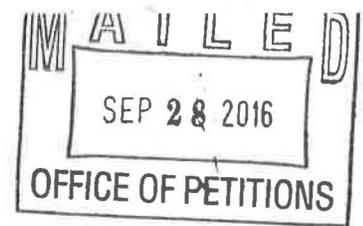




UNITED STATES PATENT AND TRADEMARK OFFICE



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

In re Application of Harmon, et al. Application No. 11/611,602 Filed: December 15, 2006 Patent No. 9,175,261 Issue Date: November 3, 2015 Attorney Docket No.: 18668-327391 DECISION ON REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

This is a response to the "APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.705(B)," filed January 4, 2016, requesting that the Office adjust the patent term adjustment from 640 days to at least 1568 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 640 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 November 3, 2015, the Office determined that applicant was entitled to 640 days of PTA. On January 4, 2016, 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 at least 1568 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 640 days of PTA. Patentee and the Office are in agreement regarding the amount of "A" delay under 35 § USC 154(b)(1)(A), "B" delay under 35 U.S.C. 154(b)(1)(B), "C" delay under 35 U.S.C. 154(b)(1)(C), and overlap under 35 § USC 154(b)(2)(A).

Art Unit: OPET

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

### **“A” Delay**

The patentee and Office agree that there are 1481 days of “A” delay. The periods of “A” delay are:

- (1) 315 days under 37 CFR 1.703(a)(1) beginning on February 16, 2008 (the day after the date that is fourteen months after the day the application was filed) and ending on December 26, 2008 (the date the first Office action was mailed);
- (2) Seven days under 37 CFR 1.703(a)(3) beginning on June 17, 2010 (the day after the date that is four months after the date a reply under 37 CFR 1.113(c) was filed) and ending on June 23, 2010 (the date of mailing of the non-final Office action).
- (3) 972 days under 37 CFR 1.703(a)(3) beginning on February 26, 2011 (the day after the date that is four months after the date that a reply under 37 CFR 1.113(c) was filed) and ending October 24, 2013, the date that the non-final Office action was mailed.
- (4) 147 days under 37 CFR 1.703(a)(2) beginning on May 16, 2014 (the day after the date that is four months after the date that a reply under 37 CFR 1.111 was filed) and ended October 9, 2014 (the date that the non-final Office action was mailed).
- (5) 40 days under 37 CFR 1.703(a)(2) beginning on May 10, 2015 (the day after the date that is four months after the date that a reply under 37 CFR 1.111 was filed) and ended June 18, 2015 (the date that the Notice of Allowance 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.<sup>1</sup>

The length of time between application and issuance is 3246 days, which is the number of days beginning on the filing date of the application (December 15, 2006) and ending on the date the patent issued (November 3, 2015).

The time consumed by continued examination is 1949 days. The time consumed by continued examination includes the following period: beginning on February 16, 2010, the filing date of the RCE and ending on June 18, 2015, the mailing date of the notice of allowance.

---

<sup>1</sup> *Novartis*, 740 F.3d at 601.

Art Unit: OPET

The number of days beginning on the filing date of application (December 15, 2006) and ending on the date three years after the filing date of the application (December 15, 2009) is 1097 days.

The result of subtracting the time consumed by continued examination (1949 days) from the length of time between the application filing date and issuance (3246 days) is 1297 days, which exceeds three years (1097 days) by 200 days. Therefore, the period of "B" delay is 200 days.

#### **"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 patentee and the Office agree regarding the period of reduction under 37 CFR 1.704(c)(8) with respect to the information disclosure statement (IDS) filed May 10, 2013.

The Office has determined that the patentee failed to engage in reasonable efforts to conclude processing or examination of its application during the following periods:

- (1) The patentee and the Office are in agreement in regards to a 15-day period pursuant to 37 CFR 1.704(b) from June 4, 2009 until June 18, 2009. The Office mailed a non-final Office action on March 3, 2009. Accordingly, the three-month response date was June 3, 2009. However, the patentee did not file a response until June 18, 2009.
- (2) The patentee and the Office are in agreement in regards to a 32-day period pursuant to 37 CFR 1.704(b) from January 16, 2010 until February 16, 2010. The Office mailed a final Office action on March 3, 2009. Accordingly, the three-month response date was June 3, 2009. However, the patentee did not file its amendment to the claims and remarks under February 16, 2010.
- (3) The patentee and the Office are in agreement in regards to a 32-day reduction pursuant to 37 CFR 1.704(b) from September 24, 2010 until October 25, 2010. The Office mailed a final Office action on June 23, 2010. Accordingly, the three-month response date was September 23, 2010. However, the patentee did not file its amendment to the claims and remarks under October 25, 2010.
- (4) The patentee and the Office are in disagreement in regards to the reduction of 928 days that was assessed pursuant to 37 C.F.R. § 1.704(c)(8), which provides that:

Art Unit: OPET

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 June 23, 2010. A RCE was filed on October 25, 2010. Supplemental replies were filed February 4, 2011 (IDS), December 23, 2011 (supplemental amendment), September 5, 2012 (IDS), and May 10, 2013 (IDS). The period beginning on the day after the filing of the RCE, October 26, 2010 and ending with the filing of the final aforementioned IDS on May 10, 2013 totals 928 days. It follows that a 928-day reduction is warranted pursuant to 37 C.F.R. § 1.704(c)(8). Accordingly, the Office properly assessed a reduction of 928 days.

With this petition, patentee asserts that no reduction is warranted, and argues that 37 C.F.R. § 1.704(c)(8) is not applicable because, *inter alia*, the submission of the supplemental reply on May 10, 2013 did not interfere with the issuance of the non-final Office action mailed October 24, 2013. Patentee's arguments have been carefully considered, but has been found to be unpersuasive, for the reduction is warranted pursuant to 37 CFR 1.704(c)(8).

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 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.*

Art Unit: OPET

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.

- (5) The patentee and the Office are in agreement in regards to a 34-day reduction pursuant to 37 CFR 1.704(c)(10) from July 22, 2015 until August 24, 2015. The Notice of Allowance was mailed June 18, 2015. Patentee filed a post-allowance amendment on July 22, 2015 to which a response thereto was mailed August 24, 2015.

### Overall PTA Calculation

#### Formula:

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

#### USPTO's Calculation:

1481 (*i.e.*, 315 + 7 + 972 + 147 + 40) + 200 (*i.e.*, 3246 - 1949 - 1097) + 0 - 0 - 1041 (*i.e.*, 15 + 32 + 32 + 928 + 34) = 640

#### Patentee's Calculation:

1481 (*i.e.*, 315 + 7 + 972 + 147 + 40) + 200 (*i.e.*, 3246 - 1949 - 1097) + 0 - 0 - 113 (*i.e.*, 15 + 32 + 32 + 34) = 1568

Patentee is entitled to PTA of 640 days. Using the formula "A" delay + "B" delay + "C" delay - Overlap - Applicant delay = X, the amount of PTA is calculated as following: 1481 + 200 + 0 - 0 - 1041 = 640 days.

Art Unit: OPET

Telephone inquiries regarding this decision may be directed to Attorney Advisor Alesia M. Brown at (571) 272-3205.<sup>2</sup>

/ROBERT CLARKE/

Robert A. Clarke

Patent Attorney,

Office of the Deputy Commissioner

for Patent Examination Policy – USPTO

---

<sup>2</sup> Petitioner will note that all practice before the Office should be in writing, and the action of the Office will be based exclusively on the written record in the Office. See 37 C.F.R. § 1.2. As such, Petitioner is reminded that no telephone discussion may be controlling or considered authority for any further action(s) of Petitioner.