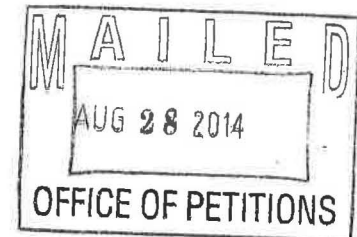




UNITED STATES PATENT AND TRADEMARK OFFICE

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

LERNER DAVID LITTENBERG
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD NJ 07090



In re Patent No. 8,419,609
Shambaugh, et al.
Issue Date: 04/16/2013
Application No. 11/243,722
Filing or 371(c) Date: 10/05/2005
Docket No.: 76527/JPW/JSW

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

This is a decision on the patent term adjustment in response to the "REQUEST FOR RECONSIDERATION AND CORRECTION OF PATENT TERM ADJUSTMENT (PTA) UNDER 37 C.F.R. §1.705(d)" filed April 23, 2013, requesting that the patent term adjustment determination for the above-identified patent be changed from 0 days to 1468 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 16, 2013, the above-identified application matured into U.S. Patent No. 8,419,609. The patent issued with a PTA of 0 days. The present request for redetermination of the patent term adjustment was timely filed within two months of the issue date of the patent.

The present petition

Patentees avers that pursuant to *Exelixis, Inc. v. Mr. David Kappos*, Case No. 1:12cv96 (E.D. Va. November 1, 2012), the filing of a Request for Continued Examination ("RCE") after the three-year pendency period has passed has no impact on PTA.

Discussion

Patentees' arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to 0 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). The Office and Patentees are in agreement that the total amount of "A" delay is 283 days. Furthermore, the Office and Patentees are in agreement that the total amount of Applicant delay is 465 days for six separate instances of Applicant delay of 95 days, 55 days, 68 days, 62 days, 88 days, and 97 days.

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 114 days of "B" delay. In this case, the application was filed on October 5, 2005, and the patent issued on April 16, 2013; thus, the application was pending for 2751 days. During this time, Applicants filed an RCE on November 14, 2008, and the Office mailed a Notice of Allowance on January 31, 2013. Under 35 U.S.C. § 154(b)(1)(B)(i), there was one time period consumed by continued examination ("RCE period") – from November 14, 2008 until the Notice of Allowance was issued on January 31, 2013 – *i.e.* 1540 days. Subtracting the RCE period from the total number of days the application was pending results in $2751 - 1540 = 1211$ days. Thus, for purposes of "B" delay, the application was pending for $1211 - 1097$ [*i.e.*, the 3 year delay period] = 114 days beyond the 3-year anniversary of the filing date.

Overall PTA Calculation**Formula:**

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

USPTO's Calculation:

$283 + 114 + 0 - 0 - 465 = 0$

Patentee's Calculation:

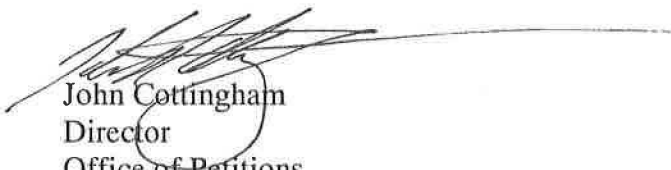
$$283 + 1654 + 0 - 4 - 465 = 1468$$

Conclusion

Patentee is entitled to PTA of zero (0) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $283 + 114 + 0 - 0 - 465 = 0$ days.

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

Telephone inquiries specific to this matter should be directed to Attorney Advisor Cliff Congo at (571) 272-3207.



John Cottingham
Director
Office of Petitions