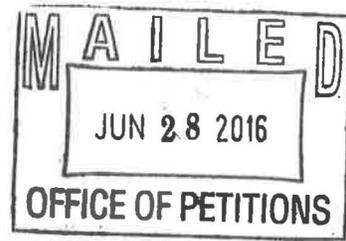




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In re Patent No. 9,161,757 :
Issued: October 20, 2015 : DECISION ON REQUEST
Application No. 12/825,709 : FOR RECONSIDERATION OF
Filed: June 29, 2010 : PATENT TERM ADJUSTMENT
Attorney Docket No.: H-US-00283DIV(203- :
4585DV) :

This decision is in a response to the “REQUEST FOR PATENT TERM ADJUSTMENT,” filed November 12, 2015, pursuant to 37 CFR 1.705(b), requesting that the Office adjust the patent term adjustment from 1189 days to 1214 days.

The request for reconsideration is granted to the extent that the determination has been reconsidered; however, the request for reconsideration of patent term adjustment is **DENIED** with respect to making any change in the patent adjustment determination under 35 U.S.C. § 154(b) of 1189 days.

This is the Director’s decision on the applicant’s request for reconsideration under 35 USC 154(b)(3)(B)(ii). Any appeal from this decision is pursuant to 35 U.S.C. § 154(b)(4)(A).

Relevant Procedural History

On October 20, 2015, the Office determined that applicant was entitled to 1189 days of PTA. On November 12, 2015, patentee filed an Application for Patent Term Adjustment under 37 CFR 1.705(d) seeking reconsideration of the patent term adjustment and requesting that the Office grant PTA in an amount of 1214 days.

On January 15, 2014, the Federal Circuit issued a decision regarding the calculation of “B” delay after an applicant files a request for continued examination (RCE). *See, Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

Decision

Upon review, the USPTO finds that patentee is entitled to 1189 days of PTA. Patentee and the Office are in agreement regarding the amount of “A” delay under 35 § USC 154(b)(1)(A), “C” delay under 35 U.S.C. 154(b)(1)(C), and overlap under 35 § USC 154(b)(2)(A).

The Office will address the “B” delay under 35 U.S.C. 154(b)(1)(B) and the amount of reduction of PTA under 35 U.S.C. § 154(b)(2)(C)(iii) and 37 CFR 1.704.

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“A” Delay

The Office and Patentee agree that there are 798 days of “A” delay. The periods of “A” delay are:

- (1) 745 days under 37 CFR 1.703(a)(1) beginning on August 30, 2011 (the day after the date that is fourteen months after the day the application was filed) and ending on September 12, 2013 (the date the first Office action was mailed);
- (2) 53 days under 37 CFR 1.703(a)(3) beginning on December 21, 2014 (the day after the date that is four months after the date that the reply to the final Office action mailed) and ending on February 11, 2015 (the date that the non-final Office action was mailed).

“B” Delay

The *Novartis* decision includes “instructions” for calculating the period of “B” delay. Specifically, the decision states,

The better reading of the language is that the patent term adjustment time [for “B” delay] should be calculated by determining the length of the time between application and patent issuance, then subtracting any continued examination time (and other time identified in (i), (ii), and (iii) of (b)(1)(B)) and determining the extent to which the result exceeds three years. *Novartis*, 740 F.3d at 601.

The length of time between application and issuance is 1940 days, which is the number of days beginning on the filing date of the application (June 29, 2010) and ending on the date the patent issued (October 20, 2015).

The time consumed by continued examination is 358 days. The time consumed by continued examination includes the following period: the period of 358 days, beginning on the filing date of the RCE (August 20, 2014) and ending on the mailing date of the notice of allowance August 12, 2015).

The number of days beginning on the filing date of application (June 29, 2010) and ending on the date three years after the filing date of the application (June 29, 2013) is 1097 days.

The result of subtracting the time consumed by continued examination (485 days) from the length of time between the application filing date and the date of issuance (1940 days) is 1582 days, which exceeds three years (1097 days) by 485 days. Therefore, the period of “B” delay is 485 days.

It is noted that Patentee calculates the time consumed by continued examination to be 491 days and assert that the Office has failed to apply the principles of *Novartis* to the instant patent.

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However, has indicated by the calculation of "B" delay set forth herein, the Office did properly calculate the period of "B" delay by properly applying *Novartis*.

"C" Delay

The patentee and the Office agree that the amount of "C" delay under 37 CFR 1.703(e) is zero.

Overlap

The patent and the Office agree that the amount of overlap under 35 § USC 154(b)(2)(A) is zero.

Reduction under 35 U.S.C. § 154(b)(2)(C)(iii) & 37 CFR 1.704 [Applicant Delay]

The Office and Patentee and are not in agreement regarding period of reduction under 37 CFR 1.704(c)(8).

The Office has determined that the patentee failed to engage in reasonable efforts to conclude processing or examination of its application with respect to the supplemental reply filed September 8, 2014 pursuant to 37 CFR 1.704(c)(8) which provides that:

Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping:

Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed;

The Office mailed a final Office action on May 20, 2014. An RCE was filed in response thereto on August 20, 2014. A supplemental reply in the form of Information Disclosure Statement (IDS) was filed September 8, 2014. The period beginning on the day after the filing of the RCE on August 20, 2014 and ending with the filing of the IDS on September 8, 2014 totals 19 days. There is no indication in the record that the supplemental reply was expressly requested by the examiner. Further, the IDS did not contain a proper statement pursuant to 37 CFR 1.704(d). Thus, the Office properly reduced the patent term adjustment 19 days pursuant to 37 CFR 1.704(c)(8).

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However, Patentee asserts that a reduction under 37 CFR 1.704(c)(8) is not warranted because the IDS filed on September 8, 2014 was in compliance with 37 C.F.R. §§ 1.97 and 1.98. Patentee further references *Arqule, Inc. v. Kappos*, 793 F.Supp. 2d 214, 225-226 (D.D.C. 2011), and states that “the court held that the Office's interpretation of § 154(b)(2)(C)(ii) "functionally negated" the "grace period statutorily guaranteed by [35 U.S.C.] § 21 (b)," wherein the plaintiff pursuant to 35 U.S.C. § 21(b) filed reply papers after a federal holiday.” Patentee argues that similar to *Arqule*, “Applicant complied with the timing requirements regarding IDS pursuant to 37 C.F.R. § 1.97(b)(4) while at the same time, the Office functionally negated the period of § 1.97(b)(4) in its application of 37 C.F.R. §§ 1.704(c)(8), regarding PTA calculations by attributing any days of Applicant delay.”

Patentee’s arguments have been carefully considered, but are found unpersuasive. The Office notes recently the Federal Circuit determined that submission of an IDS after the filing of a response to an election or restriction requirement is a reduction under 37 CFR 1.704(c)(8). *See, Gilead Sciences, Inc. v. Lee*, cv 14-1159 (Fed. Cir. 2015). In *Gilead*, the court noted that the conduct of filing an IDS after the submission of a response to an election or restriction requirement interferes with the PTO’s ability to conclude the application process because of significant time constraints faced by the PTO. *See, Gilead* at page 15. Because the “A” Delay provision of the statute penalizes the PTO if the examiner fails to respond within four months of the applicant’s response to the restriction requirement, any relevant information received after an initial response to a restriction requirement “interferes with the [PTO’s] ability to process an application. *Id.* A supplemental IDS may force an examiner to go back and review the application again, while still trying to meet his or her timeliness obligations under § 154. *Id.*

The same analysis applies to submission of an IDS document after the filing of an RCE. The Office must respond to the submission of an RCE within four months of the filing of the RCE or provide additional “A” delay. Any IDS submission by patentee after the filing of a RCE “interferes” with the [PTO’s ability] to process an application because the examiner may be forced to go back and review the application again. Accordingly, the Office maintains the reduction of applicant delay for the IDS submission after the filing of an RCE.

In view thereof, the reduction of 19 days assessed pursuant to 37 CFR 1.704(c)(8) will not be restored.

Overall PTA Calculation

Formula:

“A” delay + “B” delay + “C” delay - Overlap - Applicant delay = X days of PTA

USPTO’s Calculation:

798 (*i.e.*, 745 + 53) + 485 (*i.e.*, 1940 – 358 – 1097) + 0 – 0 – 19 = 1189

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Patentee's Calculation:

$$798 \text{ (i.e., } 745 + 53) + 485 + 0 - 0 - 0 = 1214$$

Patentee is entitled to PTA of 1189 days. Using the formula "A" delay + "B" delay + "C" delay - Overlap - Applicant delay = X, the amount of PTA is calculated as following: $798 + 485 + 0 - 0 - 19 = 1189$ days.

Telephone inquiries regarding this decision may be directed to Attorney Advisor Alesia M. Brown at (571) 272-3205.

/ROBERT CLARKE/

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