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Mail Stop Comments- Patents  
Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Attention: Kery A. Fries  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner for Patent Examination Policy

From: Japan Tobacco Inc.

Re: Comments in Response to Notice of Proposed Rulemaking, Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee, 79 Fed. Reg. 34681 (June 18, 2014)

Dear Mr. Commissioner:

Japan Tobacco Inc. hereby submits comments in response to the Notice of Proposed Rulemaking (“Notice”).

### **I. The problem to be addressed by the proposed rulemaking**

The Notice proposes amending 37 C.F.R. § 1.703(b)(1) to address the current practice of the United States Patent and Trademark Office (“Office”) of categorically denying patent term adjustment (PTA) under 35 USC § 154(b)(1)(B) subsequent to the filing of a request for continued examination. A revision of 37 C.F.R. § 1.703(b)(1) is required in view of the mandate of the controlling statutory provision, as recently interpreted in Novartis v. Lee, 740 F.3d 593 (Fed. Cir. 2014).

### **(A) Statutory and regulatory framework for B Delay**

Section 154(b)(1)(B) of Title 35 provides for extension of the term of a patent for failure of the Office to issue a patent within three years of the filing date of an application (“B Delay”). The statute provides several narrowly tailored time periods that are to be excluded from B Delay. One of the periods excluded by the statute is time consumed by continued examination requested by the applicant.

“[I]f the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including …any time consumed by continued examination of the application requested by the applicant under section 132(b) …, the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.” 35 USC § 154(b)(1)(B)(i) (emphasis added).

The Office originally promulgated 37 C.F.R. § 1.703(b)(1) in an effort to implement this statutory provision.

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed … and ending on the date a patent was issued, but not including the sum of the following periods:

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

The original regulation defines the period of “time consumed by continued examination of the application requested by the applicant” from the filing of a request for continued examination under 35 U.S.C. 132(b) to and including the date of issuance of the patent. The court in Novartis v. Lee held this regulation to be inconsistent with the controlling statute, 35 USC § 154(b)(1)(B)(i).

**(B) The proposed revision of 37 C.F.R. § 1.703(b)(1)**

The Notice proposes revising 37 C.F.R. § 1.703(b)(1) as follows

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed ... and ending on the date a patent was issued, but not including the sum of the following periods:

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

The proposed revised regulation defines the statutory period of “time consumed by continued examination of the application requested by the applicant under section 132(b)” as (i) extending from the filing of a request for continued examination under 35 U.S.C. § 132(b) to and including the date of mailing of a notice of allowance, and (ii) including post-allowance examination initiated by the Office’s mailing of an Office Action that reopens prosecution.

**(C) The date of mailing of a notice of allowance should not be included as “time consumed by continued examination of the application”**

The proposed revision to 37 C.F.R. § 1.703(b)(1) includes the date of mailing of a notice of allowance as “time consumed by continued examination of the application” that is to be excluded from B delay. For the following reasons, the proposed revision is (like the regulation it is intended to replace) inconsistent with the controlling statute.

“An ‘examination’ presumptively ends at allowance, when prosecution is closed and there is no further examination on the merits in the absence of a special reopening.” Novartis at 602. “Prosecution in an application is closed as used in this section means that ... the last Office action is ... a notice of allowance...” 37 CFR § 1.114(b).

“If prosecution in an application is closed, an applicant may request continued examination of the application...” 37 CFR § 1.114(a).

The Office’s own request for continued examination regulations under 37 CFR § 1.114 make it abundantly clear that prosecution of an application is closed on the date that a notice of allowance is mailed, at which time an applicant may file a request for continued examination if it has a submission that it wants to have considered by the examiner. However, the proposed revision to 37 C.F.R. § 1.703(b)(1) takes the untenable position that “continued examination of the application” (the language of 35 USC § 154(b)(1)(B)(i)) occurs on a date where prosecution is closed (i.e., the date that a notice of allowance is mailed) and the only way for the applicant to obtain continued examination is to file a request for continued examination.

To render it consistent with the controlling statute, the revised regulation should be further revised to specify that the “time consumed by continued examination” ends the day before the date of the mailing of the notice of allowance. Given the court’s adoption of the Novartis position “that the ‘time consumed by continued examination’ should be limited to the time before allowance...” the Office lacks any basis to reach an outcome in the revised regulation other than that provided by the court. Novartis at 601-02 (emphasis added).

In addition to the foregoing, proposed new 37 C.F.R. § 1.704(c)(12) seeks to reduce PTA (in applications where a request for continued examination is filed after a notice of allowance) for a period that includes the date of the mailing of a notice of allowance. When the effects of the two proposed new rules are considered in combination, an application in which a request for continued examination is filed would be categorically prevented from receiving PTA for *any* date on which a notice of allowance is mailed. All notice of allowance dates in continued examination cases would be either excluded from B Delay by § 1.703(b)(1) or included in an applicant delay penalty under § 1.704(c)(12) (or in some instances both, if multiple requests for continued examination are filed, resulting in a double penalty). This proposed application of the statute is directly contrary to the Novartis court’s admonition that “[s]uch time from allowance to issuance undisputedly would count toward the PTO’s three-year allotment in a case not involving a continued examination. There is no basis

for distinguishing a continued-examination case.” Novartis at 601-02 (emphasis added). This aspect of the proposed new rule thus continues the type of unjustified differential treatment of continued examination cases that Novartis had intended to eliminate.

In view of the foregoing remarks, the proposed revision to 37 C.F.R. § 1.703(b)(1) is inconsistent with the controlling statute and must be amended such that the “time consumed by continued examination of the application” concludes on the day before the mailing of a notice of allowance.

**(D) The Office may only exclude from B Delay “time consumed by continued examination of the application requested by the applicant under section 132(b)”**

The proposed revision to 37 C.F.R. § 1.703(b)(1) excludes from B Delay a period of time that does not constitute “time consumed by continued examination of the application requested by the applicant under section 132(b).” For the following reasons, the proposed revision is inconsistent with the controlling statute.

The period of time that is excluded from B Delay under 35 USC § 154(b)(1)(B)(i) is “time consumed by continued examination of the application requested by the applicant under section 132(b)” (emphasis added). Section 132(b) of Title 35 provides that “[t]he Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.” The Office provides for the filing of a request for continued examination under 37 CFR § 1.114, which sets forth the means by which an applicant may request continued examination of an application when prosecution in the application is closed.

The proposed revision to 37 C.F.R. § 1.703(b)(1) specifies two very different types of examination periods that are to be excluded from B Delay. The first begins “on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed.” The beginning date of this period faithfully reflects that which is provided in the statute, i.e., continued examination of the application requested by the applicant under section 132(b). The second excluded examination period corresponds to examination resulting from the Office reopening prosecution after allowance, with the excluded period extending from the date of mailing of an action

under 35 U.S.C. 132 to the date of mailing of a subsequent notice of allowance. This exclusion has no basis in 35 USC § 154(b)(1)(B)(i).

When an applicant files a request for continued examination under 35 U.S.C. 132(b), the time consumed by that continued examination is properly excluded from B Delay. However, when that applicant-requested continued examination ends upon the allowance of the application, so does the B Delay exclusion. If prosecution of the application is reopened after allowance as a result of the applicant filing another request for continued examination, then that additional applicant-requested continued examination period must also be excluded from B Delay. However, the Office has no statutory authority to exclude from B Delay an examination period that is initiated by the Office. If an Examiner decides to issue an Office Action after having previously allowed an application, that does not constitute “continued examination of the application requested by the applicant under section 132(b).” In such a case, the continued examination of the application requested by the applicant ended when the application was previously allowed. There is no basis for the Office to treat such Examiner-initiated examination as being requested by the applicant under section 132(b).

In addition to an absence of statutory authority for excluding Examiner-initiated post-allowance examination from B Delay, there is no principle that would justify why such a PTA reduction should occur in an allowed application where a request for continued examination had been filed previously as compared to an allowed application where no request for continued examination had been filed. It is possible that an Examiner may reopen prosecution after allowance as a result of an applicant’s post-allowance information disclosure statement. However, an applicant filing such a post-allowance information disclosure statement must meet the strict diligence requirements of 37 CFR § 1.97(e). There is no reason why a diligent applicant that happens to have previously filed a request for continued examination is selectively deserving of a PTA penalty in such a situation. This aspect of the proposed regulation would thus continue the type of unjustified differential treatment of continued examination cases that Novartis had intended to eliminate.

In view of the foregoing remarks, the proposed revision to 37 C.F.R. § 1.703(b)(1) is inconsistent with the controlling statute and must be amended such that

only “time consumed by continued examination of the application requested by the applicant under section 132(b)” is excluded from B Delay.

**(E) Suggested alternative revision to 37 C.F.R. § 1.703(b)(1)**

The following suggested revision to 37 C.F.R. § 1.703(b)(1) renders it consistent with 35 USC § 154(b)(1)(B)(i), in the manner described above. In particular, the date of mailing of a notice of allowance is removed from the period of continued examination and only the period or periods constituting continued examination requested by the applicant under 35 USC § 132(b) are excluded from B Delay.

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed ... and ending on the date a patent was issued, but not including the sum of the following periods:

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

Japan Tobacco greatly appreciates the Office’s consideration of this suggested alternative revision to 37 C.F.R. § 1.703(b)(1).

## **II. Proposed New 37 C.F.R. § 1.704(c)(12)**

The Notice proposes adding a new 37 CFR § 1.704(c)(12) and renumbering current paragraphs (c)(12) and (c)(13) as (c)(13) and (c)(14). Proposed new 37 CFR § 1.704(c)(12) reads as follows.

(12) Submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed, in which case the period of adjustment set forth in Sec. 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.

The proposed new 37 CFR § 1.704(c)(12) would result in applicant delay being assessed in those instances where an applicant files a request for continued examination after receipt of a notice of allowance.

### **(A) New 37 CFR § 1.704(c)(12) should only reduce PTA obtained under 35 U.S.C. § 154(b)(1)(B)**

The Office justifies this proposed new rule by stating that this rule of practice is proposed to ensure that an applicant does not obtain multiple periods of patent term adjustment under 35 U.S.C. 154(b)(1)(B) for the time after a notice of allowance under 35 U.S.C. 151 as a consequence of delaying issuance of the application by filing request(s) for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151.

Notice at 34683.

Despite the Office's justification above, which is entirely directed to preventing applicants from gaining PTA under the B Delay provision as a result of filing a request for continued examination, the proposed new rule would apply outside of the envisioned context and would unjustly reduce the PTA of certain applicants. In particular, applicants that do not gain PTA under 35 U.S.C. § 154(b)(1)(B) when filing a request for continued examination after allowance (e.g., for an application that has not been pending for a sufficient amount of time to accrue B Delay), will nonetheless have their PTA reduced (e.g., even if gained under provisions other than B Delay). New 37 CFR § 1.704(c)(12) should be modified so that it applies only to offset any PTA gained under 35 U.S.C.

154(b)(1)(B). No justification for the broadly effective PTA reduction has been proposed by the Office – and none exists.

**(B) Suggested alternative revision to 37 C.F.R. § 1.704(c)(12)**

The following suggested revision to 37 C.F.R. § 1.704(c)(12) renders it consistent with the Office’s stated justifications. In particular, under the proposed revision the filing of a request for continued examination after a notice of allowance will cause a reduction in only PTA that would otherwise be gained as a result of such a filing – i.e., B Delay.

(12) Submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed, in which case the period of adjustment set forth in Sec. 1.703(b) 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.

Japan Tobacco greatly appreciates the Office’s consideration of this suggested alternative revision to 37 C.F.R. § 1.704(c)(12).

**(C) 37 C.F.R. § 1.704(d) should be applied to new 37 CFR § 1.704(c)(12)**

37 C.F.R. § 1.704(d) allows for diligent applicants to avoid a PTA penalty by submitting several categories of information to the Office in an information disclosure statement filed within a short period of time after their receipt. These categories of information include (i) information first cited in a communication from a patent office in a counterpart foreign or international application or from the Office, and (ii) a communication issued by a patent office in a counterpart foreign or international application or by the Office.

The Office stated that 37 C.F.R. § 1.704(d) will not apply to new 37 CFR § 1.704(c)(12). The justification provided for this is as follows.

The provisions of Sec. 1.704(d) would not be applicable to this new provision as the information disclosure statement rules (Sec. Sec. 1.97 and 1.98) provide for the submission of an information disclosure statement after a notice of allowance under 35 U.S.C. 151 has been mailed up until the issue fee is paid without the need for the filing of a request for continued examination under 35 U.S.C. 132(b) (Sec. 1.97(d)), and the Office has a program to allow for the submission of an information

disclosure statement even after the payment of the issue fee (Quick Path Information Disclosure Statement (QPID) Pilot Program, 77 FR 27443 (May 10, 2012)).

Notice at 34683.

The Office's justification overlooks the fact that 37 C.F.R. § 1.97(e) does not allow for submission of many types of information that are permitted under a 37 C.F.R. § 1.704(d) certification. In fact, the only manner in which 37 C.F.R. § 1.97(e) overlaps with 37 C.F.R. § 1.704(d) is in reference to information first cited in a communication from a foreign patent office in a counterpart foreign application. All other categories of information permitted in a 37 C.F.R. § 1.704(d) certification do not constitute bases for filing an information disclosure statement under 37 C.F.R. § 1.97(e). The Office is therefore incorrect in its suggestion that an applicant that has information that meets the requirements of 37 C.F.R. § 1.704(d) necessarily has the option of filing a post-allowance information disclosure statement under 37 C.F.R. § 1.97(e). The proposed new rules would therefore cause many applicants that seek to diligently submit a post-allowance information disclosure statement with the type of information provided by 37 C.F.R. § 1.704(d) to have no option but to file the newly received information with a request for continued examination and receive an applicant delay penalty under new 37 CFR § 1.704(c)(12).

In view of the foregoing, 37 C.F.R. § 1.704(d) should be revised as shown below, such that a post-notice of allowance information disclosure statement that is filed with a request for continued examination and is accompanied by a § 1.704(d) certification will result in no applicant delay being assessed under the proposed new 37 CFR § 1.704(c)(12) (or a revised version thereof).

(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), or (c)(12)~~ of this section if it 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.

Japan Tobacco greatly appreciates the Office's consideration of this suggested revision to 37 C.F.R. § 1.704(d).

**(D) Any new regulation assessing applicant delay must be applied on a prospective basis only**

If the Office enacts the proposed new 37 CFR § 1.704(c)(12) (or a revised version thereof), it would be fundamentally unfair to apply the new regulation retroactively against a patent in which a request for continued examination was filed before the final regulation is enacted. The current version of 37 CFR § 1.704(c) does not assess applicant delay for filing a request for continued examination and there is no means by which an applicant could have reasonably foreseen that the currently proposed new 37 CFR § 1.704(c)(12) would be enacted. As a result, if the Office enacts the proposed new 37 CFR § 1.704(c)(12) (or a revised version thereof), it must be applied on a prospective basis only.