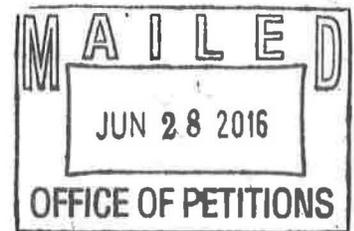




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In re Patent No. 9,101,329 : DIRECTOR'S DECISION ON
Issued: August 11, 2015 : PATENT TERM ADJUSTMENT
Application No. 12/677,601 :
Filing or 371(c) Date: May 3, 2010 :
Atty. Dkt. No.: 10021 :

This decision is in response to the "REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT IN VIEW OF NOVARTIS AND EXELIXIS," filed October 7, 2015, requesting that the patent term adjustment be increased from 601 days to 714 days.

The redetermination of patent term adjustment is **DENIED** with respect to making any change in the patent term adjustment determination under 35 U.S.C. § 154(b) of 601 days.

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

THERE WILL BE NO FURTHER CONSIDERATION OF THIS MATTER BY THE OFFICE.

Relevant Procedural History

On August 11, 2015, this patent issued with a patent term adjustment determination of 601 days. On October 7, 2015, patentee timely filed an application for patent term adjustment under 37 CFR 1.705(b) seeking an additional adjustment of 113 days in view of in Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014) and Exelixis Inc. v. Kappos, Case No. 1:12cv96 (E.D. Va. November 1, 2012).

Decision

Patentee does not dispute the Office's calculation of the 310 days of "A" delay, the calculation of zero days of "C" delay, the overlap of 12 days, or the applicant delay of 125 days. At issue is the period of "B" delay. In this regard, patentee asserts that the period of "B" delay should be increased an additional 113 days in view of Novartis, supra, and Exelixis, surpa.

Art Unit: OPET

Patentee is advised that the calculation of patent term adjustment reflected on the Letters Patent includes the period of 113 days that the patent is entitled to in view of Novartis, supra. Thus, the calculation of 428 days of "B" delay will not be increased.

The Federal Circuit reviewed the USPTO's 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. 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.

Pursuant to the Novartis decision, the USPTO has determined that patentee is entitled to 428 days of "B" delay. Pursuant to the Novartis decision, the period of time from the filing of the RCE to the mailing of the notice of allowance continues to be subtracted from "B" delay as time consumed by continued examination. In this instance, the RCE period was 454 days, resulting in the Office to determine that this application was pending 428 days beyond 3 years from the date of commencement.

The redetermination is calculated as follows: In this case, the commencement date of the application is March 12, 2010 and the patent issued on August 11, 2015; thus, the application was pending for 1979 days. A request for continued examination (RCE) was filed on January 22, 2014. A Notice of Allowance issued April 20, 2015. Under 35 U.S.C. § 154(b)(1)(B)(i), there was one time period consumed by continued examination ("RCE period"). The RCE period began on January 22, 2014 and ended on April 20, 2015 – i.e., 454 days. Subtracting the RCE period from the total number of days the application was pending results in $1979 - 454 = 1525$ days. Thus, for purposes of "B" delay, the application was pending 428 beyond the 3-year anniversary of the filing date, $1525 - 1097$ [i.e., 3 years from the actual commencement date] = 428 days.

Overall PTA Calculation

Formula:

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

USPTO's Calculation:

$310 + 428 + 0 - 12 - 125 = 601$

Patentee's Calculation

Application/Control Number: 12/677,601

Page 3

Art Unit: OPET

$$310 + 541 + 0 - 12 - 125 = 714$$

Conclusion

Patentee remains entitled to PTA of 601 days, as reflected on the patent. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as follows: $310 + 428 + 0 - 12 - 125 = 601$ days.

Telephone inquiries specific to this matter should be directed to Attorney Advisor Alesia M. Brown at (571) 272-3205.

/ROBERT CLARKE/

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for Patent Examination Policy - USPTO