

August 13, 2014

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Via email: AC96.comments@uspto.gov

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

Dear Deputy Under Secretary Lee:

The American Intellectual Property Law Association (AIPLA) is pleased to have the opportunity to present its views on the United States Patent and Trademark Office (“Office”) Notice of Proposed Rulemaking entitled “Changes to Patent Term Adjustment in View of the Federal Circuit Decision in *Novartis v. Lee*” as published in the June 18, 2014 issue of the Federal Register, 79 Fed. Reg. 34681 (“Notice”).

AIPLA is a U.S. based national bar association comprising approximately 15,000 members that are primarily lawyers in private practice and corporate practice, government service, and the academic community. AIPLA members represent a diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, unfair competition, and trade secret law, as well as other fields of law affecting intellectual property, in the United States and in jurisdictions throughout the world.

The Notice proposes changes to the rules governing the calculation of patent term adjustment (PTA) as a result of the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). Specifically, the Notice states that the Office is proposing a change to the rules of practice to provide that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance (until issuance) unless the Office actually resumes examination of the application after allowance. This is embodied in the proposed change to 37 CFR 1.703(b)(1).

Additionally, the Office is proposing a change to 37 CFR 1.704(c)(12) to provide that the submission of a request for continued examination after a notice of allowance has been mailed

will constitute a failure of 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. This proposed change is not directly related to the *Novartis* decision.

While AIPLA supports the proposed changes to the rules of practice governing the calculation of PTA to bring the Office rules and procedures into alignment with the *Novartis* decision, the following comments, questions, and concerns primarily directed to the proposed changes unrelated to the *Novartis v. Lee* decision are submitted for Office consideration.

The Proposed Changes to 37 CFR 1.704(c)(12) are Not Required by the *Novartis* Decision and Not Justified

The Director's statutory authority for reducing a period of adjustment is limited to prescribing "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)(iii). It does not seem that a request for continued examination (RCE) under 35 U.S.C. § 132(b) after a notice of allowance is such a circumstance that amounts to "unreasonable" conduct, and little justification is provided in the Notice to this end. The circumstance of an RCE filing after a Notice of Allowance is not limited to cases with or without B-delay¹ and, accordingly, is only tangentially applicable to rule changes needed to comply with the *Novartis* decision. Filing an RCE after allowance has not previously been considered a failure to engage in reasonable efforts to conclude prosecution. A compelling case for a change to this view has not been offered in the Notice.

One of the most frequent reasons that an RCE is filed after allowance is to submit references in an Information Disclosure Statement (IDS). It is not unusual for circumstances to arise in which Applicants and their patent attorneys or agents become aware of prior art or information later on in the application process. Contrary to the discussion in the proposed rules, the ability to submit an IDS without an RCE is often not possible. This is because the IDS rules 37 CFR 1.97 and 1.98 which provide for submission of an IDS after a Notice of Allowance under 35 U.S.C. § 151 has been mailed, also require a statement under 37 CFR 1.97(e). Applicants often cannot make such a statement for a variety of reasons (i.e., uncertainty regarding the timeframe that individuals may or may not have known about particular pieces of prior art, particularly in technology areas where inventors regularly review large amounts of literature in their field, disclaimer is impractically broad for certain situations, vaguely defined counterpart applications, difficulty of accurately confirming information required, etc.). The inability to submit prior art this way is not necessarily a delay to prosecution, but likely a good-faith practice aimed at reasonably providing information to the Office during prosecution while avoiding the possibility

¹ Defined by the Office as: "... [reflecting] adjustments to the term of the patent based upon the patent failing to issue within three years of the actual filing date of the application in the United States under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371. See 35 U.S.C. § 154(b) and implementing regulations 37 CFR 1.702(b) & 1.703(b). "B" delay is calculated at the time that the issue notification letter is generated and an issue date has been established." http://www.uspto.gov/patents/process/search/public_pair/guidance/pta_calc_explanation.jsp (last visited July 15, 2014).

of inadvertently making a false statement. The comments also rely on the fact that the Quick Path Information Disclosure Statement (QPIDS) Pilot Program is currently potentially available to enable IDS submissions. The availability of this pilot program, however, will not apply in many circumstances, and the continued availability of a temporary pilot program leaves uncertainty and provides little assurance to Applicants moving forward that IDS submissions can be safely submitted after allowance when necessary without their actions and efforts being deemed unreasonable.

In general, the Office's mixed stances on how to view RCEs after allowance are troubling. The statute and PTA rules expressly permit RCEs submitted after allowance and do not characterize their filing as an "unreasonable" action in prosecution. The PTA statute has already contemplated stemming abuses by excluding continued examination from the accrual of B-delay. Rather than treat the use of RCEs after allowance as an acceptable step in the examination process as permitted by the statute and rules, the Office characterizes their filing in the proposed rules as "not reasonable" for purposes of PTA calculation.

Will the Proposed Rule Changes be Retroactive?

AIPLA requests clarification whether one or both of the proposed changes to 37 CFR 1.703(b) and 1.704(c)(12) will be retroactive.. How will the Office treat existing petitions with *Novartis* issues? Will there be an interim procedure to request recalculation under *Novartis*?

How Will Circumstances with Multiple Notices of Allowance be Treated?

Additional clarity is requested with respect to the applicability of the rules when multiple consecutive Notices of Allowance are sent to an Applicant (including supplemental notices of allowance or otherwise).

The Proposed Rule Changes Improperly Subtract Applicant Delay Arising After Filing of the First RCE

The proposed rules should be revised so that Applicant delay arising after the filing of an RCE is not subtracted from accrued patent term adjustment.

Under current rule 37 CFR 1.704(b), the period of adjustment shall be reduced by the number of days, if any, beginning on the day after the date (the 3 month date) that is three months after the date of mailing or transmission of an Office communication notifying the Assignee of a rejection, objection, etc., and ending on the date a corresponding reply was filed. 37 CFR 1.704(b), for which no changes are proposed, does not distinguish between those Applicant delays that would otherwise be included in the PTA and those Applicant delays that have no influence on the PTA.

37 CFR 1.704(b) is inconsistent with the statute governing PTA and with the *Novartis* decision. 35 U.S.C. § 154(b)(1)(B) conditions the subtraction of Applicant delay on the inclusion in the PTA stating:

[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 . . . *not including (i) any time consumed by continued examination of the application requested by the applicant* under section 132 (b).

[. . .] or

(iii) *any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant* except as permitted by paragraph (3)(C), 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. (Emphasis added).

In addition, 35 U.S.C. § 154(b)(2)(C) states:

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which Applicant failed to engage in reasonable efforts to conclude prosecution of the application.

(ii) With respect to adjustments to patent term made under the authority of paragraph (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 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the Applicant.

Accordingly, 35 U.S.C. § 154(b)(2)(C)(ii) only applies to adjustments under the authority of 35 U.S.C. § 154(b)(1)(B). Thus, Applicant delays that may be deducted from the total PTA are only those that occur at the same time that Office delays would otherwise be *included* in the calculation of PTA. Any Applicant delays occurring from and including the date of the first RCE until the date of the Notice of Allowance, however, are not included in the PTA due to the subtraction under 37 U.S.C. § 154(b)(1)(B)(i), and thus cannot be subject to yet an additional subtraction.

Further, in *Novartis*, the Federal Circuit ruled that any delay attributed to the Office should result in PTA. *Novartis*, 740 F.3d at 602. Just like the time from allowance to issuance would count toward the Office's three-year allotment in a case not involving an RCE, the Office delay prior to the RCE filing would have accrued regardless of the RCE. Thus an Applicant's delay that is not included in any PTA calculation cannot be used to reduce the delay attributable the Office that would have occurred even without filing an RCE.

The proposed rules are therefore incomplete because they do not address the unjustified subtraction of Applicant delay after filing of the first RCE.

The Actual Date of the Notice of Allowance Appears to be Improperly Included in the Exclusion of Time Consumed by Continued Examination in Proposed Rule 1.703(b)(1)

Specifically, proposed Rule 1.703(b)(1) defines the exclusion stating, “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 the mailing of a notice of allowance under 35 U.S.C. § 151” (underlining added for emphasis). This appears to be contrary to *Novartis* which states: “[A]llowance-to-issuance time is not to be distinguished according to whether there is a continued examination in a prosecution ... The common-sense understanding of ‘time consumed by continued examination’ ... is time up to allowance, but not later, unless examination on the merits resumes.” *Novartis*, 740 F.3d at 602. Further, although the date of allowance is excluded from accruing under B-Delay, the date of allowance is, however, included in penalties assessed to an Applicant under proposed Rule 1.704(c)(12) for filing a RCE after a notice of allowance. Thus, an Applicant can have PTA term both excluded from B-delay under Rule 1.703 and be penalized under Rule 1.704 for the actual date of the notice of allowance. Restriction of PTA under these provisions seems contrary to the purpose of the rules as there will always be a Notice of Allowance date during prosecution of granted patents irrespective of delays.

The Proposed Rule Changes May Improperly Reduce Accrual of Office Delay

AIPLA is concerned that the underlined text below in the Office’s proposed rule is not permitted to the extent it reduces the accrual of Office delay due to reopening of prosecution by the Office after allowance, not due to an RCE:

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

The statute explicitly and only reduces the delay under the three-year rule for “(i) any time consumed by continued examination of the application requested by the applicant under section

132(b).” If the applicant did not request continued examination, and the Office is reopening prosecution on its own, this clause does not apply.

The “Time Consumed by Continued Examination” Should be Consistently Treated in the Rules

It is not clear why “time consumed by continued examination” is defined such that it includes non-contiguous periods of exclusion in certain circumstances where prosecution is reopened. The rationale for this particular definition is not set forth in the Notice or clear on its face (i.e., why is the period between a first notice of allowance and an RCE or Action reopening prosecution excluded from this definition?). Why doesn’t continued examination start at the first RCE filing and merely end at the last Notice of Allowance? Likewise, under the Office’s proposed definition, if the Office is the party responsible for delay by reopening prosecution after allowance, why is the subsequent period excluded from B-delay at all?

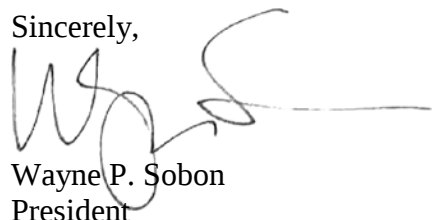
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AIPLA appreciates the opportunity to comment on the Proposed Rulemaking regarding Changes to Patent Term Adjustment calculations. AIPLA looks forward to further dialog with the Office with regard to the issues raised above.

Sincerely,

A handwritten signature in black ink, appearing to read 'Wayne P. Sobon', with a long horizontal flourish extending to the right.

Wayne P. Sobon
President

American Intellectual Property Law Association