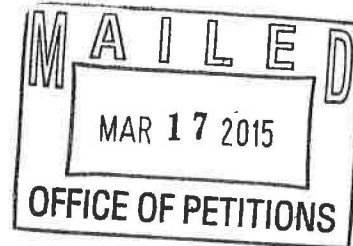




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In re Patent No. 8,647,677
Badylak, et al.
Issue Date: February 11, 2014
Application No. 12/503,774
Filing or 371(c) Date: July 15, 2009
Docket No.: 3220-209139

:
: 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 OF PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705", filed April 4, 2014, requesting that the patent term adjustment determination for the above-identified patent be changed from 455 days to 553 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 February 11, 2014, the above-identified application matured into U.S. Patent No. 8,647,677. The patent issued with a PTA of 455 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 patentees are entitled to an additional 98 days of patent term adjustment under 37 CFR 1.702(b) and 37 CFR 1.703(b).

Discussion

Patentees' arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to **455** 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 541 days. Furthermore, the Office and Patentees are in agreement that the total amount of Applicant delay is 86 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 0 days of "B" delay. In this case, the application was filed on July 15, 2009, and the patent issued on February 11, 2014; thus, the application was pending for 1,672 days. During this time, Applicants filed an RCE on December 12, 2011, and the Office mailed a Notice of Allowance on November 5, 2013. Under 35 U.S.C. § 154(b)(1)(B)(i), there was one time period consumed by continued examination ("RCE period") – from December 12, 2011, until the Notice of Allowance was issued on November 5, 2013 – *i.e.* 695 days. Subtracting the RCE period from the total number of days the application was pending results in $1,672 - 695 = 977$ days. Thus, for purposes of "B" delay, the application was pending for $977 - 1097$ [*i.e.*, the 3 year delay period] = 0 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:

$$541 + 0 + 0 - 0 - 86 = 455$$

Patentee's Calculation:

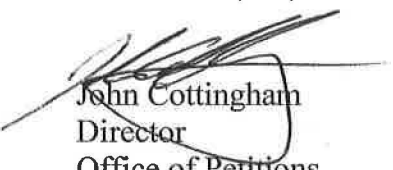
$$541 + 98 + 0 - 0 - 86 = 553$$

Conclusion

Patentee is entitled to PTA of four hundred and fifty-five (455) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $541 + 0 + 0 - 0 - 86 = 455$

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 Kenya A. McLaughlin, Attorney Advisor, at (571) 272-3222.



John Cottingham
Director
Office of Petitions