



August 18, 2014

Hon. Michelle K. Lee
Deputy Under Secretary of Commerce for
Intellectual Property and Deputy Director of
the U.S. Patent and Trademark Office

Attention: Kery Fries, Senior Legal Advisor
Via email: AC96.comments@uspto.gov

**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 Deputy Director Lee:

Intellectual Property Owners Association (IPO) submits these comments on the proposed “Changes to Patent Term Adjustment in View of the Federal Circuit Decision in *Novartis v. Lee*,” 79 Fed. Reg. 34681 (June 18, 2014).

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO’s membership includes more than 200 companies and more than 12,000 individuals who are involved in the association either through their companies or through other classes of membership.

I. INTRODUCTION

The Federal Register Notice proposes changes to the Patent Term Adjustment (PTA) rules to implement the Federal Circuit decision in *Novartis v. Lee*, 740 F.3d 593 (Fed. Cir. 2014), and also proposes other changes. IPO agrees with the proposed changes that address the circumstances before the court in *Novartis*. IPO does not agree, however, with exclusions and delays that are not supported by *Novartis* or the Patent Act.

Patent Act section 154(b)(1)(B) guarantees no more than a three year application pendency and is often referred to as “B delay.” Under the PTO’s original interpretation of this section, once an applicant filed a Request for Continued Examination (RCE), the patent no longer accrued B delay. In *Novartis*, the Federal Circuit found that the PTO’s original interpretation improperly withheld some accrued B delay. The court explained:

We reject the PTO’s view that the time after allowance, until issuance, is “time consumed by continued examination” and so is excluded from

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adjustments given to the patentee. Such 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.

As already noted, the PTO has explained that § 154(b)(1)(B) is best understood as making distinctions based on whether certain delays are attributable to the PTO. ... By the same token, allowance-to-issuance time is not to be distinguished according to whether there is a continued examination in a prosecution. Either way such time is plainly attributable to the PTO.¹

The Federal Register Notice proposes changes to 37 C.F.R. section 1.703(b)(1) to revise how the PTO determines the B delay award. The Notice also proposes changes to section 1.704 to add a new category of applicant delay that incurs a PTA deduction.

II. PTO'S PROPOSED CHANGES TO RULE 1.703(b)(1)

We are concerned about two aspects of the proposed changes to this rule.

A. The Mailing Date of a Notice of Allowance Should Not Be Included in the B Delay Exclusion Period.

The proposed changes to rule 1.703(b)(1) improperly include the mailing date of a notice of allowance in the B delay exclusion period. The mailing date of notice of allowance should not be treated as "time consumed by continued examination of the application."

According to the Patent Act, "any time consumed by continued examination of the application requested by the applicant under section 132(b)" is excluded from a B delay award.² Examination "ends at allowance, when prosecution is closed and there is no further examination on the merits in the absence of a special reopening."³ The proposed changes to section 1.703(b)(1), would mean that "continued examination of the application" occurs on a day when prosecution is closed, that is, "the date of mailing of a notice of allowance."

Moreover, including the date of mailing of a notice of allowance in the B delay exclusion period is contrary to the Federal Circuit decision in *Novartis*, where the court stated, "[W]e agree with Novartis ... that the 'time consumed by continued examination' should be limited to *the time before allowance*...."⁴

The rule should provide that "time consumed by continued examination" runs only until *the date before* the date of the mailing of the notice of allowance.

¹ *Novartis v. Lee*, 740 F.3d 593, 602 (Fed. Cir. 2014).

² Patent Act section 154(b)(1)(B)(i).

³ *Novartis*, 740 F.3d at 602.

⁴ *Novartis*, 740 F.3d at 601-02 (emphasis added).

B. Examination Not Requested by Applicant Under Patent Act Section 132(b) Cannot Be Excluded From the B Delay Award.

The proposed changes to rule 1.703(b)(1) beginning with “unless prosecution of the application is reopened” address circumstances that were not at issue in *Novartis*. We are particularly concerned about the portion of this proposed rule that would exclude from the B delay award any examination that is not “continued examination requested by the applicant under section 132(b).”⁵

The Federal Circuit in *Novartis* was not asked to consider and did not decide how a B delay award should be calculated when prosecution is reopened by the PTO after a notice of allowance that marked the end of “continued examination” under an RCE. Rather, the court steered clear of this issue, stating:

The PTO identifies several circumstances in which affirmative action is taken to resume examination after allowance, perhaps based on new information submitted by applicants in fulfillment of their continuing duty to disclose information material to patentability...(even after payment of the issue fee, but before issuance, PTO officials can take “extraordinary action to withdraw a patent from issue” and “return the . . . application to examination”); ... (applicant may request resumption of examination). But such circumstances are exceptional, and an appropriate adjustment can be made when they occur. ...⁶

Further, *Novartis* indicates the relevant questions under section 154(b)(1)(B)(i) are “whether certain delays are attributable to the PTO” and whether the examination time after allowance “was ... caused by the continued examination.”⁷ The proposed revisions to rule 1.703(b)(1) ignore both of these questions and treat all post-allowance examination time as attributable to the applicant and caused by the original continued examination, even when it is the PTO that reopens prosecution independent of any action by the applicant.

This proposed treatment of reopened prosecution is contrary to *Novartis*. Just as the court held that time from allowance to grant “is not to be distinguished according to whether there is a continued examination in a prosecution,”⁸ time from an office action reopening prosecution to grant also should not be distinguished on that basis. If no RCE has been filed and prosecution is reopened after allowance, all reopened examination time is eligible for a B delay award. That should also be true if an RCE was requested and a notice of allowance mailed before the PTO reopened prosecution.

The proposed treatment of reopened prosecution is contrary to section 154(b)(1)(B)(i). Continued examination conducted pursuant to an RCE ends when a notice of allowance is issued. If the PTO decides to reopen prosecution after issuing a notice of allowance, such time could hardly be “time consumed by continued examination of the application *requested by the applicant under section*

⁵ Patent Act section 154(b)(1)(B)(i)

⁶ *Novartis*, 740 F.3d at 602.

⁷ *Novartis v. Lee*, 740 F.3d 593, 602 (Fed. Cir. 2014).

⁸ *Novartis v. Lee*, 740 F.3d 593, 602 (Fed. Cir. 2014).

132(b).⁹ Nor does Section 154(b)(1)(B) provide a basis for excluding from a B delay award any post-allowance examination time necessitated the PTO's own initiative or by a post-allowance Information Disclosure Statement that did not require an RCE.

C. IPO's Suggested Amendments.

A revision to proposed rule 1.703(b)(1) to adjust the basic B delay exclusion period by one day and strike the clause pertaining to examination that was not requested by the applicant under section 132(b)(1) could be made as follows:¹⁰

(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 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 by the subsequent filing by Applicant of a request for continued examination**, 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 **subsequent** 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 that is the day before the date of mailing** of a subsequent notice of allowance under 35 U.S.C. 151;

III. PTO'S PROPOSED NEW RULE 1.704(c)(12)

The Federal Register Notice proposes to add to rule 1.704(c) the following new category of applicant 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 § 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 impact of this proposed new rule in combination with the PTO's proposed changes to rule 1.703(b)(1) would result in flawed PTA award calculations. According to the Federal Register Notice, this will prevent applicants from "obtain[ing] multiple periods of [B delay] adjustment ... [after allowance] as a consequence of delaying issuance ... by filing [RCEs] after a notice of allowance." We have several concerns about the proposed rule.

⁹ Patent Act section 154(b)(1)(B)(i), (emphasis added).

¹⁰ PTO's proposed changes in *italics*, IPO's proposed additions in **underline** and deletions in ~~strike through~~.

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First, the proposed new rule is over-inclusive because it would subject all applications to a PTA deduction for this new type of applicant delay, regardless of whether the application is entitled to any B delay.

Second, the proposed new rule undermines the three-month statutory time period that an applicant has to review a notice of allowance and pay the issue fee under Patent Act section 151. If an applicant identifies any defect in the allowed claims during this time period, or identifies information that it wants to submit to ensure compliance with the duty of disclosure (such as information for which a certification under rule 1.97(e) is not appropriate), there should be no PTA deduction for opting to continue prosecution by filing an RCE within the three-month statutory time period. Indeed, such a PTA deduction appears to be inconsistent with the deduction-free three-month response periods permitted in section 154(b)(2)(C)(ii) and rule 1.704(b).

Third, it is unclear if and how this proposed new rule would apply if an RCE is filed after the issue fee is paid, but before the patent is granted. For example, if the PTO takes longer than four months to issue the patent after payment of the issue fee, and during the PTO's delay the applicant determines an RCE is required, it appears proposed rule 1.704(c)(12) could be invoked to charge a PTA deduction running from the notice of allowance, through the issue fee payment, to the RCE. It cannot be correct that that entire time period would be attributed to the applicant (and deducted from any PTA award), if the PTO should have granted the patent within four months of the issue fee payment.

If the PTO does not withdraw the proposed new rule 1.704(c)(12), it should be applied on a prospective basis only, such as to applications filed on or after its effective date, or applications in which the triggering RCE is filed on or after its effective date. It would be unfair to apply the new regulation retroactively against a patent in which a request for continued examination was filed before the final rule is enacted. The current version of rule 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 rule 1.704(c)(12) would be enacted.

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IPO thanks the PTO for considering these comments and would welcome any further dialogue or opportunity to provide additional information to assist in the Office's efforts on this issue.

Sincerely,



Herbert C. Wamsley
Executive Director