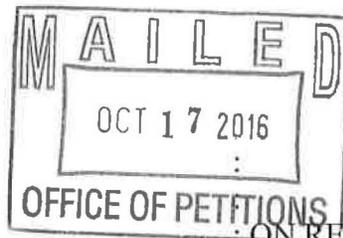




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In re Patent No. 9,055,980
Biedermann
Issue Date: 06/16/2015
Application No. 12/845551
Filing or 371(c) Date: 07/28/2010
Atty. Docket No.:65489/B884

: ON REDETERMINATION OF
: PATENT TERM ADJUSTMENT
:
:

This is a response to applicants “RENEWED REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT (37 C.F.R. § 1.705(b))”, filed December 9, 2015, requesting that the Office adjust the PTA to 367, or in the alternative 383 days. The Office has re-determined the PTA to be 403 days.

This petition is hereby **DENIED**. 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).

Relevant Procedural History

On June 16, 2015, the above-identified application matured into U.S. Patent No. 9,055,980. The patent issued with a PTA of 25 days. Patentee filed a Request for Reconsideration of Patent Term Adjustment on June 8, 2015, requesting that the Office adjust the patent term from 25 days to 61 days. Patentee and the Office were in agreement regarding the amount of “B” delay under 35 U.S.C. § 154(b)(1)(B) and the amount of overlapping days under 35 U.S.C. § 154(b)(2)(A) pursuant to the Federal Circuit’s decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014); and the amount of “A” delay under 35 U.S.C. § 154(b)(1)(A) and 37 CFR 1.702(a), however, patentee and the Office continued to disagree as to the amount of “applicant delay” under 35 U.S.C. § 154(b)(2)(C) and 1.704(c). Patentee disputed the reduction of the patent term under 37 CFR 1.704(c)(10) in connection with an amendment under 37 CFR 1.312 filed May 4, 2015.

Patentee argued that a notice in response to the amendment was mailed on May 11, 2015, and is labeled in the Image File Wrapper portion of the Patent Application Information and Retrieval System (PAIR), as Amendment After Final or under 37 CFR 1.312, initialed by the examiner”, and labeled in the Patent Term Adjustment portion of PAIR as “Response to Amendment under Rule 312”. *Petition* at p.2.

On September 10, 2015, the Office re-determined the PTA to be 111 days. The Office informed patentee that the May 11, 2015 correspondence is a document that was not mailed, and as such,

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pursuant to 37 CFR 1.704(c)(10), the reduction in connection with the amendment was properly calculated as ending on the issue date of the patent.

The Office also, *sua sponte*, noted that Office records confirmed a reduction of 86 days in connection with the filing of an Information Disclosure Statement (IDS) filed on March 11, 2014. The Office found that the IDS was accompanied by a statement pursuant to 37 CFR 1.704(d), and the reduction was therefore removed.

The Office redetermined the PTA to be 111 days.

The present Renewed Request for Reconsideration of the PTA

The present renewed request for redetermination of the patent term adjustment was timely filed within two months of the issue date of the patent. *Accord*, 37 CFR 1.6.

Patentee files the present renewed request for reconsideration of the PTA and avers that pursuant to the Manual of Patent Examining Procedure (MPEP) 714.16(d), the Examiner and Supervisory Patent Examiner were required to prepare and mail a Response to [the] Rule 312 Communication (PTO-271), and failed to follow the procedure set forth therein. Because the failure of the Examiner and SPE to follow the procedure set forth in the MPEP 714.16, and the failure was not the fault of the patentee, the resulting reduction of the patent term should not be considered Applicant delay.

Decision

Patentees' arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to **111 days** of PTA. Patentee and the Office are in agreement regarding the amount of "B" delay under 35 U.S.C. § 154(b)(1)(B) and the amount of overlapping days under 35 U.S.C. § 154(b)(2)(A) pursuant to the Federal Circuit's decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014); and the amount of "A" delay under 35 U.S.C. § 154(b)(1)(A) and 37 CFR 1.702(a), however, patentee and the Office continue to disagree as to the amount of "applicant delay" under 35 U.S.C. § 154(b)(2)(C) and 1.704(c).

Regarding the reduction, pursuant to 37 CFR 1.704(c)(10), Patentees' attention is directed to 35 U.S.C. § 154(b)(2)(C), REDUCTION OF PERIOD OF ADJUSTMENT, and section (iii), which states: "The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." Pursuant to 35 U.S.C. § 154(b)(2)(C)(iii), the Director prescribed, *inter alia*, 37 CFR 1.704(c)(10), which states that the submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, shall reduce the period of adjustment set forth in § 1.703 by the lesser of:

- (i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office

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action or notice in response to the amendment under § 1.312 or such other paper; or

(ii) Four months;

The MPEP 2732 provides, in relevant part:

37 CFR 1.704(c)(10) establishes submission of an amendment under 37 CFR 1.312 or other paper, other than a request for continued examination in compliance with 37 CFR 1.114, after a notice of allowance has been given or mailed as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. (Emphasis added).

Under 37 CFR 1.704(c)(10), papers that will be considered a failure to engage in reasonable efforts to conclude processing or examination of an application include: (1) an amendment under 37 CFR 1.312; (2) a paper containing a claim for priority or benefit or request to correct priority or benefit information (e.g., a new or supplemental application data sheet filed to correct foreign priority or domestic benefit information); (3) a request for a corrected filing receipt; (4) a certified copy of a priority document; (5) drawings; (6) a letter related to biologic deposits; (7) a request to change or correct inventorship; and (8) an information disclosure statement not accompanied by a statement in compliance with 37 CFR 1.704(d). (Emphasis added).

It is well-established that the filing of an amendment under 37 CFR 1.312 or other paper, other than a request for continued examination (RCE) in compliance with 37 CFR 1.114, after the mailing of a notice of allowance constitutes a failure to engage in reasonable efforts to conclude prosecution of the application, resulting in a reduction of patent term adjustment under 37 CFR 1.704(c)(10). The Office has calculated this period of reduction as the lesser of: (1) the number of days, if any, beginning on the date the amendment under 37 CFR 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under 37 CFR 1.312 or such other paper; or (2) four months. In the circumstance where the Office does not mail a response to the paper that triggered the delay and the patent issues in less than four months, the Office has treated the issuance of the patent as the response to the paper that triggered the delay. Accordingly, under such circumstance, the Office has calculated the period of reduction for applicant delay counting the number of days beginning on the date of filing of the triggering paper and ending on the date of patent grant.

In this instance, Office records confirm that an amendment under 37 CFR 1.312 was filed on May 4, 2015, after the mailing of a Notice of Allowance, mailed February 4, 2015. Office records further confirm that no Office action or notice in response to the amendment was mailed to Patentee. Therefore, pursuant to 35 U.S.C. § 154(b)(2)(C)(iii), and 37 CFR 1.704(c)(10)(i), the period of patent term reduction was properly reduced 44 days, beginning on May 4, 2015, the date that the amendment under 37 CFR 1.312 was filed, and ending on the date of patent grant, June 16, 2015, and is 44 days.

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Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

$295 + 133 + 0 - 0 - 317 = 111$

Patentee’s Calculation

$295 + 133 + 0 - 0 - 281 = 147$

Patentee’s Alternate Calculation

$295 + 133 + 0 - 0 - 297 = 131$

Conclusion

The present RENEWED REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT (37 C.F.R. § 1.705(b)) has been considered; however, the RENEWED REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT (37 C.F.R. § 1.705(b)), is DENIED.

Telephone inquiries specific to this decision should be directed to Attorney Advisor Derek Woods at (571) 272-3232.

/ROBERT CLARKE/
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for Patent Examination Policy