). *See Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee*, 80 FR 1346, 1354 (Jan. 9, 2015); *see also* MPEP 2732. The USPTO is not changing this indication of papers submitted after a notice of allowance that will not result in a reduction of patent term adjustment under § 1.704(c)(10), except to also exclude "an amendment under § 1.312 or other paper expressly requested by the Office" from the amendments under § 1.312 or other papers filed after a notice of allowance that will result in a reduction of patent term adjustment under § 1.704(c)(10).

Comment (7): One comment suggests that the rule change be applied prospectively because it will alter patent prosecution. The comment also asks the USPTO to clarify what impact the rule changes would have on issued patents.

Response: The changes to § 1.704 in this final rule apply to applications and patents eligible for patent term adjustment in which a notice of allowance was mailed on or after [Insert date 30 days after the date of publication in the FEDERAL REGISTER]. The USPTO, however, will decide any timely request for reconsideration in compliance with § 1.705(b) of a patent term adjustment determination in applications and patents eligible for patent term adjustment in which a notice of allowance was mailed before [Insert date 30 days after the date of publication in the FEDERAL REGISTER] consistent with the changes in this final rule if requested by the patentee.

Rulemaking Considerations

A. Administrative Procedure Act

The changes in this rulemaking involve rules of agency practice and procedure and/or interpretive rules. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015) (Interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers.” (citation and internal quotation marks omitted)); *Nat’l Org. of Veterans’ Advocates v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Rule that clarifies interpretation of a statute is interpretive.); *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.). Specifically, this rulemaking revises USPTO rules that interpret certain statutory provisions pertaining to patent term adjustment to specify a period of reduction corresponding to “the period from

the beginning to the end of the applicant’s failure to engage in reasonable efforts to conclude prosecution” (rather than to the consequences to the USPTO of the applicant’s failure to engage in reasonable efforts to conclude prosecution) for consistency with the Federal Circuit’s decision in *Supernus*. 913 F.3d at 1359.

Accordingly, prior notice and opportunity for public comment for the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c) or any other law. *See Perez*, 575 U.S. at 101 (Notice-and-comment procedures are required neither when an agency “issue[s] an initial interpretive rule” nor “when it amends or repeals that interpretive rule.”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” (quoting 5 U.S.C. 553(b)(A))). However, the USPTO chose to seek public comment before implementing the rule to benefit from the public’s input.

B. Regulatory Flexibility Act

For the reasons set forth herein, the Senior Counsel for Regulatory and Legislative Affairs in the Office General Law of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that the changes adopted in this notice will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

This rulemaking does not impose any additional requirements or fees on applicants. This rulemaking also does not change the circumstances defined as constituting 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)(iii)). This rulemaking implements the Federal Circuit’s ruling on the provisions of 35 U.S.C. 154(b)(2)(C)(i) in *Supernus* to reflect the applicable period of reduction in the event that there is a failure of an applicant to engage in reasonable efforts to conclude processing or examination. This rulemaking specifically revises the period of reduction of patent term adjustment in the provisions of 37 CFR 1.704 pertaining to deferral of issuance of a patent (37 CFR 1.704(c)(2)), abandonment of an application (37 CFR 1.704(c)(3)), submission of a preliminary amendment (37 CFR 1.704(c)(6)), submission of papers after a decision by the Patent Trial and Appeal Board or by a Federal court (37 CFR 1.704(c)(9)), and submission of papers after a notice of allowance under 35 U.S.C. 151 (37 CFR 1.704(c)(10)) to specify a period of reduction corresponding to “the period from the beginning to the end of the applicant’s failure to engage in reasonable efforts to conclude prosecution” (rather than to the consequences to the USPTO of the applicant’s failure to engage in reasonable efforts to conclude prosecution) for consistency with the Federal Circuit’s decision in *Supernus*. 913 F.3d at 1359. The changes in this rulemaking will not have a significant economic impact on a substantial number of small entities because applicants are not entitled to patent term adjustment that have not been reduced by a period equal to the period of the applicant’s failure to engage in reasonable efforts to conclude processing or examination (35 U.S.C. 154(b)(2)(C)(i) and 37 CFR 1.704(a)), and because applicants may avoid adverse patent term adjustment consequences by refraining from actions or inactions defined as constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination.

For the foregoing reasons, the changes 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 under Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review)

The USPTO has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the USPTO has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rulemaking is not an Executive Order 13771 (Jan. 30, 2017) regulatory action because it is not significant under Executive Order 12866 (Sept. 30, 1993).

F. Executive Order 13132 (Federalism)

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

G. Executive Order 13175 (Tribal Consultation)

This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

H. Executive Order 13211 (Energy Effects)

This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

I. Executive Order 13783 (Promoting Energy Independence and Economic Growth)

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

J. Executive Order 13772 (Core Principles for Regulating the United States Financial System)

This rulemaking does not involve regulation of the United States financial system under Executive Order 13772 (Feb. 3, 2017).

K. Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden, as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

L. Executive Order 13045 (Protection of Children)

This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

M. Executive Order 12630 (Taking of Private Property)

This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

N. Congressional Review Act

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

O. Unfunded Mandates Reform Act of 1995

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

P. National Environmental Policy Act

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

Q. National Technology Transfer and Advancement Act

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

R. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the USPTO 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.

This rulemaking does not impose any additional requirements (including information collection requirements) or fees for patent applicants or patentees. Therefore, the USPTO 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, Biologics, 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 1.704 is amended by revising paragraph (c) to read as follows:

§ 1.704 Reduction of Period of Adjustment of Patent Term.

* * * * *

(c) Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping:

(1) Suspension of action under § 1.103 at the applicant's request, 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 a request for suspension of action under § 1.103 was filed and ending on the date of the termination of the suspension;

(2) Deferral of issuance of a patent under § 1.314, 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 a request for deferral of issuance of a patent under § 1.314 was filed and ending on the earlier of the date a request to terminate the deferral was filed or the date the patent was issued;

(3) Abandonment of the application or late payment of the issue fee, 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 abandonment or the day after the date the issue fee was due and ending on the date the grantable petition to revive the application or accept late payment of the issue fee was filed;

(4) Failure to file a petition to withdraw the holding of abandonment or to revive an application within two months from the date of mailing of a notice of abandonment, 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 two months from the date of mailing of a notice of abandonment and ending on the date a petition to withdraw the holding of abandonment or to revive the application was filed;

(5) Conversion of a provisional application under 35 U.S.C. 111(b) to a nonprovisional application under 35 U.S.C. 111(a) pursuant to 35 U.S.C. 111(b)(5), 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 the application was filed under 35 U.S.C. 111(b) and ending on the date a request in compliance with § 1.53(c)(3) to convert the provisional application into a nonprovisional application was filed;

(6) Submission of a preliminary amendment or other preliminary paper less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 that requires the mailing of a supplemental Office action or notice of allowance, 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 preliminary amendment or other preliminary paper was filed;

(7) Submission of a reply having an omission (§ 1.135(c)), 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 the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed;

(8) Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, 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 the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed;

(9) Submission of an amendment or other paper after a decision by the Patent Trial and Appeal Board, other than a decision designated as containing a new ground of rejection under § 41.50(b) of this title or statement under § 41.50(c) of this title, or a decision by a Federal court, less than one month before the mailing of an Office action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 that requires the

mailing of a supplemental Office action or supplemental notice of allowance, 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 the decision by the Patent Trial and Appeal Board or by a Federal court and ending on date the amendment or other paper was filed;

(10) Submission of an amendment under § 1.312 or other paper, other than an amendment under § 1.312 or other paper expressly requested by the Office or 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 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 amendment under § 1.312 or other paper was filed;

(11) Failure to file an appeal brief in compliance with § 41.37 of this chapter within three months from the date on which a notice of appeal to the Patent Trial and Appeal Board was filed under 35 U.S.C. 134 and § 41.31 of this chapter, 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 three months from the date on which a notice of appeal to the Patent Trial and Appeal Board was filed under 35 U.S.C. 134 and § 41.31 of this chapter, and ending on the date an appeal brief in compliance with § 41.37 of this chapter or a request for continued examination in compliance with § 1.114 was filed;

(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.

* * * * *

Andrei Iancu,

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

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