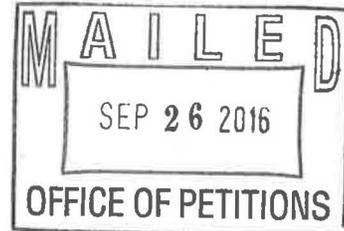




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Inventors: Daemmgen et al. :  
Patent No. 8,883,123 : FINAL AGENCY DECISION ON  
Issue Date: November 11, 2014 : REQUEST FOR RECONSIDERATION  
Application No. 11/553,492 : OF PATENT TERM ADJUSTMENT  
Filing Date: October 27, 2006 :  
Attorney Docket No. 01-1959-US-2 :

This decision is being issued in response to the “Response to the Request for Information Pertaining to the Petition under 37 C.F.R. § 1.183” (“Response”) filed September 17, 2015, which is being treated as a request under 37 C.F.R. § 1.705 and a petition under 37 C.F.R. § 1.183. The Response requests the United States Patent and Trademark Office (“Office”) adjust the patent term adjustment (“PTA”) set forth on the patent from 0 days to 509 days.

The request under 37 C.F.R. § 1.705 is **DENIED**.

The petition under 37 C.F.R. § 1.183 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).

#### Relevant Procedural History

The patent issued with a PTA determination of 0 days on November 11, 2014.

A “Petition” consisting of a request under 37 C.F.R. § 1.705 and a petition under 37 C.F.R. § 1.183 was filed on January 9, 2015. The Petition seeks an adjustment of 636 days.

The Office issued a request for information (“RFI”) on July 17, 2015.

The instant Response seeking an adjustment of 509 days was filed on September 17, 2015.

### Decision

The following determinations previously made by the Office are not in dispute:

- (1) The period of delay under 35 U.S.C. § 154(b)(1)(A) (“A Delay”) is 922 days;
- (2) The period of delay under 35 U.S.C. § 154(b)(1)(B) (“B Delay”) is 0 days;
- (3) The period of delay under 35 U.S.C. § 154(b)(1)(C) (“C Delay”) is 0 days; and
- (4) The number of days of overlapping delay (“Overlap”) between the periods of A Delay, B Delay, and C Delay is 0 days.

The RFI references seven periods of delay under 35 U.S.C. § 154(b)(2)(C) (“Applicant Delay”). The following six periods of Applicant Delay are not in dispute:

- (1) A 90-day period of delay under 37 C.F.R. § 1.704(b),
- (2) A 14-day period of delay under 37 C.F.R. § 1.704(c),
- (3) An 87-day period of delay under 37 C.F.R. § 1.704(b),
- (4) A 92-day period of delay under 37 C.F.R. § 1.704(b),
- (5) A 3-day period of delay under 37 C.F.R. § 1.704(c)(8), and
- (6) A 127-day period of delay under 37 C.F.R. § 1.704(c)(7).

The sole issue in dispute is the extent to which, if any, the following facts warrant entry of a reduction in patent term adjustment for Applicant Delay under 37 C.F.R. § 1.704(c)(8):

- (1) The Office issued a final Office action on March 5, 2010;
- (2) A reply to the Office action was filed on September 7, 2010;
- (3) An information disclosure statement (“IDS”) was filed on July 11, 2013; and
- (4) The Office issued an Office action including a restriction requirement on July 17, 2013.

The Office entered a 1,038-day reduction in patent term adjustment based on the submission of the July 11, 2013 IDS.

The Petition filed January 9, 2015, and the instant Response assert the submission of the IDS does not warrant entry of a reduction in patent term adjustment for Applicant Delay.

The Response seeks a revised PTA determination of 509 days. The Office acknowledges the correct PTA is 509 days *if* the submission of the IDS does not warrant entry of a reduction in patent term adjustment for Applicant Delay.

37 C.F.R. § 1.704(c) states in part, with emphasis added,

Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include ...

- (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 C.F.R. § 1.704(d)(1) states,

A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement:

- (i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in Sec. 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or
- (ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in Sec. 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

The provisions of 37 C.F.R. § 1.704(c)(8) apply to the submission of a supplemental reply *or other paper* after a reply has been filed. A reply to an Office action was filed on September 7, 2010. The IDS at issue was submitted on July 11, 2013. Therefore, the IDS was submitted after a reply to an Office action was filed.

The IDS was submitted *prior* to the Office issuing an action under 35 U.S.C. § 132 (“Office action”) or a notice of allowance under 35 U.S.C. § 151 (“Allowance”) in response to the September 7, 2010 reply. Specifically, the IDS was submitted on July 11, 2013, and a restriction requirement was issued in response to the reply on July 17, 2013.

The Petition asserts the IDS should not be considered a “supplemental response” because the IDS was allegedly filed after the examiner “completed and entered the restriction requirement.”<sup>1</sup> The Petition asserts the provisions of 37 C.F.R. § 1.704(c)(8) do not apply because the IDS is “not a ‘supplemental response’ and [the IDS] should not trigger a PTA reduction.”<sup>2</sup> The Response asserts “the IDS should not be considered a supplemental response under the rule” because the IDS “was filed **after** the Examiner took action and completed and entered the Restriction Requirement in PAIR.”<sup>3</sup>

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<sup>1</sup> Petition, page 1.

<sup>2</sup> *Id.* at 3.

<sup>3</sup> Response, page 2.

The date an Office action is mailed, not the date the Office action is “completed and entered” into PALM, is relevant when calculating the patent term adjustment. For example, the periods of delay set forth in 37 C.F.R. §§ 1.703(a)(1)-(a)(5) end on the date the Office mails an Office action or Allowance, not the date the Office completes and enters an Office action or Allowance into PALM.

Applicants participate in the Office’s Electronic Office (e-Office) program. An applicant participating in the program agrees to receive notifications via e-mails informing the applicant a communication can be retrieved via Private Patent Application Information Retrieval (“PAIR”) in lieu of receiving a mailed copy of the communication. *See* Electronic Office Action, 1343 Off. Gaz. Pat. Office 45 (June 2, 2009). With respect to “Office actions under 35 U.S.C. 132(a), the mailroom/notification date [identified in the communication] is the date of the notice under 35 U.S.C. 133.” *Id.* at 46. “The mailroom/notification dates will also be considered the date of mailing of the correspondence for *all* other purposes (e.g., 37 CFR 1.71(g)(2), 1.97(b), 1.701 through 1.705).” *Ibid.* (emphasis added). The “Notification Date” on the PTOL-90A accompanying the restriction requirement is July 17, 2013, which is after the date the IDS was filed.

Applicants argue the submission of the IDS on July 11, 2013, did not cause or contribute to Office Delay in the issuance of an Office action on July 17, 2013. However, the scope of 37 C.F.R. § 1.704(c)(8) is not limited to papers that result in actual delay. *See Gilead Sciences, Inc. v. Rea*, 976 F. Supp. 2d 833, 836-837 (E.D. Va. 2013).

Pursuant to 37 C.F.R. §§ 1.704(c)(8) and 1.704(d), the submission of a “supplemental reply or other paper” after a reply has been filed and before the issuance of an Office action or Allowance will result in a reduction in patent term adjustment unless at least one of the following is true:

- (1) The examiner expressly requested the submission of the paper; and/or
- (2) A statement under 37 C.F.R. § 1.704(d) was filed with the IDS.

Applicants do not allege the examiner expressly requested the submission of the IDS, and a statement under 37 C.F.R. § 1.704(d) was not filed for the IDS. Therefore, the Office’s acted properly when the Office entered a 1,038-day reduction in patent term adjustment based on the

The Petition and Response request the suspension of 37 C.F.R. § 1.704(c)(8) pursuant to 37 C.F.R. § 1.183 in the alternative.

37 C.F.R. § 1.183 states,

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director’s designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in § 1.17(f).

The RFI indicates Applicants may filed a statement under 37 C.F.R. § 1.704(d) *if applicable* with a petition under 37 C.F.R. § 1.183 requesting waiver of the requirement for the statement to be filed with the IDS. The petition under 37 C.F.R. § 1.183 does not include a statement under 37 C.F.R. § 1.704(d). The petition also does not establish the IDS was promptly filed within the time limits set forth in 37 C.F.R. § 1.704(d)(1).

The Petition asserts the “rigid application” of 37 C.F.R. § 1.704(c)(8) “de-incentivizes Applicant to **timely** submit prior art.”<sup>4</sup> The Petition states the Manual of Patent Examining Procedure “makes clear that the *timely* observance of [37 C.F.R.] § 1.56 is in the public’s best interest.”<sup>5</sup> The Office acknowledges the July 11, 2013 IDS was timely filed. However, the fact an IDS is timely filed with the Office does not preclude the entry of a reduction in patent term adjustment for Applicant Delay based on the submission of the IDS. Indeed, the statute itself expressly contemplates that timely responses by an applicant (e.g., those that are made between three and six months after an Office action) will nevertheless be considered to be applicant delay. *See* 35 U.S.C. § 154(b)(2)(C)(ii).

The provisions of 37 C.F.R. §§ 1.704(c)(8) and 1.704(d) encourage the prompt, not simply timely, submission of an IDS. For example, by measuring the amount of applicant delay under 37 C.F.R. § 1.704(c)(8) from the filing date of the earlier reply to the filing date of the later supplemental reply or paper, the Office encourages early submission of such papers (by minimizing the amount of applicant delay imposed) while properly balancing the effect of such submissions against the Office’s requirement to respond to the earlier reply within four months under 35 U.S.C. § 154(b)(1)(A). *See* Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56366, 56385 (Sept. 18, 2000) (responses to Comments 35 and 36).

The Office has considered all the facts and determined that applicants have failed to establish an extraordinary situation exists where justice requires waiver of 37 C.F.R. 1.704(c)(8) exists.

In view of the prior discussion, the Office’s entry of a 1,038-day reduction in patent term adjustment based on the submission of the July 11, 2013, is proper.

The correct period of Applicant Delay is 1,451 (90 + 14 + 87 + 92 + 3 + 127 + 1,038) days.

### Conclusion

The PTA to be set forth on a patent is the sum of the days of A Delay, B Delay, and C Delay reduced by the number of days of Overlap and Applicant Delay.

The sum of 922 days of A Delay, 0 days of B Delay, and 0 days of C Delay reduced by 0 days of Overlap and 1,451 days of Applicant Delay is *negative 529* days. However, the PTA for a patent cannot be less than 0 days. As a result, the correct PTA is 0 days as set forth on the patent.

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<sup>4</sup> Petition, page 2 (emphasis in the original).

<sup>5</sup> *Id.* at 3 (emphasis in the original).

Telephone inquiries specific to this decision should be directed to Attorney Advisor Steven Brantley at (571) 272-3203.

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