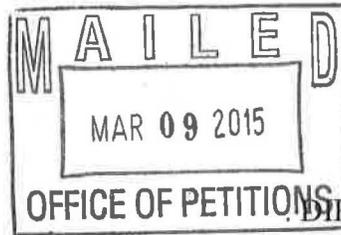




UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov



In re Patent No. 8,431,604
Issued: April 30, 2013
Application No. 10/590,265
Filing or 371(c) Date: June 14, 2007
Dkt. No.: 030270-1073 (7353US01)

DIRECTOR'S DECISION ON
: PATENT TERM ADJUSTMENT
: and Notice of Intent to Issue Certificate
: of Correction
:

This decision is in response to the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT," filed November 5, 2014, requesting that the patent term adjustment be increased from 956 days to 1901 days.

The redetermination of patent term adjustment is **DENIED** with respect to according a patent term adjustment determination under 35 U.S.C. § 154(b) of 1901 days.

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

This redetermination of patent term adjustment is the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4) that triggers a 180-day period for applicant disagreeing with the Office redetermination to commence a civil action in the District Court for the Eastern District of Virginia.

Relevant Procedural History

The above-identified application matured into U.S. Patent No. 8,431,604 on April 30, 2013. The patent issued with a patent term adjustment of 956 days. On June 27, 2013, an application for patent term adjustment was filed. On September 22, 2014, a redetermination of application for patent term adjustment was mailed, advising patentee that the patent was entitled to an overall patent term adjustment of 1583 days. On November 5, 2014, patentee sought reconsideration of the redetermination of patent term adjustment, referencing Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014), and asserting entitlement to an overall patent term adjustment of 1901.

Decision

Patentee does not dispute the Office's calculation of 947 days of "A" delay, of zero days of "C" delay, of 118 days of overlap, or the 118 days of applicant delay. The sole issue remains the period of "B" delay.

With respect to the first period of continued examination, Patentee argues in pertinent part as follows:

“Applicant has analyzed and applied the 3 year Issuance of Patent rule per *Novartis v. Lee*, 2013-1160 (Fed. Cir. 2014). Per *Novartis*, time spent in a continued examination is excluded from the USPTO 3-year issue deadline under 35 USC 154(b)(1)(B), no matter when the continued examination begins

However, per *Novartis*, the exclusion period ends at allowance **unless examination on the merits resumes**. Slip Op. at 15 (“The common-sense understanding of “**time consumed by continued examination**,” 35 USC 154(b) (1) (B) (i), is time up to allowance, but not later, **unless examination on the merits resumes**.”). The first Request for Continued Examination under 35 U.S.C. §1.329(b) was filed on July 25, 2011 and **examination on the merits resumed** when the PTO issued a Non-Final Rejection on September 26, 2011. Therefore, per *Novartis*, the exclusion period for the instant application should only be calculated from the filing of the Request for Continued Examination on July 25, 2011 up until the mailing of the Non-Final Rejection on September 26, 2011 (when examination on the merits resumed). Measuring from the filing of the Request for Continued Examination on July 25, 2011, up until the mailing of the Non-Final Rejection on September 26, 2011, totals to 63 exclusion days.”

With respect to the second period of continued examination, Patentee argues in pertinent part as follows:

“[P]er *Novartis*, the exclusion period for the instant application should only be calculated from the filing of the Request for Continued Examination on June 22, 2012 up until the mailing of the Notice of Allowance on July 16, 2012. Measuring from the filing of the Request for Continued Examination on June 22, 2012, up until the mailing of the Notice of Allowance on July 16, 2012, totals to 24 exclusion days.”

With respect to the third period of continued examination, Patentee argues in pertinent part as follows:

“[P]er *Novartis*, the exclusion period for the instant application should only be calculated from the filing of the Request for Continued Examination on October 16, 2012 up until the mailing of the Notice of Allowance on December 4, 2012. Measuring from the filing of the Request for Continued Examination on October 16, 2012, up until the mailing of the Notice of Allowance on December 4, 2012, totals to 49 exclusion days.”

Therefore, Patentee argues that the application is entitled to an overall period of “B” delay 1212 days (1349 days (August 21, 2006 [date three years from the date of commencement] to April 30, 2013 [date of issuance]) less the three periods of continued examination of 63 days + 24 days + 50 days); i.e., 1349 days – 137 days.

Patentee’s arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to 1583 days of patent term adjustment. The Office has revisited the amount

of “B” delay under 35 U.S.C. § 154(b)(1)(B) and the amount of overlapping days under 35 U.S.C. § 154(b)(2)(A) pursuant to the Federal Circuit’s decision in Novartis AG v. Lee, supra.

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). 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. The Federal Circuit issued its mandate in the Novartis appeal on March 10, 2014.

Pursuant to the Novartis decision, the UPSTO has determined that patentee is entitled to 1031 days of “B” delay. 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. In this instance, the RCE period was 317 days, resulting in the Office to determine that this application was pending 1031 days beyond 3 years from the actual filing date.

The redetermination is calculated as follows: In this case, the date of commencement is August 21, 2006 and the patent issued on April 30, 2013; thus, the application was pending for 2445 days.

A request for continued examination (RCE) was filed on July 25, 2011. A Notice of Allowance issued on March 22, 2012. Under 35 U.S.C. § 154(b)(1)(B)(i), time period consumed by continued examination (“RCE period”) began on July 25, 2011 and ended on March 22, 2012 – i.e., 242 days.

Further, a request for continued examination (RCE) was filed on June 22, 2012. A Notice of Allowance issued on July 16, 2012. Under 35 U.S.C. § 154(b)(1)(B)(i), time period consumed by continued examination (“RCE period”) began on June 22, 2012 and ended on July 16, 2012 – i.e., 25 days.

Further, a request for continued examination (RCE) was filed on October 16, 2012. A Notice of Allowance issued on December 4, 2012. Under 35 U.S.C. § 154(b)(1)(B)(i), time period consumed by continued examination (“RCE period”) began on October 16, 2012 and ended on December 4, 2012 – i.e., 50 days.

Be advised that 37 CFR 1.703(b)(1) was 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 mailing of the notice of allowance under 35 U.S.C. 151. 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. 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. See, 80 Fed. Reg. 6 (January 9, 2015).

Also, worth noting is comment 1 at 80 Fed. Reg. 1349 is worth noting wherein it states:

“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.”

Thus, subtracting the RCE period totaling 317 days from the total number of days the application was pending results in $2445 - 317 = 2128$ days. Thus, for purposes of “B” delay, the application was pending 1031 beyond the 3-year anniversary of the filing date, $2128 - 1097$ [i.e., 3 years from the actual filing date] = 1031 days.

In Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010), the United States Court of Appeals for the Federal Circuit determined that overlap occurs when the calendar days overlap between the “A” and “B” delays. Under this interpretation, the Office finds that there are 277 overlapping days.

Overall PTA Calculation

Formula:

“A” delay + “B” delay + “C” delay - Overlap - applicant delay = X

USPTO’s Calculation:

$947 + 1031 + 0 - 277 - 118 = 1583$

Patentee’s Calculation:

$948 + 1349 - 278 - 118 = 1901$

Conclusion

Patentee is entitled to PTA of 1583 days. Using the formula “A” delay + “B” delay + “C” delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $947 + 1031 + 0 - 277 - 118 = 1583$ days.

The application is being forwarded to the Certificates of Corrections Branch for issuance of a certificate of correction. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by 1583 days.

Telephone inquiries specific to this matter should be directed to Attorney Advisor Alesia M. Brown at (571) 272-3205.

/JOHN COTTINGHAM/
Director
Office of Petitions/
Petitions Officer

Enclosure: Copy of DRAFT Certificate of Correction

DRAFT COPY

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 8,431,604

DATED : April 30, 2013

INVENTOR(S) : Netz, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by 956 days

Delete the phrase "by 956 days" and insert – by 1583 days--