



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. 8,986,009
Volkl et al.
Issue Date: 03/24/2015
Application No. 12/991,191
Filed: 01/11/2011
Attorney Docket No: 10107
DECISION FOR REQUEST
FOR RECONSIDERATION
OF PATENT TERM

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT IN VIEW OF NOVARTIS AND EXELIXIS" filed May 4, 2015, which is treated as a request that the patent term adjustment indicated on the face of the Letters of Patent be corrected from four hundred thirty-five (435) days to five hundred thirty-four (534) days.

The request for reconsideration is granted to the extent that the determination has been reconsidered; however, the request for reconsideration of patent term adjustment is DENIED with respect to making any change in the patent adjustment determination under 35 U.S.C. 154(b) of 435 days. This decision is the Director's decision on the applicant's request for purposes of seeking judicial review under 35 U.S.C. § 154(b)(4).

BACKGROUND

On March 24, 2015, the above-identified application matured into U.S. Patent No. 8,986,009, with a patent term adjustment of 435 days. On May 4, 2015, the present request for reconsideration was filed.

Patentee asserts that the B delay period should be increased by 99 days to account for the period between the mailing of the notice of allowance on December 15, 2014, and the issue date of the patent on March 24, 2015.

Patentee does not dispute the A delay of 375 days, the 0 days of C delay, the 0 overlapping days, or the 90 days of applicant delay.

STATUTE AND REGULATION

35 U.S.C. 154(b)(1)(B) provides that:

GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.—
Subject to the limitations under paragraph (2), if the issue of an original patent is

Art Unit: OPET

delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

The implementing regulation, 37 CFR 1.702(b), as revised, applies to any patent granted on or after January 14, 2013.¹

Three-year pendency. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including:

(1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b);

(2) Any time consumed by an interference or derivation proceeding under 35 U.S.C. 135(a);

(3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181;

(4) Any time consumed by review by the Patent Trial and Appeal Board or a Federal court; or

(5) Any delay in the processing of the application by the Office that was requested by the applicant.

In pertinent part, 37 CFR 1.703(b) provides for calculation of the periods, as follows:

Period of adjustment of patent term due to examination delay.

...

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods²:

¹ *Revisions to Patent Term Adjustment*, 78 Fed. Reg. 19416, 20 (April 1, 2013).

² (1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued;

Art Unit: OPET

OPINION

Patentee's argument has been carefully considered. Upon review, the USPTO finds that patentee is entitled to **435** days of PTA. 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*, 740 F.3d 593 (Fed. Cir. 2014). Patentee and the Office are in agreement regarding the amount of "A" delay under 35 U.S.C. § 154(b)(1)(A) and 37 CFR 1.702(a). Patentee and the Office are also in agreement regarding the amount of "applicant delay" under 35 U.S.C. § 154(b)(2)(C) and 1.704(b).

As for the amount of "B" delay, 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 USPTO has determined that the patentee is entitled to 150 days of "B" delay. The application commenced the national stage on November 8, 2010. On March 24, 2015, the patent issued; thus, the application was pending for 1598 days. During this time, the applicant filed an RCE – on December 30, 2013. Under 35 U.S.C. § 154(b)(1)(B)(i), there was a time period consumed by continued examination ("RCE period"). The RCE period was from December 30, 2013, the date the RCE was filed, until a notice of allowance was issued

(2)(i) The number of days, if any, in the period beginning on the date an interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and (ii) The number of days, if any, in the period beginning on the date prosecution in the application was suspended by the Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension;

(3)(i) The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181; (ii) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under § 41.39 of this title in the application under secrecy order and ending on the date the secrecy order was removed; (iii) The number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order was removed; and (iv) The number of days, if any, in the period beginning on the date of notification under § 5.3(c) of this chapter and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151; and,

(4) The number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and § 41.31 of this title and ending on the date of the last decision by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145, or on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first, if the appeal did not result in a decision by the Board of Patent Appeals and Interferences.

Art Unit: OPET

on December 15, 2014 – *i.e.*, 351 days. Subtracting the RCE period from the total number of days the application was pending results in $1598 - 351 = 1247$ days. Thus, for purposes of “B” delay, the application was pending for $1247 - 1097$ [*i.e.*, 3 years from the actual filing date] = 150 days beyond the 3-year anniversary of the filing date. The 150-day period of “B” delay extends from November 9, 2010, the day after the date three years after the date the application commenced the national stage and ending on December 29, 2013, the day before the date the RCE was filed (51 days), and from December 16, 2014, the day after the date the notice of allowance was mailed to March 24, 2015, the date the patent issued (99 days).

Total applicant delay is 90 days.

Total A delay is 375 days.

Total C delay is 0 days.

Total overlap is 0 days.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

$$375 + 150 + 0 - 0 - 90 = 435$$

Patentee’s Calculation:

$$375 + 249 (150+99) + 0 - 0 - 90 = 534$$

Conclusion

Patentee is entitled to PTA of four hundred thirty-five (435) days. Using the formula “A” delay + “B” delay + “C” delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $375 + 150 + 0 - 0 - 90 = 435$ days.

CONCLUSION

The request for reconsideration of the revised patent term adjustment is **denied**.

The Office acknowledges the submission of the \$200.00 fee set forth in 37 CFR 1.18(e).

Application/Control Number: 12/991,191

Page 5

Art Unit: OPET

Telephone inquiries specific to this matter should be directed to Attorney Advisor Douglas I. Wood at 571-272-3211.

/ROBERT CLARKE/

Robert A. Clarke

Patent Attorney

Office of the Deputy Commissioner
for Patent Examination Policy