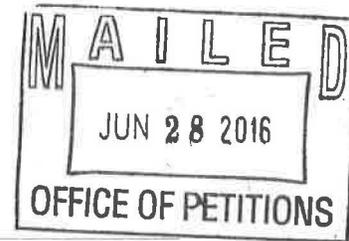




UNITED STATES PATENT AND TRADEMARK OFFICE



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In re Patent No. 8,617,365 :
Ian Harding : REQUEST FOR RECONSIDERATION
Issue Date: December 31, 2013 : OF REDETERMINATION OF
Application No. 10/908,664 : PATENT TERM ADJUSTMENT
Filing or 371(c) Date: May 21, 2005 :
Attorney Docket No. AGAM.P-036 :

This is a response to patentee's "Request for Reconsideration of Patent Term Adjustment" filed March 16, 2015, which is being treated under 37 CFR 1.705(b) as a request that the Office adjust the patent term adjustment (PTA) from 1225 days to 1859 days.

The request for reconsideration is granted to the extent that the Office has reconsidered the determination; 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 1225 days.

This redetermination of patent term adjustment is the Director's decision on the patentee's request for reconsideration for purposes of seeking judicial review under 35 U.S.C. § 154(b)(4).

Relevant Procedural History

On December 31, 2013, this patent issued with a PTA in the amount of 1668 days. On February 13, 2014, patentee timely filed a request for redetermination of patent term adjustment and fee. On January 16, 2015, the Office mailed a redetermination of patent term adjustment adjusting the PTA to 1225 days. The Office set an extendable period of two months from the date of the redetermination to request reconsideration of the patent term adjustment. The decision indicated that the Office would *sua sponte* issue a certificate of correction adjusting the PTA to 1225 days, after the period for response had expired. On March 16, 2015, patentee timely filed a request for reconsideration of patent term adjustment.

Patentee disputes the assessment of 634 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the submission of the Information Disclosure Statement ("IDS") on June 7, 2013, after the filing of a RCE in response to the final Office action on September 12, 2011. In particular, patentee asserts that the Office's characterization of the period between the filing of the RCE on September 12, 2011, and the submission of the IDS on June 7, 2013, as applicant delay, is in error. Patentee states:

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The IDS filed on June 7, 2013 contained a single document: a written transcript of oral proceedings before the Opposition Division of the European Patent Office held on May 16, 2013. This was not a communication from the European Patent Office; it was a transcript of what was said during the May 16 oral proceedings - by Patentee's technical experts, Patentee's European representatives, and the opposing party's representatives and technical experts. Thus, this written transcript was not cited in any communication from a patent office in a counterpart foreign application, nor was it a communication issued by a patent office in a counterpart foreign application. Further, the transcript reflects the personal knowledge of Patentee's representatives and the inventor himself and, as experts in the art, it is impossible to determine exactly when the information contained within the transcript was acquired. Accordingly, neither of the certification statements provided under 37 CFR 1.704(d) are applicable in this case, despite the oral proceedings occurring within 30 days of the filing of the June 7, 2013 IDS. Applicants filed the IDS on June 7, 2013, as soon as they were able to obtain a copy of the transcript, because "The Office does not consider an information disclosure statement filed more than thirty days after the information has been brought to applicant's attention to be promptly submitted." Revision of Patent Term Adjustment Provisions Relating to Information Disclosure Statements, 76 Fed. Reg. 74700, 74701 (December 1, 2001).

Patentee respectfully notes that the resolution of the European opposition proceedings allowed the Examiner to issue a Notice of Allowance almost immediately after the case had been untouched by the Examiner for more than 1.5 years. Thus, the timely filing of this IDS actually expedited the close of prosecution. In no way can this filing be considered a failure to engage in reasonable efforts to conclude prosecution of the application.

Additionally, Patentee respectfully submits that the filing of an IDS after an RCE has been filed but before a first substantive Office action has issued is not the filing of a "supplemental reply or other paper" under 37 C.F.R. 1.704(8). Once an RCE has been filed by an Applicant, Applicant has to wait for the Examiner to act. In many cases, the issuance of a first substantive action after the filing of an RCE takes years. Had Patentee waited to file the IDS until after receiving a first Office action on the merits after the filing of an RCE, Patentee could have received years of additional patent term as a result of the Office's failure to act in a timely fashion. The Office's characterization of a timely filed IDS during this period as a "supplemental reply" resulting in reduction of patent term adjustment penalizes Patentee for complying with the duty of disclosure and the USPTO's own standard of "prompt" submission. Additionally, it is also in direct conflict with public policy, contrary to the USPTO's goals of promoting quality examination and compact prosecution, in conflict with the statute's goal of encouraging applicants to "engage in reasonable efforts to conclude ... examination," and in conflict with the IDS requirements set forth in 37 CFR 1.97. The filing of an IDS after an RCE but before the issuance of ANY further papers by the USPTO should be treated identically to the situation where an IDS is filed after

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the filing of an application, but before the issuance of an Office action (whether on the merits or not) by the USPTO.

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Decision

The Office finds that patentee is entitled to **1225** days of PTA. The Office and patentee are in agreement regarding 1520 days of “A” delay under 35 U.S.C. § 154(b)(1)(A), 877 days of “B” delay under 35 U.S.C. § 154(b)(1)(B), zero (0) days of “C” delay under 35 U.S.C. § 154(b)(1)(C), and 324 days of overlap under 35 U.S.C. § 154(B)(2)(A). However, the Office and patentee are in disagreement regarding the amount of applicant delay under 35 U.S.C. § 154(b)(2)(C)(iii) and 37 CFR 1.704. Therefore, the Office will address the only outstanding issue in dispute, the amount of applicant delay pursuant to 37 CFR 1.704.

The Office has carefully considered patentee’s arguments, but does not find them persuasive. Congress expressly delegated authority to the Director to “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.” 35 U.S.C. 154(b)(2)(C)(iii). The basis for the reduction of PTA for the submission of the IDS on June 7, 2013, after filing a reply to final Office action on September 12, 2011, is 37 CFR 1.704(c)(8).

37 CFR 1.704(c)(8) provides:

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[.]

Furthermore, Section 2732 of the Manual of Patent Examining Procedure (MPEP) states:

37 CFR 1.704(c)(8) establishes submission of a supplemental reply or other paper after a reply has been filed as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. The submission of a supplemental reply or other paper (e.g., an

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information disclosure statement (IDS) or petition) after an initial reply was filed requires the Office to restart consideration of the initial reply in view of the supplemental reply or other paper, which will result in a delay in the Office's response to the initial reply. The submission of an information disclosure statement that is filed after a reply to a restriction requirement (and prior to the subsequent Office action and without a safe harbor statement under 37 CFR 1.704(d) is an applicant delay. *See Gilead Sciences Inc. v. Lee*, 778 F.3d 1341, 113 USPQ2d 1837 (Fed. Cir. 2015). Similarly, the filing of an information disclosure statement after a request for continued examination (RCE) but prior to a subsequent Office action is deemed an applicant delay under 37 CFR 1.704(c)(8). 37 CFR 1.704(c)(8) does not apply to a supplemental reply or other paper that was expressly requested by the examiner.

In this instance, the Office mailed a final rejection on April 11, 2011. In response, applicant filed a reply in compliance with 37 CFR 1.113(c) in the form of an RCE and submission under 37 CFR 1.114 on September 12, 2011. After filing the reply, applicant submitted an IDS on June 7, 2013. Patentee states that certification statements under 37 CFR 1.704(d) are not applicable in this case. Additionally, there is no showing in the record that the examiner expressly requested the filing of the IDS. Consequently, the Office entered 634 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the period beginning on September 13, 2011, the day after the date the reply in compliance with 37 CFR 1.113(c) was filed, and ending on June 7, 2013, the date the IDS ("other paper") was filed.

Patentee asserts that the USPTO should treated the submission of an IDS after an RCE as if the IDS was filed after the filing of an application, but before the issuance of an Office action. What is material is that an RCE is not the filing of a new application. *See MPEP 706.07(h)*. Rather, an RCE is a reply. An RCE is a request by an applicant for continued examination which is effectuated by filing a submission and paying a specified fee. As used in this instance, the RCE was the reply to a final Office action. Thus, the IDS filed after the RCE was an "other paper ... after a reply has been filed," within the meaning of 37 CFR 1.704(c)(8). Accordingly, the period of reduction for applicant delay for the submission of the IDS after the filing of the RCE was properly calculated pursuant to 37 CFR 1.704(c)(8).

Moreover, as the applicant delay at issue involves an IDS (other paper) filed after a RCE (reply) to an Office action, the situation is analogous to decision in *Gilead Science Inc. v. Lee*, which involved an IDS filed after a reply to a restriction requirement. The rationale of *Gilead* is applicable. In *Gilead*, the court noted that the filing of an IDS after an initial reply to a restriction requirement makes it increasingly difficult for the USPTO to satisfy the statutory-mandated time requirement in 35 U.S.C. § 154(b)(1)(A)(ii) to conclude the application process because of significant time constraints faced by the USPTO. *See Gilead* at 1350-51. "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.* at 1350 (*quoting Gilead Scis, Inc. v. Rea*, 976 F.Supp.2d 833,

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837 (2013) (“*Gilead I*”). “[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* at 1350 (quoting *Gilead I* at 837-38).

The same analysis applies to the submission of an IDS document after filing a RCE and submission in response to a final rejection. The Office must respond to the RCE and submission under § 1.114(c) (reply) within four months of its filing or provide additional “A” delay. The submission of an IDS after the filing of a response (*i.e.* RCE) “interferes” with the USPTO’s ability to process an application because it adds additional documents the examiner must consider before responding to the reply. *See Gilead* at 1351.

In view thereof, the Office maintains the 634 days of applicant delay for the submission of the IDS on June 7, 2013. The Office concludes the correct amount of applicant delay remains 848 (57 + 94 + 63 + 634) days.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

1520 + 877 + 0 – 324 – 848 = 1225

Patentee’s Calculation

1520 + 877 + 0 – 324 – 214 = 1859

Conclusion

The Office affirms that patentee is entitled to PTA in the amount of one thousand two hundred twenty-five (1225) days. Using the formula “A” delay + “B” delay + “C” delay - overlap - applicant delay = X, the amount of PTA is calculated as follows: 1520 + 877 + 0 – 324 – 848 = 1225 days. A correction of the determination of patent term adjustment under 35 U.S.C. § 154(b) to 1859 days is not merited. Accordingly, the request for redetermination of patent term adjustment is **denied**.

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The Office will *sua sponte* issue the certificate of correction in an amount of **1225** days. The Office notes that it did not issue the certificate of correction after the redetermination mailed on January 16, 2015, because patentee timely filed a request for reconsideration.

Telephone inquiries specific to this matter should be directed to Christina Tartera Donnell, Attorney Advisor at (571) 272-3211.

/ROBERT CLARKE/

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