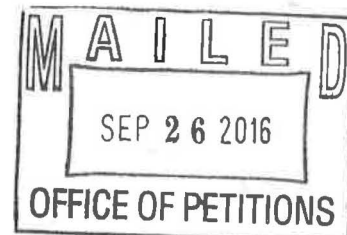




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In re Patent No. 9,022,931 :
Brauer, et al. : FINAL AGENCY DECISION
Issue Date: May 5, 2015 : ON REQUEST FOR
Application No. 12/156,043 : RECONSIDERATION OF
Filing or 371(c) Date: May 29, 2008 : PATENT TERM ADJUSTMENT
Docket No.: 247082-333USPT :
(07DC061) :

This is a response to applicants' "Request for Reconsideration of Redetermination of Patent Term Adjustment" filed October 19, 2015, requesting that the Office reconsider the patent term adjustment (PTA) of 1,309 days to 1,884 days. The Office has re-determined the PTA to be 1,309 days.

The request is **DENIED**.

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

On May 5, 2015, the patent issued with a PTA determination 1,309 days. On June 23, 2015, applicants filed an "Application for Patent Term Adjustment under 37 CFR 1.705(b)" seeking an adjustment of the determination of 1,309 days. A communication was mailed, responsively, on August 19, 2015, informing applicants that, on redetermination, the USPTO found that the patentees are entitled to 1,309 days of PTA. On October 19, 2015, applicants filed the present request for reconsideration.

The present petition

Patentees dispute the reduction to the patent term adjustment of 575 days for the filing of an Information Disclosure Statement (IDS) on May 16, 2014. In summary, patentees maintain that the reduction to the patent term adjustment for an IDS filed after the filing of a Request for Continued Examination under 37 CFR 1.114, but prior to the mailing of an Office action, is governed by 37 CFR 1.704(c)(6), rather than 37 CFR 1.704(c)(8). Patentees further assert that the period of reduction under 37 CFR 1.704(c)(8) entirely overlaps with the period excluded from the period of adjustment to the patent term pursuant to 37 CFR 1.702(b). Applicants assert that the 810-days excluded pursuant to 37 CFR 1.702(b)(1) from the adjustment to the patent term under 37 CFR 1.703(b)(1) is to be considered applicant delay and the 575-day period of reduction to the patent term entirely overlaps with the 810-days of adjustment to the patent term.

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Governing Statutes, Rules, and Regulations

35 U.S.C. 154(b)(2)(A) (C)

(C) REDUCTION OF PERIOD OF ADJUSTMENT.—

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) The Director shall 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.

37 CFR 1.704(c)(8)

(c) 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:

(8) 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;

37 CFR 1.702(b)

(b) Three-year pendency. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including: (1) Any time

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consumed by continued examination of the application under 35 U.S.C. 132(b);

(2) Any time consumed by an interference or derivation proceeding under 35 U.S.C. 135(a);

(3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181;

(4) Any time consumed by review by the Patent Trial and Appeal Board or a Federal court; or

(5) Any delay in the processing of the application by the Office that was requested by the applicant.

37 CFR 1.703(b)(1)

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods: (1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of the mailing of the notice of allowance under 35 U.S.C. 151;

Discussion

The Office has revisited the reduction to the patent term adjustment of 575 for the filing of an IDS on May 16, 2014, five hundred and seventy-five days after a RCE was filed on October 18, 2012. Patentees' arguments have been considered but are not 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 May 16, 2014, after filing a reply to final Office action on October 18, 2012, is 37 CFR 1.704(c)(8) which allows for a reduction to the patent term adjustment for 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 the case of the supplemental IDS, the IDS may not subject the application to a reduction of the patent term if the IDS is accompanied by a statement under 37 CFR 1.704(d). A review of the application file did not reveal that the examiner expressly requested the IDS to be filed and that the IDS was not accompanied by a statement under 37 CFR 1.704(d). A reduction to the patent term adjustment of 575 days was entered with said period being calculated beginning on October 19, 2012, the day after the date the RCE was filed, and ending on May 16, 2014, the date the IDS was filed. The reduction is warranted pursuant to 37 C.F.R. § 1.704(c)(8).

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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 authorized under 35 U.S.C. 132(b), while filing an application is authorized under 35 U.S.C. 111. 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” 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 applicants’ argument that the period of reduction under 37 CFR 1.704(c)(8) entirely overlaps with the period excluded from the period of adjustment to the patent term pursuant to 37 CFR 1.702(b), the 810-day period excluded from the patent term adjustment is made pursuant to 37 CFR 1.702(b)(1) and 37 CFR 1.703(b)(1) which set forth the grounds for adjustment of the patent term for examination delay. The 810-day period is a period of continued examination under 35 U.S.C. 132(b) and is not added to/included as part of the period of delay of the Office pursuant to 37 CFR 1.702(b). The period of continued examination is not considered a reduction to the patent term adjustment under 37 CFR 1.704 for applicant delay in which applicant failed to engage in

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reasonable efforts to conclude prosecution of the application. Rather, it is period during which no adjustment under 37 CFR 1.702(b) to the patent term is accrued and is not counted against the three-year time period in which the Office has to issue the patent. The 575-day period of reduction under 37 CFR 1.704(c)(8) for applicant delay cannot overlap with the 810-day exclusion from the adjustment under 37 CFR 1.702(b)(1) as the reduction to the patent term adjustment for applicant delay is governed by 37 CFR 1.704, and the exclusion of the period of continued examination is governed by 37 CFR 1.702 and 1.703 and pertains to the period of adjustment to the patent term for Office delay in issuing the patent.

Overall PTA Calculation

Formula:

USPTO's Calculation:

$$1,327 + 627 + 0 - 9 - 636 = 1,309$$

Applicants' Calculation:

$$1,327 + 627 + 0 - 9 - 61 = 1,884$$

Conclusion

Patentee is entitled to PTA of one thousand, three hundred and nine (1,309) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $1,327 + 627 + 0 - 9 - 636 = 1,309$

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e).

Telephone inquiries specific to this matter should be directed to Kenya A. McLaughlin, Attorney Advisor, at (571) 272-3222.

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