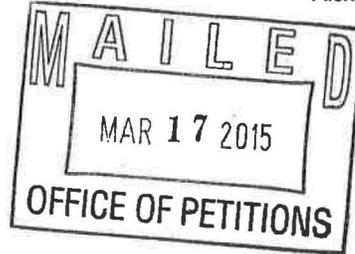




UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOVO NORDISK INC.
INTELLECTUAL PROPERTY DEPARTMENT
800 Scudders Mill Road
Plainsboro NJ 08536



In re Patent No. 8,410,047
Bock, et al.
Issue Date: April 2, 2013
Application No. 11/629,238
Filing or 371(c) Date: October 3, 2008
Docket No.: 6,899.204-US

:
: DECISION
: ON REQUEST FOR
: RECONSIDERATION OF
: PATENT TERM ADJUSTMENT
:

This is a decision on the patent term adjustment in response to the “RESPONSE TO DETERMINATION OF PATENT TERM ADJUSTMENT” filed November 10, 2014, requesting that the patent term adjustment determination for the above-identified patent be changed from 1,079 days to 1,080 days.

The request is **DENIED**.

This decision on 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.

On April 2, 2013, the above-identified application matured into U.S. Patent No. 8,410,047. The patent issued with a PTA of 1,393 days. On May 31, 2013, patentees filed an “Application for Patent Term Adjustment under 37 CFR 1.705(d).” On July 1, 2014, the Office issued a redetermination of patent term adjustment concluding that the revised patent term adjustment is 1,079 days. The present request for redetermination of the patent term adjustment was timely filed within two months of the date the redetermination of patent term adjustment was mailed.

The present petition

Patentees aver that the revised patent term adjustment is 1,080 days. In support, patentees’ state, in pertinent part, that:

[t]he Redetermination states the “time period from the Request for Continued Examination] is March 15, 2011 until the notice of allowance was issued on February 13, 2013—i.e., 702 days.”...The Redetermination stated that the 702 days was excluded from

the amount of USPTO “B” delay in order to arrive at the calculated 1,079 days of PTA. However, this calculation includes the February 13, 2013, date on which the notice of allowance was issued...In *Novartis AG v. Lee*, 704 F.3d 593 (Fed. Cir. 2014), the Federal Circuit opined on the time exclusion against USPTO “B” delay as set forth in 35 USC 154(b)(1)(B)(i), stating that “we agree with Novartis that...’time consumed by continued examination’ should be limited to the time before allowance, as long as no later examination actually occurs.” *Novartis*, 704 F.3d at 601-602 (emphasis added). Similarly, the Court states that 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.” *Id.* At 602 (emphasis added). Thus, the Court held that the day of the notice of allowance is not counted as time consumed by continued examination.

Excerpt taken from “Response to Redetermination of Patent Term Adjustment, filed November 10, 2014, pgs. 1-2.

Discussion

Patentees’ arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to **1,079** days of PTA. The Office has revisited the amount of “B” delay under 35 U.S.C. § 154(b)(1)(B) and the period to be excluded from the “B” delay as “time consumed by continued examination” pursuant to the Federal Circuit’s decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). The Office and Patentees are in agreement that the total amount of “A” delay is 763 days. Furthermore, the Office and Patentees are in agreement that the total amount of Applicant delay is 131 days. The Office and Patentees are not in agreement as to the period to be excluded from the “B” delay as “time consumed by continued examination.” Patentees maintain that the period to be excluded from the “B” delay is 701 days. The Office has again determined that the period to be excluded from the “B” delay as “time consumed by continued examination” is 702 days.

It is noted that in the Final Rule published January 9, 2015, titled, “Changes to Patent Term Adjustment in View of the Federal Circuit Decision in *Novartis v. Lee*”, the Office noted thusly,

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 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.

Excerpt taken from Final Rule, titled, “Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee”, Vol. 80, No. 6, January 9, 2015, p. 1349.

The above-cited excerpt from the Final Rule makes clear that, relative to the calculation of “B” delay and the period excluded as “time consumed by continued examination”, the date on which the notice of allowance is mailed is to be included in the calculation of the period excluded from the “B” delay. Accordingly, the period excluded from the “B” delay as “time consumed by continued examination” in the instant matter is 702 days and begins on, and includes, March 15, 2011, the date the first Request for Continued Examination was filed, and ends on, and includes February 13, 2013, the date the only Notice of Allowance was mailed.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

763 + 506 + 0 – 59 – 131 = 1,079

Patentee's Calculation:

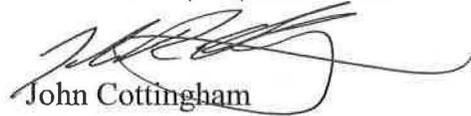
$$763 + 507 + 0 - 59 - 131 = 1,080$$

Conclusion

Patentee is entitled to PTA of one thousand, seventy-nine (1,079) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $763 + 506 + 0 - 59 - 131 = 1,079$.

The Office will issue a certificate of correction indicating that the patent term adjustment is corrected from 406 days to 1,079 days.

Telephone inquiries specific to this matter should be directed to Kenya A. McLaughlin, Attorney Advisor, at (571) 272-3222.



John Cottingham
Director
Office of Petitions

Enclosure: Draft Certificate of Correction

DRAFT COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT : 8,410,047 B2

DATED : Apr. 2, 2013

INVENTOR(S) : Bock, 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 (406) days

Delete the phrase "by 406 days" and insert – by 1079 days--