

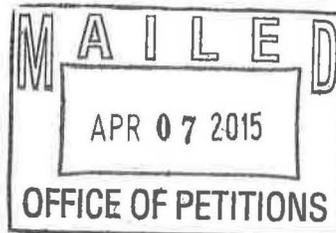


UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Patent No. 8,486,624
Scherer et al.
Issue Date: July 16 2013
Application No. 11/979,262
Filed: October 31, 2007
Attorney Docket No. 103779-0540
Title: LAFORA'S DISEASE GENE

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: DIRECTOR'S DECISION ON
: PATENT TERM ADJUSTMENT
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This is a response to the "RESPONSE TO THE REDETERMINATION OF PATENT TERM ADJUSTMENT", requesting that the Office adjust the patent term to 880 days.

This petition is hereby **DENIED**. This constitutes a final decision on this petition. No further requests for reconsideration will be entertained. Judicial review of this petition decision may be available if the USPTO issues a final agency action adverse to the petitioner in the underlying proceeding or examination to which it relates, or, if this decision does not relate to any ongoing proceeding or examination, if it otherwise constitutes final agency action under 5 U.S.C. 704.

Relevant Procedural History

On July 16, 2013, this patent issued with a patent term adjustment determination of 678 days. On July 1, 2013, patentee filed this request for redetermination of patent term adjustment, requesting that patentee be granted a patent term adjustment of 1315 days. A redetermination of patent term adjustment was mailed on September 29, 2014 providing 649 days of patent term adjustment. On November 21, 2014 patentee filed a response to the redetermination of patent term adjustment requesting 880 days of patent term adjustment.

Decision

Patents' arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to 649 days of PTA. Patentee and the Office are in agreement regarding the amount of "B" delay under 35 U.S.C. § 154(b)(1)(B); the amount of overlapping days under 35 U.S.C. § 154(b)(2)(A) pursuant to the Federal Circuit's decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014); the amount of "A" delay under 35 U.S.C. § 154(b)(1)(A) and 37 CFR 1.702(a), however, patentee and the Office continue to disagree as to the amount of "applicant delay" under 35 U.S.C. § 154(b)(2)(C) and 1.704(c).

Regarding patentee delay, Office records confirm that the patentee filed a second RCE on November 30, 2013, and thereafter filed Information Disclosure Statements ("IDS") on April 11,

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2012 and July 18, 2012. A review of the IDS, confirms that the IDS did not contain the language required by 37 CFR 1.704(d)¹. As such, pursuant to 37 CFR 1.704(c)(8), the application was assessed a reduction of 231 days, commencing December 1, 2011, the day after the date that the RCE was filed, and ending on July 18, 2012, the date the IDS was filed.

Patentee provides that the RCE was timely filed pursuant to 37 CFR 1.97(b)(4). The Rule, 37 CFR 1.97(b)(4) provides, in relevant part, that an IDS "shall be considered by the Office if it is filed by the applicant within any one of the following time periods: (4) Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114." Patentee argues that this section provides that this section provides that an IDS filed after an RCE but before the first Office action is similar to an IDS filed in a brand new application that has not yet received a first Office action on the merits. Patentee avers that 37 CFR 1.704(c)(8) does not govern post-RCE submissions.

Patentee's arguments have been carefully considered. Patentee conflates consideration of the IDS by the examiner pursuant to 37 CFR 1.97(b)(3), with the Patent Term Adjustment Statute and Rules establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. The Office notes that the rules governing examination of an application are separate and distinct from the rules governing patent term adjustments. The determination of patent term adjustment is governed by statute 35 U.S.C. § 154(b) and the authority to make judgments with respect thereto is not delegated to the Patent Corps. "Examiners make no decisions regarding patent term extensions." MPEP § 2720. Any questions as to patent term adjustments are delegated to the Office of the Deputy Commissioner for Patent Examination Policy pursuant to MPEP § 1002.02(b) 25 and 26.

Patentees' attention is directed to 35 U.S.C. § 154(b)(2)(C), REDUCTION OF PERIOD OF ADJUSTMENT, and section (iii), which states: "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." Pursuant to 35 U.S.C. § 154(b)(2)(C)(iii), the Director prescribed, *inter alia*, 37 CFR 1.704(c)(8), which reduces the patent term for (8) [s]ubmission 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.

¹ (1) 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 § 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 § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

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In this instance, and pursuant to 35 U.S.C. § 154(b)(2)(C)(iii), and 37 CFR 1.704(c)(8), the patent term was properly reduced 231 days, beginning on December 1, 2011, the day after the date the *reply* (the RCE and submission), was filed, and ending on July 18, 2012, the date that IDS was filed. (Emphasis added).

Petitioner's attention is further directed to 37 CFR 1.704(d)(1)(i) and (ii), which provides the circumstances wherein the filing of a paper containing only an IDS will not be considered a failure to engage in reasonable efforts to conclude prosecution. As noted *supra*, the IDS filed July 18, 2012 did not contain the language required by 37 CFR 1.704(d), and the reduction of 231 days in connection with the filing of the IDS on July 18, 2012 is appropriate.

Based upon the above, the Office agrees with patentee that the submission of the IDS on July 18, 2012 does not warrant a reduction based up 37 CFR 1.704 (c)(6). However, the reduction is proper under 37 CFR 1.704 (c)(8).

Overall PTA Calculation

Formula:

"A" delay + "B" delay + "C" delay - Overlap - applicant delay = X

USPTO's Calculation:

791 + 202 + 0 - 0 - 344 = 649

Patentee's Calculation

993 - 113 = 880

Conclusion

The present RESPONSE TO THE REDETERMINATION OF PATENT TERM ADJUSTMENT has been considered; however, the RESPONSE TO THE REDETERMINATION OF PATENT TERM ADJUSTMENT is DENIED. Patentee remains entitled to 649 days of patent term adjustment.

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Telephone inquiries specific to this decision should be directed to Attorney Advisor Charlema Grant at (571) 272-3215.

/JOHN COTTINGHAM/
Director
Office of Petitions
Office of Deputy Commissioner
For Patent Examination Policy