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In re Patent No. 9,028,521 :
Robert C. Smith :
Issue Date: May 12, 2015 : REQUEST FOR REDETERMINATION
Application No. 12/128,752 : OF PATENT TERM ADJUSTMENT
Filing or 371(c) Date: May 29, 2008 :
Atty Docket No. H-US-00913 (203-5521) :

This is in response to patentee’s “REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT” filed July 8, 2015, which is being treated under 37 CFR 1.705(b) as a request that the Office adjust the patent term adjustment determination (PTA) from 886 days to 1772 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 886 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 May 12, 2015, this patent issued with a PTA in the amount of 886 days. On July 8, 2015, patentee timely filed a request for redetermination of patent term adjustment and fee. Specifically, patentee disagrees with the USPTO’s calculation of “B” delay. Patentee asserts that the correct amount of “B” delay is 425 days based on the Federal Circuit’s holding in Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014).

Furthermore, patentee disputes the assessment of 731 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the submission of the Information Disclosure Statement (“IDS”) on May 12, 2014, after the filing of a RCE in response to a final Office action on May 11, 2012. In support of the argument, patentee states, in pertinent part:

1 The Office notes that applicant submitted three Information Disclosure Statements (“IDSs”) after filing a reply (RCE) to the final rejection on May 11, 2012. The Office calculated the three periods of applicant delay under 37

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Applicant respectfully submits that the IDS filed on May 12, 2014 was in compliance with 37 C.F.R. §§ 1.97 and 1.98. Specifically, the IDS was filed before the mailing of a first Office Action after the filing of a RCE^[1] in compliance with 37 C.F.R. § 1.97(b)(4).

In view of these requirements, Applicant respectfully submits that the Office's application of § 1.704(c)(8) was in error. The court in *Arqule, Inc. v. Kappos*^[1] held that the Office's interpretation of 37 C.F.R. § 154(b)(2)(C)(ii) "functionally negate[d] ... the grace period statutorily guaranteed by [35 U.S.C.] § 21(b)," where the plaintiff, pursuant to 35 U.S.C. § 21(b) filed reply papers the day after a federal holiday. As noted above, similar to *Arqule*, Applicant complied with the timing requirements of 37 C.F.R. § 1.97(b)(4), by filing the IDS "[b]efore the mailing of a first Office action after the filing of a request for continued examination." Applicant respectfully submits that this application of § 1.704(c)(8) functionally negates the time period allowed by 37 C.F.R. § 1.97(b)(4). Accordingly, Applicant respectfully submits that 37 C.F.R. § 1.704(c)(8) and 37 C.F.R. § 1.97 are incongruent such that the Office promulgated rules that directly compete with one another, thereby functionally negating each other. For at least the reasons above, Applicant respectfully submits that the Office has improperly attributed 731 days of Applicant delay as a failure to "engage in reasonable efforts to conclude prosecution of the application," under 35 U.S.C. § 154(b)(2)(C) and 37 C.F.R. § 1.704. Accordingly, Applicant respectfully submits that the correct applicant delay attributable to filing the IDS on May 12, 2014 is 0 days.

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Additionally, patentee disputes the assessment of 166 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the submission of the IDS on December 6, 2011, after the filing of the reply to the non-final Office action on June 23, 2011. In support of the argument, patentee states, in pertinent part:

Applicant respectfully submits that the application of 37 C.F.R. § 1.704(c)(8) is arbitrary and capricious, and in direct odds with the requirements of 37 C.F.R. § 1.97. In view of Applicant's compliance with 37 C.F.R. §§ 1.97(c)(2), 1.98, Applicant respectfully submits that the Office improperly attributed 166 days of Applicant delay as a failure to "engage in reasonable efforts to conclude prosecution of the application," under 35 U.S.C. § 154(b)(2)(C) and 37 C.F.R. § 1.704. Accordingly, Applicant respectfully submits the 166 days of Applicant delay under 35 U.S.C.

CFR 1.704(c)(8) for the submission of the IDSs as follows: (1) 48 days for the IDS filed June 28, 2012; (2) 231 days for IDS filed December 18, 2012; and (3) 731 days for the IDS filed May 12, 2014. As the 731-day period of applicant delay completely overlapped with the other two periods of applicant delay, the Office assessed a single period of 731 days pursuant to 37 CFR 1.704(c)(8).

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§ 154(b)(2)(C) and 37 C.F.R. § 1.704(c)(8) was unduly attributed to Applicant. Accordingly, Applicant respectfully submits that the correct applicant delay attributable to filing the IDS on December 6, 2011 is 0 days.

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Decision

The Office finds that patentee is entitled to **886** days of PTA. The Office and patentee are in agreement regarding the calculation of 1464 days of “A” delay, 0 days of “C” delay, and 117 days of overlap. The Office and patentee are in disagreement regarding the amounts of “B” delay and applicant delay. Therefore, the Office has revisited the determination of the amount of “B” delay in view of the Federal Circuit’s decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014) and the amount of applicant delay under 37 CFR 1.704.

The Office has carefully considered patentee’s arguments, but does not find them persuasive.

As to the amount of “B” delay, the Office notes that the Federal Circuit reviewed the statutory interpretation of 35 U.S.C. § 154(b)(1)(B)(i) and issued a decision regarding the effects of a Request for Continued Examination (“RCE”) on “B” delay in the *Novartis* appeal. In *Novartis*, the Federal Circuit agreed with the Office that “no [“B” delay] adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application’s filing.” *Novartis*, 740 F.3d at 601. However, the *Novartis* court found that if the Office issues a notice of allowance after an RCE is filed, the period after the notice of allowance should not be excluded from the “B” delay period but should be counted as “B” delay. *Id.* at 602. The Federal Circuit issued its mandate in the *Novartis* appeal on March 10, 2014.

In present case, the Office finds that patentee incorrectly calculated the period of “B” delay using the entry date of “Allowability Notice” instead of the mail date of the Notice of Allowance. Patentee avers the correct calculation of the “B” delay period is the sum of the period beginning on May 30, 2011, the day after three years from the filing date of the application, and ending on May 10, 2012, the day before the filing of the RCE, and the period beginning on February 23, 2015, the date of the “Allowability Notice”, and ending on May 12, 2015, the date the patent issued.

Pursuant to 37 CFR 1.703(b), “B” delay is calculated as the number of days, in the period beginning on the day after the date that is three years after the date on which the application was filed, and ending on the date a patent was issued, but not including the number of days in the period beginning on the date on which a RCE was filed and ending on the date of mailing of the Notice of Allowance under 35 U.S.C. 151. The “Allowability Notice” is not “a written notice of allowance of the application ... mailed to the applicant” pursuant to 35 U.S.C. 151, but rather is an internal communication in PAIR that is not mailed.

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Pursuant to the *Novartis* decision, the USPTO has determined patentee is entitled to 416 days of “B” delay. In this case, applicant filed the application on May 29, 2008, and the patent issued on May 12, 2015. Thus, the application was pending for 2540 days. During this period, applicant filed a RCE on May 11, 2012. The Office mailed a Notice of Allowance on March 4, 2015. Under 35 U.S.C. § 154(b)(1)(B)(i), the time period consumed by continued examination (“RCE period”) began on May 11, 2012, and ended on March 4, 2015 – *i.e.*, 1028 days. Subtracting the RCE period from the total number of days the application was pending results in $2540 - 1028 = 1512$ days. Thus, for purposes of “B” delay, the application was pending for $1512 - 1096$ [i.e., 3 years from the actual filing date] = 416 days beyond the three-year anniversary of the filing date.

As to the amount of applicant delay, patentee’s reliance on 37 CFR 1.97 to support the argument that no applicant delay accrued for the filing of the IDSs is without merit. The provisions of 37 CFR 1.97 sets forth the timing requirements for submitting an IDS. Neither the timely filing of an IDS within one of the four periods indicated in 37 CFR 1.97 nor compliance with the requirements of 37 CFR 1.98 is a basis for calculating applicant delay for PTA purposes. 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 three IDS after filing a reply (RCE) to the final Office action on May 11, 2012, and the IDS filed December 6, 2011, after the filing of a reply to the non-final Office action on June 23, 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.

With regard to the 166 days of applicant delay, 37 CFR 1.97 is not controlling with respect to calculating applicant delay. The Office mailed a non-final Office action on March 25, 2011. In response, applicant filed a reply on June 23, 2011. After the filing of the reply, applicant submitted an IDS on December 6, 2011. A review of the IDS 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. Consequently, the Office entered 166 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the period beginning on June 24, 2011, the day after the date the reply was filed, and ending on December 6, 2011, the date the IDS ("other paper") was filed.

With regard to the 731 days of applicant delay, the application history shows that the Office mailed a final rejection on February 17, 2012. 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 May 11, 2012. After the filing of the reply, applicant submitted IDSs on June 28, 2012, December 18, 2012, and May 12, 2014. A review of the IDSs revealed that they did not include a proper statement under 37 CFR 1.704(d). Furthermore, there is no showing in the record that the examiner expressly requested the filing of the IDSs. Thus, the IDSs filed after the RCE (the reply) were "other paper[s]... after a reply has been filed," within the meaning of 37 CFR 1.704(c)(8) and constituting applicant delay.

Moreover, as the 713 days of applicant delay involve the submission of 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,

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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 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. Accordingly, the Office properly assessed 731 days of applicant delay pursuant to 37 CFR 1.704(c)(8) for the period beginning on May 12, 2012, the day after the date the reply in compliance with 37 CFR 1.113(c) was filed, and ending on May 12, 2014, the date the last IDS (“other paper”) was filed.

In view thereof, the Office maintains the 897 (731 + 166) days of applicant delay for the submission of the IDSs.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

1464 + 416 + 0 – 117 – 897 = 886

Patentee’s Calculation

1464 + 425 + 0 – 117 – 0 = 1772

Conclusion

The Office affirms that patentee is entitled to PTA in the amount of eight hundred eighty-six (886) days. Using the formula “A” delay + “B” delay + “C” delay - overlap - applicant delay = X, the amount of PTA is calculated as follows: 1464 + 416 + 0 – 117 – 897 = 886 days. A correction of the determination of patent term adjustment under 35 U.S.C. § 154(b) to 1772 days is not merited. Accordingly, the request for redetermination of patent term adjustment is **denied**.

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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