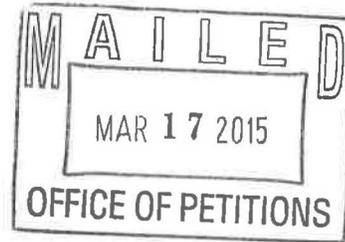




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In re Patent No. 8,609,845 :
Cohen et al. : DIRECTOR'S DECISION ON
Issue Date: December 17, 2013 : PATENT TERM ADJUSTMENT
Application No. 12/538,794 :
Filed: August 10, 2009 :
Attorney Docket No. :
146392011001 :
Title: PYRROLIDINE INHIBITORS :
OF IAP :



This is a response to the "Request for Reconsideration of Patent Term Adjustment" filed pursuant to 37 CFR 1.705(b) on March 17, 2014 requesting that the Office adjust the PTA from 0 days to 61 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 61 days.

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

This redetermination of 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.

Relevant Procedural History

On December 17, 2013, this patent issued with a patent term adjustment determination of 0 days. On March 17, 2014, patentee filed this request for redetermination of patent term adjustment with a one month extension of time, requesting that patentee be granted a patent term adjustment of 61 days.

Decision

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Patentee agrees with the Office's calculation of A delay of 161 days, C delay of 0 day, 0 days of overlap and 233 days of applicant delay. Patentee disputes B delay.

Patentee contends that the USPTO failed to properly account for the delay under 35 U.S.C. §154(b)(1)(B), referred to as the "B delay." Patentee maintains that the B delay is 133 days (not 0 days). With a B delay of 133, Patentee states that the correct PTA is 61 days.

The Office accorded 0 days of B delay based upon the Office's former interpretation of rule 37 CFR 1.703(b)(1) which excluded from the amount of "B" delay the period beginning on the date of filing of the continued examination and ending on the date of the issuance of the patent. 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.

Pursuant to the *Novartis* decision, the USPTO has determined that patentee remains entitled to 0 days of "B" delay. Patentee's calculation of 133 days of "B" delay fails to account for the fact that 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 663 days, resulting in the Office continuing to determine that this application was pending 0 days beyond 3 years from the actual filing date.

The redetermination is calculated as follows: the application was filed on August 10, 2009 and the patent issued on December 17, 2013. Thus, the application was pending for 1591 days. During this period, applicant filed one RCE on October 14, 2011. The Office mailed a single Notice of Allowance on August 6, 2013. Under 35 USC 154(b)(1)(B)(i), the time period consumed by

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continued examination ("RCE period") began on October 14, 2011 and ended on August 6, 2013 i.e., 663 days. Subtracting the RCE period from the total number of days the application was pending results in $1591 - 663 = 928$ days. Thus, for purposes of "B" delay, the application was pending for $928 - 1097$ [i.e., 3 years (including a leap year) from the actual filing date] = 0 days beyond the three-year anniversary of the filing date.

The Office finds that there are 0 days of overlapping days of Office delay. In *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the United States Court of Appeals for the Federal Circuit determined that overlap occurs when the calendar days overlap between the "A" and "B" delays.

Overall PTA Calculation

Formula:

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

USPTO's Calculation:

$161 + 0 + 0 - 0 - 233 = 0$

Patentee's Calculation

$161 + 133 + 0 - 0 - 233 = 61$

Conclusion

Patentee remains 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 follows: $161 + 0 + 0 - 0 - 233 = 0$ days.

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