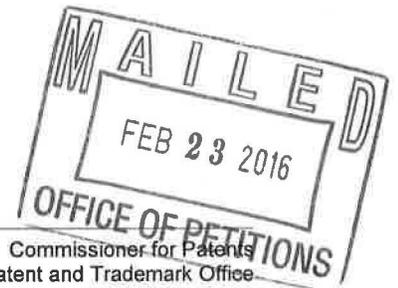




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In re Patent No. 8,847,766 :  
Zdeblick et al. : DIRECTOR'S DECISION ON  
Issue Date: September 30, 2014 : PATENT TERM ADJUSTMENT  
Application No. 11/912,475 :  
Filed: June 23, 2008 :  
Attorney Docket No. PRTS-010 :  
(PRO-60) :  
Title: PHARMA-INFORMATICS :  
SYSTEM :

This is a response to the "Request for Reconsideration of Patent Term Adjustment" filed pursuant to 37 CFR 1.705(b) on September 14, 2015 requesting that the Office adjust the PTA from 1431 days to 1641 days.

The request for patent term adjustment is **DENIED** with respect to making any change in the patent term adjustment determination under 35 U.S.C. § 154(b) of 1431 days.

**THERE WILL BE NO FURTHER CONSIDERATION OF THIS MATTER BY THE OFFICE.**

This decision is the Director's decision on the applicant's request for reconsideration for purposes of seeking judicial review under 35 U.S.C. § 154(b)(4).

**Relevant Procedural History**

On September 30, 2014, this patent issued with a patent term adjustment determination of 1122 days. On December 24, 2014, patentee filed a request for redetermination of patent term adjustment, requesting that patentee be granted a patent term adjustment of 1608 days. A redetermination of patent term adjustment was mailed on June 26, 2015 granting a patent term adjustment of 1431 days. The instant request for redetermination of the patent term adjustment was filed on September 14, 2015 with a one month extension of time, requesting a patent term adjustment of 1641 days.

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**Decision**

Patentee agrees with the Office's calculation of A delay of 1188 days, C delay of 0 day and 395 days of overlap. Patentee disputes the 356 days of applicant delay and B delay of 994.

Patentee disputes the 21 day reduction for the filing of the IDS after the November 13, 2012 Notice of Allowance. Patentee argues:

According to the USPTO's QPIDS Frequently Asked Questions, if an RCE filing and a QPIDS are filed concurrently after a notice of allowance, and prosecution is subsequently reopened, then no applicant delay would be assessed with the filing of the QPIDS. Similarly, if prosecution is not subsequently reopened after the QPIDS filing, an Applicant would be assessed Applicant Delay and no RCE would be necessary.

Under the present factual situation, the filing of the IDS and the subsequent RCE filing after the Notice of Allowance issued on November 13, 2012, which reopened prosecution goes no further than if the references were filed as a QPIDS and prosecution was subsequently reopened. Therefore, by analogy, Applicant respectfully requests reconsideration of the Applicant Delay assessed for the filing of the November 20, 2012 IDS. As such, Applicant respectfully submits the total delay for circumstances constituting a failure by the Applicant to engage in reasonable efforts to conclude processing or examination as set forth in 37 C.F.R. § 1.704 (Applicant delay) should be 335 days and not 356 days, as was calculated by the Office.

In essence Patentee seeks to claim the benefits of the Quick Path Information Disclosure Statement hereinafter "QPIDS" without having ever submitting the documents required for a QPIDS submission. A QPIDS submission requires:

- (1) A transmittal form that designates the submission as a QPIDS submission, such as form PTO/SB/09.

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(2) An IDS, including a timeliness statement as set forth in 37 CFR 1.97(e) and the IDS fee set forth in 37 CFR 1.17(p).

(3) A Web-based ePetition to withdraw from issue under 37 CFR 1.313(c)(2), including the petition fee set forth in 37 CFR 1.17(h).

(4) A RCE, including the RCE fee under 37 CFR 1.17(e).

(5) An authorization to charge all fees associated with the QPIDS submission to a USPTO deposit account.

A review of the record confirms that a transmittal form that designates the submission as a QPID submission, a web based ePetition to withdraw from issue under 37 CFR 1.313(c)(2) including petition fee and an RCE and fee were not filed on November 20, 2012 after the mailing of the Notice of Allowance. As such, the facts provided do not allow the Office to treat this analogous to a QPIDS submission where the IDS submitted on November 20, 2012 was not accompanied by an RCE or the other requirements for a QPIDS submission. Therefore, the IDS submitted on November 20, 2012 and the subsequent RCE filed on December 20, 2012 cannot be treated as a conditional RCE. Instead the submission of the IDS after the mailing of the Notice of Allowance is properly treated under 37 CFR 1.704(c)(10).

Consequently, the reduction of 21 days pursuant to 37 CFR 1.704(c)(10) is required for the submission of the IDS on November 20, 2012. The IDS was not accompanied by a 1.704(d) statement.

37 CFR 1.704 (c)(10) provides:

(10) Submission of an amendment under § 1.312 or other paper, other than a request for continued examination in compliance with §1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

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

or

ii) Four months;

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The reduction period is 21 days, counting the number of days in the period beginning on November 20, 2012, the date of filing of the IDS and ending on December 10, 2012, the date of mailing of the supplemental Notice of Allowability. As such the 21 day reduction will remain.

Applicant delay totals 356 (54 + 59 + 21 + 186 + 36) days.

Patentee also disputes the calculation of 994 days of "B" delay. Patentee contends that the USPTO failed to properly account for the delay under 35 U.S.C. §154(b)(1)(B), referred to as the "B delay." Patentee maintains that the B delay is 1183 days (not 994 days). With a B delay of 1183, Patentee states that the correct PTA is 1641 days. Specifically, patentee argues the second time period consumed by RCE period should be calculated as 3 days not 192 days. Patentee argues:

Applicant respectfully submits that the USPTO delay under 35 U.S.C. § 154(b)(1)(B) (type B delay) should be 1,183 days and not 994 days, as was calculated by the Office. The Federal Circuit reviewed the statutory interpretation of 35 U.S.C. § 154(b)(1)(B)(i) and issued a decision regarding the effects of a Request for Continued Examination ("RCE") on "B" delay in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). The *Novartis* court found that if the Office issues a notice of allowance after an RCE is filed, the period after the notice of allowance should not be excluded from the "B" delay period but should be counted as "B" delay. Accordingly, Applicant respectfully submits that the RCE filed on November 18, 2013 and the subsequent Notice of Allowability mailed on November 20, 2015 should have only resulted in an "RCE period" of 3 days and not 192 days as calculated by the Office. As such the total amount of "B" delay should be 1,183 days and not 994 days, as was calculated by the Office.

Patentee's argument is not convincing, the Federal Circuit reviewed the statutory interpretation of 35 U.S.C. § 154(b)(1)(B)(i) and issued a decision regarding the effects of a

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Request for Continued Examination ("RCE") on "B" delay in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). In *Novartis*, the Federal Circuit agreed with the Office that "no ["B" delay] adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application's filing." *Novartis*, 740 F.3d at 601. However, the *Novartis* court found that if the Office issues a notice of allowance after an RCE is filed, the period after the notice of allowance should not be excluded from the "B" delay period but should be counted as "B" delay. *Id.* at 602.

Patentee's calculation of 1183 days of "B" delay fails to account for the fact that pursuant to the *Novartis* decision the period of time from the filing of the RCE to the mailing of the notice of allowance continues to be subtracted from "B" delay as time consumed by continued examination. Any period of examination after the mailing of a Notice of Allowance resulting from the filing of a subsequent request for continued examination would be considered "time consumed by continued examination". See *The Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis in Novartis v. Lee* 80 Fed. Reg. 1346, 1349 (January 9, 2015).

Pursuant to the *Novartis* decision, the USPTO has determined that the patentee remains entitled to 994 days of "B" delay. In this case, the commencement date of the application is October 29, 2007 and the patent issued on September 30, 2014. Thus, the application was pending for 2529 days. During this period, applicant filed two RCEs. The first RCE was filed on December 20, 2012. The second RCE was filed on November 18, 2013. The Office mailed three Notices of Allowance on November 13, 2012, August 22, 2013 and May 28, 2014. Under 35 USC 154(b)(1)(B)(i), the first time period consumed by continued examination ("RCE period") began on December 20, 2012 and ended on August 22, 2013, i.e., 246 days. The second time consumed by RCE period began November 18, 2013 and ended on May 28, 2014, i.e., 192 days. The time periods total 438 days. Subtracting the RCE period from the total number of days the application was pending results in  $2529 - 438 = 2091$  days. Thus, for purposes of "B" delay, the application was pending for  $2091 - 1097$  [i.e., 3 years from the actual filing date (including a leap year)] = 994 days beyond the three-year anniversary of the filing date.

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**Overall PTA Calculation**

Formula:

"A" delay + "B" delay + "C" delay - Overlap - applicant delay =  
X

USPTO's Calculation:

1188 + 994 + 0 - 395 - 356 = 1431

Patentee's Calculation

1188 + 1183 + 0 - 395 - 160 = 1641

**Conclusion**

Patentee remains entitled to PTA of one thousand four hundred thirty-one (1431) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as follows: 1188 + 994 + 0 - 395 - 356 = 1431 days.

Telephone inquiries specific to this matter should be directed to Attorney Advisor Charlema Grant at (571) 272-3215.

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