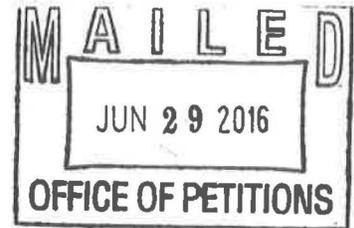




UNITED STATES PATENT AND TRADEMARK OFFICE



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

In re Patent No. 8,765,813 :
Wade et al. : REQUEST FOR RECONSIDERATION
Issue Date: July 1, 2014 : OF REDETERMINATION OF
Application No. 11/012,723 : PATENT TERM ADJUSTMENT
Filing or 371(c) Date: December 16, 2004 :
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 August 13, 2015, which is being treated under 37 CFR 1.705(b) as a request that the Office reconsider the redetermination of patent term adjustment mailed July 17, 2015, and adjust the patent term adjustment (PTA) from 2196 to 2777 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 2196 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 July 1, 2014, this patent issued with a PTA of 2096 days. On August 28, 2014, patentee timely filed a request for redetermination of patent term adjustment and fee. On July 17, 2015, the Office mailed a redetermination of patent term adjustment adjusting the PTA to 2196 days. The Office provided patentee two months, plus extensions of time, from the mail date of the redetermination to request reconsideration of the patent term adjustment. The Office indicated that the USPTO would *sua sponte* issue a certificate of correction adjusting the PTA to 2196 days, after the period for response had expired. On August 13, 2015, patentee timely filed a request for redetermination of patent term adjustment.

Patentees again dispute the assessment of 581 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the submission of the Information Disclosure Statement (“IDS”) on July 24, 2013, after the filing of the reply to the final Office action on December 21, 2011. The Office notes that applicants submitted five supplemental Information Disclosure Statements (“IDSs”) after filing a reply (RCE) to the final rejection on December 21, 2011. The Office calculated the

Art Unit: OPET

five periods of applicant delay under 37 CFR 1.704(c)(8) for the submission of the IDSs as follows: (1) 581 days for the supplemental IDS filed July 24, 2013; (2) 36 days for the supplemental IDS filed January 26, 2012; (3) 89 days for the supplemental IDS filed March 19, 2012; (4) 111 days for the supplemental IDS filed April 10, 2012; and (5) 453 days for the supplemental IDS filed March 18, 2013. As the 581 days of applicant delay completely overlapped with the other four periods of applicant delay, the Office assessed a single period of 581 days pursuant to 37 CFR 1.704(c)(8).

Patentee avers that the 581-day reduction under 37 CFR 1.704(c)(8) for the filing of the IDSs 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 December 21, 2011, was fully responsive to the final Office action. Patentee maintains that neither the IDS filed July 24, 2013, nor the earlier filed IDSs were "supplemental" to the reply (RCE) submitted on December 21, 2011. Rather, patentee argues that IDSs were 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 581-day reduction under 37 CFR 1.704(c)(8) for the filing of the IDSs. Specifically, patentee states, in pertinent part:

The Decision [of the USPTO mailed July 17, 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 July 24, 2013 IDS, and the other five earlier-filed IDSs 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

Art Unit: OPET

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), 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 July 24, 2013 IDS, and the other earlier-filed IDS filed after RCE, under 37 CFR § 1.704(c)(6). However, that rule does not support any deduction for Applicant Delay for the July 24, 2013 IDS or the other earlier-filed IDSs filed after RCE.

...

This rule does not support a PTA deduction stemming from the July 24, 2013 IDS, or the other earlier-filed IDSs filed after RCE, because none of the IDSs were filed "less than one month before the mailing of" the first Office action in the RCE. Rather, the first Office action (Notice of Allowance dated February 21, 2014) was not mailed until over two years from the first IDS after RCE and nearly 7 months after the latest IDS after RCE.

Request, 08/13/15, pp. 3-5.

Decision

The Office finds that patentee is entitled to **2196** days of PTA. The Office and patentee are in agreement regarding the amounts of 1790 days of "A" delay under 35 U.S.C. § 154(b)(1)(A), 1595 days of "B" delay under 35 U.S.C. § 154(b)(1)(B), zero (0) days of "C" delay under 35

Art Unit: OPET

U.S.C. § 154(b)(1)(C), and 451 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 July 24, 2013, and the earlier-filed IDSs after filing a reply to final Office action on December 21, 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[.]

In this instance, the Office mailed a final rejection on August 3, 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 December 21, 2011. After the filing of the reply, applicants submitted IDSs on January 26, 2012, March 19, 2012, April 10, 2012, March 18, 2013, and July 24, 2013. A review of the IDSs revealed that they 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 IDSs. Consequently, the Office entered 581 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the period beginning on December 22, 2011, the day after the date the reply in compliance with 37 CFR 1.113(c) was filed, and ending on July 24, 2013, the date that the last 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

Art Unit: OPET

IDSs filed after the RCE were “other paper[s]... 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 IDSs 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 IDSs (other papers) 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 under § 1.114(c) 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 581 days of applicant delay for the submission of the last IDS on July 24, 2013. The Office concludes the correct amount of applicant delay remains 738 (79 + 30 + 48 + 581) days.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

1790 + 1595 + 0 – 451 – 738 = 2196

Art Unit: OPET

Patentee's Calculation

$$1790 + 1595 + 0 - 451 - 157 = 2777$$

Conclusion

The Office affirms that patentee is entitled to PTA in the amount of two thousand one hundred ninety-six (2196) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as follows: $1790 + 1595 + 0 - 451 - 738 = 2196$ days. A correction of the determination of patent term adjustment under 35 U.S.C. § 154(b) to 2777 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 **2196** days. The Office notes that it did not issue the certificate of correction after the redetermination mailed on July 17, 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/
Robert A. Clarke
Patent Attorney,
Office of the Deputy Commissioner
for Patent Examination Policy - USPTO