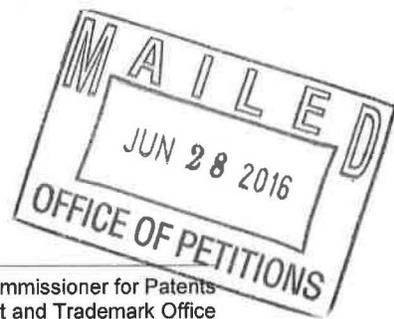




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In re Patent No. 8,753,646 :
Abe et al. : DECISION ON REQUEST FOR
Issue Date: June 17, 2014 : RECONSIDERATION OF
Application No. 12/311,365 : DETERMINATION OF
Filing or 371(c) Date: March 27, 2009 : PATENT TERM ADJUSTMENT
Attorney Docket No. IPV-DPT VACCINE :

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 September 29, 2015, which is being treated under 37 CFR 1.705(b) as a request that the Office reconsider the decision mailed July 31, 2015, and adjust the patent term adjustment (PTA) from 610 to 777 days, or in the alternative, 771 days, 741 days or 737 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 610 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 June 17, 2014, this patent issued with a PTA of 461 days. On August 14, 2014, patentee timely filed a request for redetermination of patent term adjustment under 37 CFR 1.705(b) requesting that the Office adjust the patent term adjustment (PTA) from 461 to 777 days.

On July 31, 2015, the Office mailed a decision granting the request for reconsideration to the extent that the Office adjusted the PTA to 610 days. The decision provided patentee two (2) months, plus extensions of time, from the mail date of the decision 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 610 days, after the period for response had expired.

On September 29, 2015, patentees filed the present request for reconsideration within two months of the mail date of the decision on July 31, 2015. Patentees again dispute the assessment of 167 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the submission of the Information Disclosure Statement ("IDS") on August 8, 2012, after the filing of the reply to the

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final Office action on February 23, 2012. In particular, patentee avers that the 167-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 February 23, 2012, was fully responsive to the final Office action and that the IDS submitted on August 8, 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 167-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 July 31, 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 August 8, 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). 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),

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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 August 8, 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 August 8, 2012 IDS.

This rule does not support a PTA deduction stemming from the August 8, 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 (Non-Final Office Action dated September 30, 2013) was not mailed until more than one year after the IDS after RCE.

Request, 09/29/15, pp. 3-5.

Alternatively, patentee argues that if there is a reduction for the submission of the IDS on August 8, 2012, the Office should assess either 6 days, 36 days, or 40 days of applicant delay based on the following calculations:

Applicant believes there are only 6 days of Applicant delay for the IDS filed 6 days past the 30 days beginning on July 3, 2012, which marked the date of receipt of the foreign action by an individual designated under 37 CFR 1.56(c). It would run contrary to the USPTO's IDS rules to deduct the time before the foreign Office Action was received by an individual designated under 37 CFR 1.56(c) as Applicant delay.

...

Applicants further alternatively argue that the IDS filed on August 8, 2012, should at most count as 36 days of Applicant delay. Because the IDS was not filed within 30 days of the foreign office action and did not include the Statement Under 37 CFR 1.704(d), the number of days between July 3, 2012 (the date the European Office Action was first received by an individual designated under 37 CFR 1.56(c)) and filing of the IDS on August 8, 2012 = 36 days.

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Applicants further alternatively argue that the IDS filed on August 8, 2012, should at most count as 40 days of Applicant delay because the underlying event (issuance of the European Office Action in a related application) which triggered the need to file an IDS happened on June 29, 2012. The time between the IDS-triggering event (June 29, 2012) and the filing of the IDS (Aug. 8, 2012) is only 40 days. Obviously, there was no basis to file any IDS until the triggering event occurred, namely the issuance of the European Office Action, so it does not make sense to deduct more than 40 days for the IDS even if the above arguments are not accepted.

Request, 09/29/15, pp. 7-8.

Decision

The Office finds that patentee is entitled to **610** days of PTA. The Office and patentee are in agreement regarding the amounts of 765 days of “A” delay under 35 U.S.C. § 154(b)(1)(A), 103 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 reduction of PTA for the submission of the IDS on August 8, 2012, after filing a reply to final Office action on February 23, 2012, 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[.]

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In this instance, the Office mailed a final rejection on November 23, 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 February 23, 2012.¹ On August 8, 2012, after the filing of the reply, applicants submitted an IDS. A review of the IDS, filed August 8, 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 August 8, 2012. Consequently, the Office entered 167 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the period beginning on February 24, 2012, the day after the date the reply in compliance with 37 CFR 1.113(c) was filed, and ending on August 8, 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 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”

¹ It is noted that the Office entered a period of 464 days of “A” delay pursuant to 37 CFR 1.703(a)(3) for mailing a non-final Office action on September 30, 2013, more than four months after the submission of the reply in compliance with 37 CFR 1.113(c) in the form of a RCE and submission on February 23, 2012.

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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.

As to patentee’s alternate arguments that the Office should assess applicant delay in the amount of either 6 days, 36 days, or 40 days for the filing of the IDS, the Office finds those arguments without merit. The Office notes that the basis for calculating applicant delay is based in the rules and statute. The methods of calculating applicant delay for the filing of the IDS on August 8, 2012, suggested by patentee are not supported by either the statute or the implementing regulations of 37 CFR 1.704.

In view thereof, the Office maintains the 167 days of applicant delay for the submission of the IDS on August 8, 2012. The Office concludes the correct amount of applicant delay remains 258 (91 + 167) days.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

$765 + 103 + 0 - 0 - 258 = 610$

Patentee’s Calculation

$765 + 103 + 0 - 0 - 91 = 777$

Conclusion

The Office affirms that patentee is entitled to PTA in the amount of six hundred ten (610) days. Using the formula “A” delay + “B” delay + “C” delay - overlap - applicant delay = X, the amount of PTA is calculated as follows: $765 + 103 + 0 - 0 - 258 = 610$ days. A correction of the determination of patent term adjustment under 35 U.S.C. § 154(b) to 777 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 **610** days. The Office notes that it did not issue the certificate of correction after the redetermination mailed on July 31, 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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