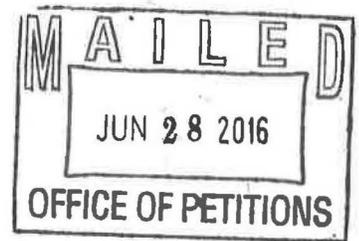




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In re Patent No. 8,410,035 :
Kaneshige et al. : REQUEST FOR RECONSIDERATION
Issue Date: April 2, 2013 : OF REDETERMINATION OF
Application No. 11/886,960 : PATENT TERM ADJUSTMENT
Filing or 371(c) Date: December 18, 2007 :
Attorney Docket No. 055053-0129 :

This is a response to patentee's "REQUEST FOR RECONSIDERATION OF REDETERMINATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705(d)" filed July 8, 2015, which is being treated under 37 CFR 1.705(b) as a request that the Office reconsider the decision mailed April 8, 2015, and adjust the patent term adjustment (PTA) from 275 to 875 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 275 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 April 2, 2013, this patent issued with a PTA of 772 days. On August 28, 2013, patentee timely filed a request for redetermination of patent term adjustment, accompanied by a request for a three-month extension of time and fee. On October 6, 2014, the Office mailed a redetermination of patent term adjustment adjusting the PTA to 257 days. The Office set an extendable period of two months from the date of the redetermination to request reconsideration of the patent term adjustment. On December 3, 2014, patentee timely filed a request for reconsideration. On April 8, 2015, the Office mailed a redetermination of patent term adjustment adjusting the PTA to 275 days. The Office provided patentee two months, plus extensions of time, 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 275 days, after the period for response had expired. On July 8, 2015, patentee timely filed a request for redetermination of patent term adjustment, accompanied by a request for a one-month extension of time and fee.

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Patentees again dispute the assessment of 600 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the submission of the Information Disclosure Statement (“IDS”) on February 29, 2012, after the filing of the reply to the final Office action on July 9, 2010. In particular, patentee avers that the 600-day reduction under 37 CFR 1.704(c)(8) for the filing of the IDS is improper because that rule does not apply to post-RCE submissions while an application is designated as a “Docketed New Case – Ready for Examination.” Patentee argues that 37 CFR 1.704(c)(8) does not refer to, nor is there any indication in the Federal Register Notice (final rule) that 37 CFR 1.704(c)(8) applies to post RCE-submissions. *See Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term*, 65 FR 56366-94 (Sep. 18, 2000). Furthermore, patentee asserts that the RCE filed July 9, 2010, was fully responsive to the final Office action and that the IDS submitted on February 29, 2012, was not “supplemental” to that reply. Rather, patentee argues that IDS was filed as an independent effort to comply with the duty of disclosure.

Moreover, patentee takes issue with the Office’s reliance on the decision in *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015) in support of the 600-day reduction under 37 CFR 1.704(c)(8) for the filing of the IDS. Specifically, patentee states, in pertinent part:

The Decision [of the USPTO mailed April 8, 2015] relies on the Federal Circuit decision in *Gilead Scis., Inc. v. Lee*, 778, F.3d 1341 (Fed. Cir. 2015), as allegedly supporting the deduction here, but that case does not hold that either the PTA statute in general or 37 CFR § 1.704(c)(8) in particular permit a deduction for Applicant Delay when an IDS is filed in an RCE while the application is docketed in PAIR as “Docketed New Case -- Ready for Examination.” Rather, that case addressed a deduction under 37 CFR § 1.704(c)(8) when an IDS is filed after a response to a restriction requirement has been filed, e.g., when an application is undergoing active examination.

The Decision tries to analogize the situation here with that before the court in *Gilead*, asserting that the IDS had “the potential to result in a delay in prosecution.” However, that possibility is directly addressed and accounted for in 37 CFR § 1.704(c)(6), which is the rule that Patentee believes to be most relevant, as discussed in more detail below.

As noted above, at the time of the February 29, 2012 IDS after RCE, the USPTO had designated the status of the application as “Docketed New Case - Ready for Examination.” That is consistent with how post-RCE applications are docketed in an examiner's workflow, since, as Patentee understands, post-RCE applications are docketed on an examiner's “Special New” applications docket. The “new case” designation also is consistent with how the USPTO treats post-RCE applications for IDS purposes, as reflected in the parallel language of 37 CFR 1.97(b)(3) and (4). Because the USPTO treats a post-RCE application as a new application for docketing, examination, and IDS purposes, the USPTO should evaluate the PTA impact of any post-RCE IDS under 37 CFR § 1.704(c)(6), not 37 CFR § 1.704(c)(8).

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Indeed, the fact that the IDS rules treat IDSs filed "[b]efore the mailing of a first Office action on the merits" similarly to IDSs filed "[b]efore the mailing of a first Office action after [an RCE]" supports Patentee's position that 37 CFR § 1.704(c)(6), not 37 CFR § 1.704(c)(8), should apply to post-RCE submissions, as discussed in more detail below. It does not make sense to treat such applications the same for IDS purposes but differently for PTA purposes, particularly when neither the language of 37 CFR § 1.704(c)(8) nor the Federal Register commentary indicate that it applies to post-RCE applications that are designated by the USPTO in PAIR as "Docketed New Case - Ready for Examination."

...

It is 37 CFR § 1.704(c)(6), not 37 CFR § 1.704(c)(8), that applies to submissions made in a "new" application. Because the USPTO designated the post-RCE application as a "Docketed New Case - Ready for Examination" and treated it as a new application for examination and IDS purposes, the USPTO should evaluate the PTA impact of the February 29, 2012 IDS filed after RCE, under 37 CFR § 1.704(c)(6). However, that rule does not support any deduction for Applicant Delay for the February 29, 2012 IDS.

...

This rule does not support a PTA deduction stemming from the February 29, 2012 IDS because the IDS was not filed "less than one month before the mailing of" the first Office action in the RCE. Rather, the first Office action was not mailed until 6 months later.

Request, 07/08/15, pp. 3-5.

Decision

The Office finds that patentee is entitled to **275** days of PTA. The Office and patentee are in agreement regarding the amounts of 917 days of "A" delay under 35 U.S.C. § 154(b)(1)(A), 18 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 zero (0) 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

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reduction of PTA for the submission of the IDS on February 29, 2012, after filing a reply to final Office action on July 9, 2010, 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[.]

In this instance, the Office mailed a final rejection on March 9, 2010. 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 July 9, 2010. On February 29, 2012, after the filing of the reply, applicants submitted an IDS. A review of the IDS, filed February 29, 2012, revealed that it did not include a proper statement under 37 CFR 1.704(d). Additionally, there is no showing in the record that the examiner expressly requested the filing of the IDS on February 29, 2012. Consequently, the Office entered 600 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the period beginning on July 10, 2010, the day after the date the reply in compliance with 37 CFR 1.113(c) was filed, and ending on February 29, 2012, the date that the IDS (“other paper”) was filed.

With respect to determining the applicable provisions for calculating applicant delay, the designation in PAIR after the filing of the RCE of the application as “Docketed New Case – Ready for Examination” is not controlling. 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) and constituting applicant delay. 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), not 37 CFR 1.704(c)(6).

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*, 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

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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, 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 reply in the form of a RCE and submission under § 1.114(c) within four months of its filing or provide additional “A” delay. The submission of an IDS after the filing of a response in the form of an 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 600 days of applicant delay for the submission of the IDS on February 29, 2012. The Office concludes the correct amount of applicant delay remains 660 (30 + 30 + 600) days.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

917 + 18 + 0 – 0 – 660 = 275

Patentee’s Calculation

917 + 18 + 0 – 0 – 60 = 875

Conclusion

The Office affirms that patentee is entitled to PTA in the amount of two hundred seventy-five (275) days. Using the formula “A” delay + “B” delay + “C” delay - overlap - applicant delay =

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X, the amount of PTA is calculated as follows: $917 + 18 + 0 - 0 - 660 = 275$ days. A correction of the determination of patent term adjustment under 35 U.S.C. § 154(b) to 875 days is not merited. Accordingly, the request for redetermination of patent term adjustment is **denied**.

The Office will *sua sponte* issue the certificate of correction in an amount of **275** days. The Office notes that it did not issue the certificate of correction after the redetermination mailed on April 8, 2015, because patentee timely filed a request for reconsideration.

The Office finance records indicate that patentee paid a second petition fee in the amount of \$400 on July 8, 2015. This duplicate payment of \$400 is unnecessary and will be refunded in due course.

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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