This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT", ("request for reconsideration"), filed November 17, 2014, which requests the United States Patent and Trademark Office ("Office") correct the patent term adjustment determination ("PTA") set forth on the patent to indicate the term of the patent is extended or adjusted by one thousand one hundred seventy-two (1,172) days.

The request for reconsideration for the Office to correct the PTA set forth on the patent to indicate the term of the patent is extended or adjusted by 1,172 days is DENIED. This decision is a final agency action within the meaning of 5 U.S.C. § 704.

Relevant Procedural History

The patent issued with a PTA determination of 230 days on June 11, 2013. A request seeking an adjustment of 1397 days was timely filed on June 24, 2013. The request was dismissed on October 17, 2014. The PTA determination set forth in the October 17, 2014 redetermination is 1003 days (568 days of A Delay + 861 days of B Delay + 0 days of C Delay - 0 days of Overlap - 426 days of Applicant Delay). A request for reconsideration was timely filed on November 17, 2014.

Decision

The PTA is based on the following determination previously made by the Office in the October 17, 2014 redetermination:
(1) The period of delay under 35 U.S.C. § 154(b)(1)(A) ("A Delay") is 568 days;
(2) The period of delay under 35 U.S.C. § 154(b)(1)(B) ("B Delay") is 861 days;
(3) The period of delay under 35 U.S.C. § 154(b)(1)(C) ("C Delay") is 0 days;
(4) The number of days of overlapping delay ("Overlap") between the periods of A Delay, B Delay, and C Delay is 0 days; and
(5) The period of delay under 35 U.S.C. § 154(b)(2)(C) ("Applicant Delay") is 426 days.

The PTA is the sum of the days of A Delay, B Delay, and C Delay reduced by the number of days of Overlap and Applicant Delay. In other words, the following formula may be used to calculate the PTA:

\[ \text{PTA} = \text{A Delay} + \text{B Delay} + \text{C Delay} - \text{Overlap} - \text{Applicant Delay} \]

The redetermination set forth a PTA of 1003 days (568 days of A Delay + 861 days of B Delay + 0 days of C Delay - 0 days of Overlap - 426 days of Applicant Delay).

The request for reconsideration asserts the Office improperly excluded time consumed by continued examination from the period of B Delay and, as a result, incorrectly calculated the period of B Delay, and the period of Overlap. The request for reconsideration asserts the correct period of B Delay is 1031 days, and the period of Overlap is 1 day. The request for reconsideration argues the correct PTA is 1172 days (568 days of A Delay + 1031 days of B Delay + 0 days of C Delay - 1 day of Overlap - 426 days of Applicant Delay).

As will be discussed, the period of B Delay is 861 days, and the period of Overlap is 0 days. Therefore, the correct PTA is 1003 days (568 days of A Delay + 861 days of B Delay + 0 days of C Delay - 0 days of Overlap - 426 days of Applicant Delay).

**A Delay**

The request for reconsideration does not dispute the Office's prior determination the period of A Delay is 568 days. The Office has recalculated the period of A Delay as part of the Office’s redetermination of the PTA and confirmed the period of A Delay is 568 days.

**B Delay**

The request for reconsideration disputes the Office’s prior determination the period of B Delay is 861 days; arguing the continued examination exclusion period is 240 days, rather than 410 days. The Office has recalculated the period of B Delay as part of the Office’s redetermination of the PTA and confirmed the period of B Delay is 861 days.

The commencement date is December 18, 2006

A request for continued examination ("RCE") was filed December 19, 2011.

A non-final Office action was mailed on March 28, 2012.
An amendment was filed on July 27, 2012.

A Notice of Allowance ("NOA") was issued on September 12, 2012.

A second RCE was filed November 21, 2012.

Another NOA was issued on April 10, 2013.

The patent issued on June 11, 2013.

The impact the submission of a RCE has on the calculation of B Delay is addressed in Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. Jan. 15, 2014). The decision indicates time consumed by continued examination is not part of the period of B Delay even if the RCE is filed more than three years after the filing date. The decision also indicates time consumed by continued examination does not include the time period after allowance unless examination on the merits of the application resumes.

The request for reconsideration disputes the end date for the exclusion period. The request for reconsideration argues the end date of the exclusion period is the date examination on the merits resumes, not necessarily the date of the mailing of a notice of allowance.

The first RCE was filed on December 19, 2011. The request for reconsideration argues examination on the merits resumed when the Office issued a non-final Office action on March 28, 2012. Therefore, the request for reconsideration asserts the excluded period should be calculated from the filing of the first RCE on December 19, 2011 up until the mailing of the non-final Office action on March 28, 2012, which totals 100 exclusion days.

The second RCE was filed on November 21, 2012. A Notice of Allowance was mailed on April 10, 2013. The request for reconsideration asserts the exclusion period should be calculated from the filing of the second RCE on November 21, 2012, up until the mailing of the Notice of Allowance on April 10, 2013, which totals 140 exclusion days.

The Office amended 37 CFR 1.703(b) to conform with Novartis. Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee, Final Rule, 80 Fed. Reg. 1346 (January 9, 2015.) The changes to 37 CFR 1.703 in this final rule apply to any patent granted before, on, or after January 9, 2015. Therefore, the rule applies to the present patent.

Amended rule 37 CFR 1.703(b)(1) states:

[The period of B Delay does not include] the number of days, if any, in the period beginning on the date on which any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151.
Page 1348 of the rule package states:

[37 CFR] 1.703(b)(1) is amended to provide that the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days, if any, in the period beginning on the date on which any 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 the notice of allowance under 35 U.S.C. 151.

Amended rule 37 CFR 1.703(b) is clear that the end date of the calculation is the date of mailing of the notice of allowance.

With respect to the argument that the end date of the calculation should be the date before the notice of allowance was mailed, consider Comment 1 of the January 9, 2015 rule package, reproduced below:

**Comment 1:** Several comments suggest that “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) does not include the date of mailing of a notice of allowance, citing *Novartis*, 740 F.3d at 601 et seq.

**Response:** 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. . . .”) (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.

Returning to the salient dates in this analysis:
The commencement date is December 18, 2006.

A request for continued examination ("RCE") was filed December 19, 2011.

A Notice of Allowance ("NOA") was issued on September 12, 2012.

A second RCE was filed November 21, 2012.

Another NOA was issued on April 10, 2103.

The patent issued on June 11, 2013.

In view of Novartis and the January 9, 2015 revisions to 37 CFR 1.703(b)(1), the period of time consumed by continued examination is not part of the period of B Delay. The time consumed by continued examination includes the following two periods of time:

1. The 269 day period beginning on the date the first RCE was filed and ending on and including the date the subsequently mailed NOA was issued; and
2. The 141 day period beginning on the date the second RCE was filed and ending on and including the date the subsequently mailed NOA was issued.

The number of days consumed by continued examination is 410 (269 + 141) days.

The Novartis decision includes “instructions” for calculating the period of B Delay. Specifically, the decision states,

The better reading of the language is that the patent term adjustment time [for B Delay] should be calculated by determining the length of the time between application and patent issuance, then subtracting any continued examination time (and other time identified in (i), (ii), and (iii) of (b)(1)(B)) and determining the extent to which the result exceeds three years.

The length of time between commencement date and issuance is 2368 days. The time consumed by continued examination is 410 days. The number of days beginning on the commencement date and ending on the date three years after the commencement date is 1097 days. The result of subtracting the time consumed by continued examination (410 days) from the length of time between commencement date and issuance (2368 days) is 1958 days, which exceeds three years (1097) by 861 days. Therefore, the period of B Delay is 861 days.

C Delay

The request for reconsideration does not dispute the Office’s prior determination the period of C Delay is 0 days. The Office has recalculated the period of C Delay as part of the Office’s redetermination of the PTA and confirmed the period of C Delay is 0 days.
Overlap

The request for reconsideration disputes the Office’s prior determination the number of days of Overlap is 0 days. The Office has recalculated the number of days of Overlap as part of the Office’s redetermination of the PTA and confirmed the number of days of Overlap is 0 days.

Applicant Delay

The request for reconsideration does not dispute the Office’s prior determination the period of Applicant Delay is 426 days. The Office has recalculated the period of Applicant Delay as part of the Office’s redetermination of the PTA and confirmed the period of Applicant Delay is 426 days.

Conclusion

The request for reconsideration asserts the correct PTA is 1,172 (568 days of A Delay + 1,031 days of B Delay + 0 days of C Delay - 1 days of Overlap - 426 days of Applicant Delay).

As previously discussed, the correct period of B Delay is 861 days, and the period of Overlap is 0 days. Therefore, the correct PTA is 1,003 days (568 days of A Delay + 861 days of B Delay + 0 days of C Delay - 0 days of Overlap - 426 days of Applicant Delay).

Telephone inquiries specific to this decision should be directed to Attorney Advisor Shirene Willis Brantley at (571) 272-3230.

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