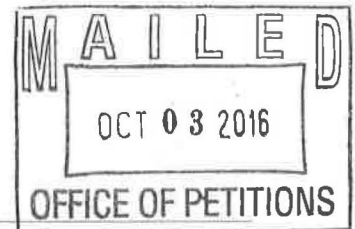




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In re Patent No. 9,044,382 :  
Tureci et al. :  
Issue Date: June 2, 2015 : DECISION  
Application No. 11/596,649 :  
Filed: January 29, 2007 :  
Attorney Docket No. 24859US01 :

This is a decision on patentee's "APPLICATION FOR RECONSIDERATION OF THE PATENT TERM ADJUSTMENT UNDER 35 USC § 154(b) INDICATED IN THE PATENT (37 CFR §1.705(d))" filed July 31, 2015, requesting that the Office adjust the patent term adjustment from 826 days to 878 days. The Office has reviewed the calculations and determined that the patent term adjustment of 826 days is correct.

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 June 2, 2015, this patent issued with a patent term adjustment determination of 826 days. On July 31, 2015, patentee timely filed this APPLICATION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT seeking an adjustment of the determination to 878 days.

#### Decision

Patentee agrees with the Office's calculation of "A" delay of 1580 days, "C" delay of 0 days and overlap of 0 days. At issue are the period of applicant delay and the period of "B" delay. Patentee does not explicitly state disagreement with the calculation of "B" delay; however, patentee's calculation includes a "B" delay of 380, while the Office's calculation includes a "B" delay of 379 days.

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Patentee contests the application(s) of 37 CFR § 1.704(c)(10) to reduce the patent term adjustment in the present application due to a paper filed after the Notice of Allowance has been mailed. Patentee asserts that:

The USPTO is believed to be characterizing the paper filed by the Patentee entitled, Replacement Drawings, on April 13, 2015, after the February 20, 2015, mailing date of the Notice of Allowance, as an alleged amendment under § 1.312 or other paper delaying prosecution. The USPTO is believed to be characterizing the issue date of the patent as the date a response was mailed to the alleged paper delay prosecution. The reduction of PTA asserted by the USPTO is the difference between April 13, 2015, and the issue date of the patent, plus one day, which is 51 days.

Further patentee respectfully contends that:

it should not be penalized for the failure of the Office to adequately review the drawings which were presented at the time of filing in 2006, until after the Office issued a Notice of Allowance (in 2015). Furthermore, at the express request of the Office, Patentee was given two months in which to file over 60 replacement drawing sheets; a request with which Patentee complied within approximately two weeks from receiving the Notice. Further, the IFW entry at 04-13-15, the same day the replacement drawing sheets were filed, shows "Workflow - Drawings Finished", which suggests that the submission of replacement drawing sheets was reviewed and accepted. From all the above, none of the actions taken by Patentee is indicative of any delay or failure to reasonably conclude prosecution of the application. Indeed, it is respectfully submitted that it was the Office's failure to request replacement Drawings until after the application was published and after a Notice of Allowance had been issued (over 8 years from submitting the Drawings). Thus, Patentee should not be charged with any reduction in the amount of PTA days arising from the submission of replacement drawings.

#### ON APPLICANT DELAY

The Office has reviewed the disputed calculation of applicant delay and has determined that the period of reduction of 51 days for filing of drawings after mailing of the Notice of Allowance

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is correct. Patentee's arguments have been considered but not found persuasive.

It is undisputed that after the mailing of the notice of allowance on February 20, 2015, patentee filed corrected drawings on April 13, 2015. Further, no response to the filing of the drawings was mailed or sent by the Office. On June 2, 2015, the application issued as a patent.

It is immaterial to the calculation of patent term adjustment that the filing was in response to a Notice mailed by the Office on March 30, 2015 or that patentee responded within two months. These are factors relevant to the circumstances that constitute applicant delay pursuant to 37 CFR §§1.704(c)(8) and 1.704(b). The applicant delay at issue here is evaluated pursuant to 37 CFR 1.704(c)(10).

37 CFR 1.704(c)(10)<sup>1</sup> provides that:

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:

(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

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<sup>1</sup> Paragraph (c)(10) was revised to add the language "other than a request for continued examination in compliance with § 1.114." See *Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee*, 80 FR 1346, Jan. 9, 2015, effective Mar. 10, 2015.

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(ii) Four months;

This reduction is not predicated on whether the submission after the mailing of the notice of allowance was or was not requested by the Office. This reduction is based on a paper, recognized not to be an amendment under 1.312, being filed after the mailing of the notice of allowance and being deemed as substantially interfering with the patent issuance process by definition.

Upon promulgation of this rule, the Office explained the basis for this circumstance being an applicant "failure to engage in reasonable efforts to conclude examination or processing," as follows:

All papers filed after allowance of an application substantially delay the Office's ability to process an application for a patent because the Office does not wait for payment of the issue fee to begin the process of preparing the application for publication as a patent. Section 1.704(c)(10) as adopted should deter applicants from filing papers after allowance which could have a beneficial impact upon the Office's ability to publish applications as patents more quickly.

The mailing of a notice of allowance under 35 U.S.C. 151 concludes the examination process and starts the process of preparing the application for issuance as a patent.

The Office has specifically advised applicants that under 37 CFR 1.704(c)(10), papers that will be considered a failure to engage in reasonable efforts to conclude processing or examination of an application include: ... (5) drawings. Moreover, the Office has stated that "If the Office does not mail a response to the paper that triggered the delay under this provision and the patent issues in less than four months, then the applicant delay under this provision will end on the date of the patent issuance. The Office will treat the issuance of the patent as the response to the paper that triggered the delay."

In this instance the Office advised applicant that all of the drawing sheets contain a solid/broken line and that a drawing (Fig. 41) is continued onto a second page (or more) without proper labeling under 37 CFR 1.84(u)(1). On April 13, 2015, applicant filed replacement drawings. Applicant acknowledged that the substitute figures were submitted to clarify the

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figures in view of blurriness due to the copying process, and Figure 41 was labelled as "continued" as it spans multiple pages.

The Office did not mail a response to the filing of the replacement drawings (which is not uncommon practice with respect to the filing of replacement drawings after the mailing of the notice of allowance). The Office could have, but did not, promulgate that the notation in the records of "Workflow-Drawings Finished" would be considered the response to the filing of the replacement drawings. The issuance of the patent, is deemed the response to the filing of the replacement drawings for purposes of calculating applicant delay under 37 CFR 1.704(c)(10) when no response is mailed or sent within four months.

In view of applicant's actions in filing in the first instance blurry drawing figures not suitable for publishing as a patent and not fully in compliance with the patent rules, and not filing replacement drawings to cure these deficiencies before the mailing of the notice of allowance, the Office delay beginning on April 13, 2015, the date of filing of the replacement drawings and ending on June 2, 2015, the issue date of the patent grant, is by rule properly attributed to applicant.

In view thereof, total applicant delay remains 1133 days.

#### ON "B" DELAY

The Office accorded 379 days of "B" delay (with 0 days of overlap). This calculation is in accordance with the controlling decision in *Novartis*, which provides guidance for the Office in calculating "B" delay considering the time consumed by continued examination.

Patentee's attention is further directed to *Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee*, 80 FR 1346 (January 9, 2015), which provides:

If a first request for continued examination is filed before a notice of allowance has been mailed and a second request for continued examination is filed after a notice of allowance has been mailed, the time consumed by continued examination of the application under 35 U.S.C.

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132(b) is the number of days in the period beginning on the date on which the first request for continued examination was filed and ending on the date of mailing of the notice of allowance following the first request for continued examination, plus the number of days in the period beginning on the date on which the second request for continued examination was filed and ending on the date of mailing of the notice of allowance following the second request for continued examination. If a second request for continued examination is filed without a notice of allowance having been mailed between the filing of the first and second requests for continued examination and a notice of allowance is mailed after the second request for continued examination, the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days in the period beginning on the date on which the first request for continued examination was filed and ending on the date of mailing of the notice of allowance.

Further, Comment 1 of the rule states the Office's position with respect to the "time consumed by continued examination of the application requested by the applicant under section 132(b)" under 35 U.S.C. 154(b)(1)(B)(i) including the date of mailing of a notice of allowance.

The Federal Circuit decision in Novartis does not specifically state whether the date of mailing of a notice of allowance is considered part of the 'time consumed by continued examination of the application requested by the applicant under section 132(b)' within the meaning of 35 U.S.C. 154(b)(1)(B)(i).

The Federal Circuit decision in Novartis simply discusses the time period ''before allowance'' and the ''time after allowance, until issuance.'' See Novartis, 740 F.3d at 602 (''we reject the PTO's view that the time after allowance, until issuance, is 'time consumed by continued examination' '' and '' 'time consumed by continued examination' . . . is time up to allowance, but not later'') (emphasis added). The mailing of the notice of allowance is the action which concludes examination of the application and closes prosecution of the application. See id. ('' 'examination' presumptively ends at allowance, when prosecution is closed and there is no further examination on the merits. . .

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.'') (emphasis added). Thus, it is appropriate to consider the ``time consumed by continued examination of the application requested by the applicant under section 132(b)'' as including the date of mailing of the notice of allowance in an application that has been allowed after the filing of a request for continued examination. In addition, treating the period of ``time consumed by continued examination of the application requested by the applicant under section 132(b)'' as ending on the date on which a notice of allowance is mailed (rather than the day before the date on which a notice of allowance is mailed) is consistent with how the Office treats the date on which a patent issues for purposes of 35 U.S.C.

154(b)(1)(A)(iv) (four months to issue patent term adjustment provision) and 154(b)(1)(B) (the three-year pendency patent term adjustment provision). Specifically, the Office treats the four-month period in 35 U.S.C. 154(b)(1)(A)(iv) and the three year period in 35 U.S.C. 154(b)(1)(B) as ending on the date the patent issues (rather than day before date the patent issues), even though the patent has been granted and is in force on the date the patent issues.

The commencement date of this application is November 20, 2006<sup>2</sup>, and the patent issued on June 2, 2015; thus, the application was pending for 3,117 days.

A first request for continued examination (RCE) was filed on August 25, 2010. A second RCE was filed on January 24, 2014. A Notice of Allowance did not issue until February 20, 2015. Under 35 U.S.C. § 154(b)(1)(B)(i), there was one time period consumed by continued examination ("RCE period"). The RCE period began on August 25, 2010 and ended on June 2, 2015 - i.e., 1641 days. Subtracting the RCE period from the total number of days the application was pending results in 3117 - 1641 = 1576 days.

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<sup>2</sup>In this case, no express request for early processing was made. The priority date of the international application is May 18, 2004. The 30-month period pursuant to 35 U.S.C. 371(b) expired on November 18, 2006. As the expiration of the 30-month period pursuant to 35 U.S.C. 371(b) fell on a Saturday (November 18, 2006), the period expired on the subsequent business day, November 20, 2006. See PCT Rule 80.5.

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Thus, for purposes of "B" delay, the application was pending for 1641 - 1097 [i.e., 3 years from the actual filing date] = 379 days beyond the 3-year anniversary of the filing date.

Therefore, "B" delay is 379 days.

**Overall PTA Calculation**

Formula:

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

USPTO's Calculation:

1580 + 379 + 0 - 0 - 1133 = 826

Patentee's Calculation

1580 + 380 + 0 - 0 - 1082 = 878

**Conclusion**

The patent term adjustment (PTA) remains **eight hundred twenty-six (826)** days of PTA. Using the formula "A" delay + "B" delay + "C" delay - Overlap - Applicant delay = X, the amount of PTA is calculated as follows: 1580 + 379 + 0 - 0 - 1133 = 826 days.

As the patent issued with 826 days of PTA, no further action will be undertaken by the Office with respect to the patent term adjustment.

Telephone inquiries specific to this matter should be directed to Attorney Advisor, Nancy Johnson at (571) 272-3219.

/ROBERT CLARKE/  
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