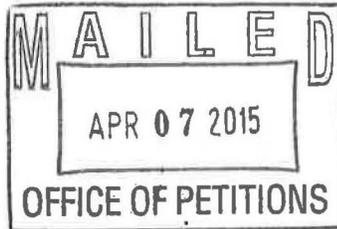




UNITED STATES PATENT AND TRADEMARK OFFICE



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

In re Patent No. 8,796,804 :
Issue Date: August 5, 2014 : DECISION DENYING REQUEST
Application No. 12/107,627 : FOR REDETERMINATION OF
Filing or 371(c) Date: April 22, 2008 : PATENT TERM ADJUSTMENT
Attorney Docket No. TSM07-0818 :

This is in response to patentee's "APPLICATION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT PURSUANT TO 37 C.F.R. § 1.705" filed August 21, 2014, which is being treated under 37 CFR 1.705(b) as a request that the Office correct the patent term adjustment determination ("PTA") from 1114 days to 1250 days.

The request is **DENIED**.

This redetermination of patent term adjustment is the Director's decision on patentee'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 August 5, 2014, this patent issued with a PTA of 1114 days. On August 21, 2014, patentee timely filed the present request for redetermination of patent term adjustment within two months of the issue date of the patent.

Patentee seeks 1250 days of PTA. Patentee solely disputes the calculation of "B" delay. Patentee requests 140 days of "B" delay based on the Federal Circuit's interpretation of 35 U.S.C. § 154(b)(1)(B) set forth in *Novartis AG v. Lee*, No. 2013-1160 (Fed. Cir. Jan. 15, 2014). Patentee calculates the period of "B" delay as follows:

Under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. §§ 1.702(b) and 1.703(b) as modified by the Federal Circuit's decision in *Novartis*, a delay of 136 days (*e.g.*, the period between April 22, 2011 (*e.g.*, the day after three years after the filing date listed in paragraph 1) and August 5, 2014 (*e.g.*, the issue date listed in paragraph 14), but excluding the period between April 1, 2010 (*e.g.*, the filing date of the Request for Continued Examination listed in paragraph 7) and March 21, 2014 (*e.g.*, the mailing

Art Unit: OPET

date of the Notice of Allowance listed in paragraph 12)). Before *Novartis*, the Office excluded the period between March 21, 2014 and August 5, 2014 in the calculation of delay under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. §§ 1.702(b) and 1.703(b).

Request, 08/21/14, pp. 2-3.

Decision

The Office has carefully considered patentee's arguments. Upon review, the Office finds that patentee is entitled to **1114** days of PTA. The Office and patentee are in agreement regarding the calculation of 1145 days of "A" delay, 0 days of "C" delay, 0 days of overlap, and 31 days of applicant delay. The Office has revisited the determination of 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).

As to the amount of "B" delay, the Office notes that the interpretation of the "B" delay was based upon 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. However, 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 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. The Federal Circuit issued its mandate in the *Novartis* appeal on March 10, 2014.

Pursuant to the *Novartis* decision, the USPTO has determined patentee is entitled to zero (0) days of "B" delay. In this case, applicant filed the application on April 22, 2008, and the patent issued on August 5, 2014. Thus, the application was pending for 2297 days. During this time, applicant filed the first RCE on April 1, 2010. The Office mailed a Notice of Allowance on March 21, 2014. Under 35 U.S.C. § 154(b)(1)(B)(i), the time period consumed by continued examination ("RCE period") began on April 1, 2010, and ended on March 21, 2014 – *i.e.*, 1451 days. Subtracting the RCE period from the total number of days the application was pending results in $2297 - 1451 = 846$ days. Thus, for purposes of "B" delay, the application was pending for $846 - 1096$ [*i.e.*, 3 years from the actual filing date] = 0 days beyond the three-year anniversary of the filing date.

Art Unit: OPET

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

1145 + 0 + 0 - 0 - 31 = 1114

Patentee’s Calculation

1145 + 136 + 0 - 0 - 31 = 1250

Conclusion

The Office affirms that patentee is entitled to PTA of one thousand one hundred fourteen (1114) days. Using the formula “A” delay + “B” delay + “C” delay - overlap - applicant delay = X, the amount of PTA is calculated as following: 1145 + 0 + 0 - 0 - 31 = 1114 days. A correction of the determination of patent term adjustment under 35 U.S.C. § 154(b) to 1250 days is not merited. As the front page of the patent properly reflects the PTA determination of 1114 days, no further action is required. 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.

/JOHN COTTINGHAM/
Director
Office of Petitions