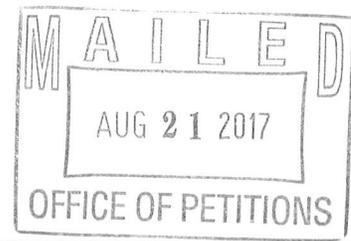




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In re Patent No. 9,435,995 :
Le at al. : DECISION DENYING REQUEST
Issue Date: September 6, 2016 : FOR REDETERMINATION OF
Application No. 13/006,390 : PATENT TERM ADJUSTMENT
Filing or 371(c) Date: January 13, 2011 :
Attorney Docket No. PC-001 :

This is in response to patentee's "REQUEST FOR RECONSIDERATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705(d) IN VIEW OF *EXELIXIS*" filed November 4, 2016, which is being treated under 37 CFR 1.705(b) as a request that the Office adjust the patent term adjustment ("PTA") from 312 days to at least 1,076 days.

The request is **DENIED**.

This decision is the Director's decision on patentee's request for reconsideration for the purposes of seeking judicial review under 35 U.S.C. 154(b)(4).

Relevant Procedural History

On September 6, 2016, this patent issued with a PTA in the amount of 312 days. On November 4, 2016, patentee timely filed the present request for redetermination of patent term adjustment, seeking an adjustment of the determination to at least 1,076 days. Specifically, patentee solely disagrees with the USPTO's calculation of "B" delay. Patentee asserts that the correct amount of "B" delay is 967 days based on the decision in *Exelixis, Inc. v. Kappos*, 906 F. Supp. 2d 474 (E.D. Va. 2012).

Decision

Upon review, the Office finds that patentee is entitled to 312 days of PTA. The Office and patentee are in agreement regarding 416 days of "A" delay under 35 U.S.C. 154(b)(1)(A), zero (0) days of "C" delay under 35 U.S.C. 154(b)(1)(C), zero (0) days of overlap under 35 U.S.C. 154(B)(2)(A), and 307 days of applicant delay under 35 U.S.C. 154(b)(2)(C)(iii) and 37 CFR 1.704. However, the Office and patentee are in disagreement regarding the amount of "B" delay under 35 U.S.C. 154(b)(1)(B).

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The Office will revisit the amount of “B” delay in view of the Federal Circuit’s decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014) and pursuant to 35 U.S.C. 154(b)(1)(B).

As to the amount of “B” delay, the U.S. Court of Appeals for the Federal Circuit (“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 the *Novartis* appeal. 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. That is, the Federal Circuit determined that any time consumed by continued examination under 35 U.S.C. 132(b) is subtracted in determining the extent to which the period of “B” delay defined in 35 U.S.C. 154(b)(1)(B) exceeds three years, regardless of when the continued examination was initiated. *See* MPEP 2731. Nevertheless, the Federal Circuit 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, unless the Office actually resumes examination of the application after allowance. *Id.* at 602; *see* MPEP 2731.

Pursuant to the *Novartis* decision, the USPTO has determined patentee is entitled to 203 days of “B” delay. In this case, applicant filed the application on January 13, 2011, and the patent issued on September 6, 2016. Thus, the application was pending for 2064 days. During this time, applicant filed a RCE on April 3, 2014. The Office mailed a Notice of Allowance on May 5, 2016. Under 35 U.S.C. 154(b)(1)(B)(i), the time period consumed by continued examination (“RCE period”) began on April 3, 2014, and ended on May 5, 2016 – *i.e.*, 764 days. Subtracting the RCE period from the total number of days the application was pending results in $2064 - 764 = 1300$ days. Thus, for purposes of “B” delay, the application was pending for $1300 - 1097$ [i.e., 3 years from the actual filing date]¹ = 203 days beyond the three-year anniversary of the filing date.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

$416 + 203 + 0 - 0 - 307 = 312$

¹ January 13, 2011 – January 13, 2014 = 1097 days

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Patentee's Calculation

$$416 + 967 + 0 - 0 - 307 = 1,076$$

Conclusion

The Office affirms that patentee is entitled to PTA in the amount of three hundred twelve (312) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $416 + 203 + 0 - 0 - 307 = 312$ days. A correction of the determination of patent term adjustment under 35 U.S.C. 154(b) to 1,076 days is not merited. Accordingly, the request for redetermination of patent term adjustment is **denied**. This decision may be viewed as a final agency action. *See* MPEP 1002.02(b).

The Office acknowledges receipt of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Christina Tartera Donnell, Attorney Advisor at (571) 272-3211.

/ROBERT CLARKE/

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Office of the Deputy Commissioner

for Patent Examination Policy - USPTO