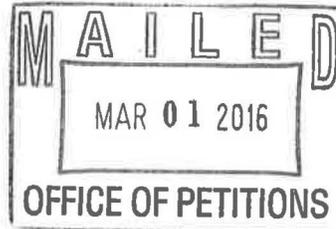




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In re Patent No. 8,822,653 :  
Sexton et al. : DIRECTOR'S DECISION ON  
Issue Date: September 2, 2014 : PATENT TERM ADJUSTMENT  
Application No. 12/985,914 :  
Filed: January 6, 2011 :  
Attorney Docket No. :  
D0617.70050US01 :  
Title: PLASMA KALLIKREIN :  
BINDING PROTEINS :

This is a response to the "Request for Reconsideration of Patent Term Adjustment" filed pursuant to 37 CFR 1.705(b) on October 5, 2015 requesting that the Office adjust the PTA from 348 days to 466 days.

The request for patent term adjustment is **DENIED** with respect to making any change in the patent term adjustment determination under 35 U.S.C. § 154(b) of 348 days.

**THERE WILL BE NO FURTHER CONSIDERATION OF THIS MATTER BY THE OFFICE.**

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**

On September 2, 2014, this patent issued with a patent term adjustment determination of 414 days. On November 3, 2014, patentee filed a request for redetermination of patent term adjustment, requesting that patentee be granted a patent term adjustment of 466 days. A redetermination of patent term adjustment was mailed on June 4, 2015 granting a patent term

adjustment of 348 days. The instant request for redetermination of the patent term adjustment was filed on October 5, 2015 with a two month extension of time, requesting a patent term adjustment of 466 days.

### **Decision**

Patentee agrees with the Office's calculation of A delay of 288 days, B delay of 239, C delay of 0 day and 0 days of overlap. Patentee disputes the 179 days of applicant delay.

Patentee argues the reduction of 118 days pursuant to 37 CFR 1.704 (c)(10) for the submission of the document titled "Submission of Prior Art Documents" filed on May 8, 2014 is incorrect because only papers filed after allowance that require responses by the Office constitute applicant's failure to engage in reasonable efforts to conclude processing or examination of an application.

"Applicant's filing of the "Submission of Prior Art Documents" does not require a response by the Office; nor does it require the Office to consider the cited references, which were either already in the records or not prior art. Rather, filing of this document was merely to place the search report and the cited references in the file for a complete record. Indeed, the filing of the "Submission of Prior Art Documents" did not cause substantial interference and delay in the patent issue process -- the Office did not respond to this submission and the issue process was not delayed."

37 CFR 1.704 (c)(10) provides:

(10) Submission of an amendment under § 1.312 or other paper, other than a request for continued examination in compliance with §1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper;

or

ii) Four months;

The Office has considered patentee's argument but does not find it persuasive. Section 1.704(c)(10) provides the circumstances constituting a "failure to failure to engage in reasonable efforts to conclude processing or examination of an application". The submission of the "Submission of Prior Art Documents" which consisted of a search report and cited references after the mailing of the notice of allowance is a circumstance constituting a "failure to failure to engage in reasonable efforts to conclude processing or examination of an application".

*The Clarification of 37 CFR 1.704(c)(10) - Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a Notice of Allowance has been mailed*, 1247 OG 111 (June 26, 2001), states that after the Notice of Allowance has been mailed, submissions by an applicant that cause a delay in processing or examination of an application will be considered a "failure to engage in reasonable efforts" to conclude prosecution. The submission of such papers is considered a failure to engage in reasonable efforts to conclude processing or examination is that delaying the submission of such papers until after an application is allowed causes substantial interference and delay in the patent issue process. In which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of: (1) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or (2) four months. See § 1.703(c)(10). *The Clarification of 37 CFR 1.704(c)(10) - Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a Notice of Allowance has been mailed* does not state that a reduction under 37 CFR 1.704(c)(10) only applies where the submission requires a response by the Office.

Further, *Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee*, 80 Fed. Reg. 1346, 1354-1355 (January 9, 2015) specifically names the documents submitted after the Notice of Allowance that will not be considered a failure to engage in reasonable efforts to conclude processing of the application. The documents listed do not include the submission of prior art, a search report or cited

references which are typically submitted with an IDS under 37 CFR 1.98. In addition, the list of documents that are considered a failure to engage in reasonable efforts to conclude processing includes the submission of an information disclosure statement not accompanied by a statement in compliance with §1.704(d). Patentee is reminded that the list of the papers that constitute failure to conclude processing is exemplary not exhaustive. There is no debate "Submission of Prior Art Documents" which consisted of a search report and cited references was submitted after the mailing of the Notice of Allowance and therefore is properly calculated as a reduction pursuant to 37 CFR 1.704(c)(10).

Further, the reduction of 118 days differs from the 52 day reduction which was removed in that the information disclosure statement submitted on April 29, 2014 was accompanied by a statement pursuant to 37 CFR 1.704(d).

37 CFR 1.704(d) provides:

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. This thirty-day period is not extendable.

The submission provided on May 8, 2014 was not accompanied by a statement pursuant to 37 CFR 1.704(d). As such the 118 day reduction will remain.

**Overall PTA Calculation**

Formula:

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

USPTO's Calculation:

288 + 239 + 0 - 0 - 179 = 348

Patentee's Calculation

288 + 239 + 0 - 0 - 61 = 466

**Conclusion**

Patentee remains entitled to PTA of three hundred forty-eight (348) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as follows: 288 + 239 + 0 - 0 - 179 = 348 days.

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

/Robert Clarke/  
Patent Attorney  
Office of the Deputy Commissioner  
for Patent Examination Policy