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OFFICE OF PETITIONS

In re Patent of Steidl et al. : FINAL AGENCY DECISION

Patent No. 7,867,495 : ON

Issued: January 11, 2011 : REQUEST FOR RECONSIDERATION

Application No. 11/914,599 : OI

Filing Date: November 16, 2007 : DECISION ON APPLICATION

Attorney Docket No. 047744-0117 : FOR

For: ANTI-GM-CSF ANTIBODIES AND : PATENT TERM ADJUSTMENT

USES THEREFOR

This is a decision on the "RESPONSE TO, AND REQUEST FOR RECONSIDERATION OF, DECISION ON APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. 1.705," filed February 2, 2011, requesting reconsideration of the decision of December 2, 2010, and restoration of 47 days of patent term.

The request for reconsideration of the decision of December 2, 2010, is granted to the extent that the decision of December 2, 2010, has been reconsidered; however, the request for reconsideration is **DENIED** with respect to making any change in the patent adjustment determination under 35 U.S.C. § 154(b). This decision may be viewed as a final agency action within the meaning of 5 U.S.C. § 704 and for purposes of seeking judicial review. See MPEP 1002.02.

BACKGROUND

On June 16, 2010, the Office mailed a Determination of Patent Term Adjustment under 35 U.S.C. 154(b) in the above-identified application. Applicants were advised of a patent term adjustment to date of 67 days. In response, applicants timely filed a request for reconsideration of the patent term adjustment under 37 CFR 1.705(b) on September 15, 2010, requesting that the patent term adjustment be corrected to 109 days. On December 2, 2010, the Office mailed a dismissal of the petition, maintaining a 67 day patent term adjustment. On January 11, 2011, the above-identified application matured into U.S. Patent No. 7,867,495, with a revised patent term adjustment of 3 days. Patentees filed the present reconsideration petition within two months of

the mailing of the December 2, 2010 dismissal, on February 2, 2011. Page 1 of the present petition states, "...This filing concerns only the assertion of 47 days of Applicant delay that was first raised in the Notice of Allowance, and is without waiver of any additional PTA to which Applicant may be entitled." Patentees renew their dispute of the cumulative reduction of 47 days of PTA for applicant delay in filing supplemental responses on December 8, 2008 and December 9, 2008. Patentees state that the responses were filed at the request of the examiner and, therefore, no reductions are warranted

RELEVANT REGULATION

37 CFR § 1.704 Reduction of period of adjustment of patent term.

. . . .

(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;

OPINION

Patentees' arguments have been considered, but not found persuasive. The record does not support a conclusion that the supplemental reply of December 8, 2008 and the supplemental reply of December 9, 2008 were filed in response to an express request by the Examiner.

As of September 24, 2008, Claims 1, 4, 7, and 10-38 were pending.

The Office mailed a restriction requirement on September 24, 2008.

A reply to the restriction requirement was filed October 23, 2008.

An IDS was filed October 28, 2008.

An interview summary form mailed December 4, 2008, indicates the examiner and attorney Simon J. Elliott held a telephonic interview on December 3, 2008. The form indicates they discussed Claims 1, 4, 7, 10-23, 33, 37, and 38. The form states, with emphasis added in bold,

The ... rejections over the claims [were] discussed. Attorney discussed submitting a supplemental amendment to obviate the rejections....

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04)

MPEP 713.04 states, with emphasis added,

A complete written statement as to the substance of any face-to-face, video conference, electronic mail or telephone interview with regard to the merits of an application must be made of record in the application, whether or not an agreement with the examiner was reached at the interview. See 37 CFR 1.133(b), MPEP § 502.03 and § 713.01....

The action of the U.S. Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, except where the interview was initiated by the examiner and the examiner indicated on the "Examiner Initiated Interview Summary" form (PTOL-413B) that the examiner will provide a written summary.

The interview summary form is <u>not</u> an Examiner Initiated Interview Summary form, which appears to indicate applicants called the examiner instead of the examiner calling applicants with a request.

Applicants filed a supplemental amendment on December 8, 2008. Their comments on the actual substance of the interview state,

The Examiner Interview Summary dated December 4, 2008, reflects the substance of the discussions.... The foregoing amendments to the claims reflect amendments discussed with the examiner. We thank the Examiner for the courtesy of an interview.

Applicants argue the December 8, 2008 supplemental amendment was expressly requested by the examiner, within the meaning of § 1.704(c)(8). Accordingly, applicants argue no reduction is warranted. The Office does not concur. Examiner Mertz never explicitly requested applicants submit a supplemental amendment. Examiner Mertz states, "Attorney discussed submitting a supplemental amendment to obviate the rejections." See Interview Summary, mailed December 4, 2008. Applicants' remarks on page 9 of the supplemental preliminary amendment do not include a statement that the examiner requested the submission of the amendment. There is insufficient contemporaneous evidence in the record to support the conclusion that the December 8, 2008 supplemental reply was expressly requested by the examiner. No rejections having been made by the examiner, and no art having been cited by the examiner, it cannot be said that the examiner called for an amendment to obviate an art rejection that does not appear to have been made. If anything, it appears that applicant contacted the examiner prior to the first Office action.

37 CFR 1.2 states,

All business with the Patent and Trademark Office should be transacted in writing....
The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The language quoted above means that the Office will not pay attention to any allegation that an examiner made a specific statement if any doubt exists as to whether the statement was made.

The examiner's interview summary form clearly indicated applicants were required make the substance of the interview of record. If applicants' December 8, 2008 response had included the alleged full substance of the interview, the examiner would have had the matter fresh in his mind and could have indicated in the record if he disagreed with any portion of their summary. By requiring applicants to make the substance of the interview of record, the examiner ensured all transactions were in writing.

Patentees are now, at a substantially later date, attempting to demonstrate a reduction in patent term adjustment is not warranted based on an alleged request made by the examiner during the December 3, 2008 interview. However, by relying on the alleged request, applicants are indicating the alleged request was not an insubstantial (lacking any substance) comment. Therefore, if the examiner requested the filing of a supplemental amendment, the following errors were made:

- 1. The examiner made an error by not indicating he requested the filing of a supplemental amendment,
- 2. Applicants made an error in failing to mention the examiner's request in their response, and
- 3. Applicants made an error in alleging the examiner's summary "reflects the substance of the discussions" since they are now alleging (in effect) that it only partially reflected the substance of the interview.

Patentees cite the following language in MPEP 2732:

If an amendment is requested by an examiner, the examiner will have the paper processed so that it is included as part of an interview summary or examiner's amendment and not a separate paper for PALM to flag in the patent term adjustment calculation.

Patentees assert that because the Office assumes the burden of correctly processing any papers, the failure to correctly process the papers, and the resulting loss of PTA, should not be borne by applicants. Patentees, in essence, assert the Office has the burden of proving the examiner did not make an alleged statement/request during an interview summary. However, proving an examiner did not make a statement is almost impossible. In other words, if the burden of proving examiners did not make an alleged statement during an interview was on the Office, then parties

could basically allege examiners made any statement they wish because it would be almost impossible for the Office to prove the examiners did not make the statement.

With respect to the December 8, 2008 response, applicants failed to avail themselves of the opportunity to make the alleged request of record and thereby allow the examiner to consider their allegation that she had made the request. If applicants had done so, and the examiner had not commented on the matter, the Office would assume the lack of comment was an indication the examiner did not disagree with the allegation. The declaration provided by Attorney Elliot on February 2, 2011 states that based upon his records and memory, the filings of December 8 and 9, 2008 were in response to express requests of the Examiner, made by telephone. It is noted this declaration was provided over 2 years after the events at issue. There is insufficient contemporaneous evidence in the record to support the conclusion that the December 8, 2008 and December 9, 2008 supplemental replies were expressly requested by the examiner. Furthermore, prior to the first Office action, applicant has the right to file a preliminary amendment and so there would be no need for the examiner to require the filing of an amendment.

The Office properly entered a 37 CFR 1.704(c)(8) reduction of 46 days, beginning on October 24, 2008, the day after the October 23, 2008 election was filed, and ending on December 8, 2008, the date the supplemental preliminary amendment was filed. No change will be made.

Applicants argue the December 9, 2008 supplemental amendment was expressly requested by the examiner, within the meaning of 37 CFR 1.704(c)(8). To support their position, applicants point to page 9 of the second supplemental preliminary amendment, which states, in pertinent part, "These new claims accord with those agreed upon in the December 9, 2008 telephone conference between Examiner Mertz and the undersigned representative. Entry, consideration and allowance of all pending claims is respectfully sought." Applicants do **not** state the new claims were filed at the request of the examiner.

It is noted that there is no Interview Summary for a telephone conference that allegedly took place on December 9, 2008 in the record.

Applicants' petition under 37 CFR 1.705(b), filed September 15, 2010, states the examiner requested applicants "file amended claims to advance prosecution, with the goal of a first action allowance." However, applicants' December 9, 2009 amendment did not amend any of the claims, but instead added claims 76-89. The addition of new claims appears in no way to increase the allowability of the claims that were already presented. It is unlikely an examiner would request addition of the claims as part of a goal of issuing a first action allowance.

There is insufficient contemporaneous evidence in the record to support the conclusion that the December 9, 2008 supplemental reply was expressly requested by the examiner.

The Office properly entered a 37 CFR 1.704(c)(8) reduction of 1 day for the December 9, 2008 second supplemental preliminary amendment. No change will be made.

Patentees state the October 23, 2008 filing is strictly concerned with responding to the requirement for restriction and/or election of species that was set forth in the restriction requirement of September 23, 2008. Patentees argue the December 8, 2008 and the December 9, 2008 filings address possible future rejections, and therefore cannot be supplemental amendments to the October 23, 2008 filing. However, 37 CFR (c)(8) applies to the filing of any "supplemental amendment or other paper" after a reply has been filed. The timing of the filing, not its contents, is the pivotal issue.

CONCLUSION

Accordingly, the decision of December 2, 2010 on application for patent term adjustment has been reconsidered and the request for restoration of 47 days of patent term is **DENIED**.

The patent term adjustment is three (3) days, which is the sum of 114 days of delay under 35 U.S.C. § 154(b)(1)(A) and 56 of delay under 35 U.S.C. § 154(b)(1)(B), reduced by 167 (47 + 118 + 2) days of Applicant delay.

No fees will be refunded.

Telephone inquiries specific to this matter should be directed to Shirene Willis Brantley, Senior Petitions Attorney, at (571) 272-3230.

Anthony Knight

Director, Office of Petitions