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OFFICE OF PETITIONS

In re Application of :
Richard AXEL et al. :
Application No. 08/477,159 : **ON PETITION**
Filed: June 7, 1995 :
Attorney Docket No.: 17668-A7-A/J :

This is a decision on the petitions filed December 14, 2006 under 37 CFR 1.181(a)(3) requesting that the Director exercise his supervisory authority and overturn the decisions of the Director, Technology Center 1600 (Technology Center Director), dated October 12, 2006, which refused to either withdraw the finality of the Office action mailed January 16, 2004, or compel the entry of the amendment after final filed June 16, 2004 and the affidavit and amendment after final filed February 21, 2005.

The petitions to overturn the decisions of the Technology Center Director dated October 12, 2006, are **DENIED**¹.

BACKGROUND

The instant application was filed June 7, 1995 and claims priority through a chain of seven other applications to application serial no. 06/124,513 filed February 25, 1980.

Prosecution has been reopened twice under the provisions of 37 CFR 1.129(a).

The relevant prosecution history follows.

On April 23, 2003 a non-final Office action was mailed.

On October 27, 2003 a response was filed.

On January 16, 2004 a final Office action was mailed.

On March 19, 2004 a petition to vacate the final Office action was filed.

On June 1, 2004 a decision dismissing the petition was mailed.

On June 14, 2004 a petition requesting reconsideration of the petition decision of June 1, 2004 was filed.

On June 16, 2004 an amendment after final was filed.

On July 19, 2004 a Notice of Appeal was filed.

On November 23, 2004 a decision dismissing the request for reconsideration of the petition decision was mailed.

On December 1, 2004 an Advisory Action was mailed denying entry of the amendment after final filed June 16, 2004.

On January 27, 2005 a petition requesting review of the petition decision of November 23, 2005 was filed.

On February 4, 2005 a petition requesting entry of the amendment filed June 16, 2004 under 37 CFR 1.116 was filed.

On February 21, 2005 an amendment after final and an affidavit were filed.

On September 23, 2005 an Advisory Action was mailed denying entry of the amendment after final and affidavit filed February 21, 2005.

On November 25, 2005 a petition requesting entry of the amendment filed February 21, 2005 under 37 CFR 1.116 was filed

On January 17, 2006 decisions dismissing the petitions of January 27, 2005, February 4, 2005, and November 25, 2005 were mailed.

On March 20, 2006 petitions requesting review of the petition decisions of January 17, 2006 were filed.

On October 12, 2006 decisions dismissing the petitions of March 20, 2006 were mailed.

The instant petitions were filed December 14, 2006.

STATUTE, REGULATION, AND EXAMINING PROCEDURE

37 CFR 1.104 states:

(a) Examiner's action.

(1) On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

(2) The applicant, or in the case of a reexamination proceeding, both the patent owner and the requester, will be notified of the examiner's action. The reasons for any adverse action or any objection or requirement will be stated in an Office action and such information or references will be given as may be useful in aiding the applicant, or in the case of a reexamination proceeding the patent owner, to judge the propriety of continuing the prosecution.

37 CFR 1.113 states:

(a) On the second or any subsequent examination or consideration by the examiner the rejection or other action may be made final, whereupon applicants, or for ex parte reexaminations filed under § 1.510, patent owner's reply is limited to appeal in the case of rejection of any claim (§ 1.191), or to amendment as specified in § 1.114 or § 1.116. Petition may be taken to the Commissioner in the case of objections or requirements not involved in the rejection of any claim (§ 1.181). Reply to a final rejection or action must comply with § 1.114 or paragraph (c) of this section. For final actions in an inter partes reexamination filed under § 1.913, see § 1.953.

(b) In making such final rejection, the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the application, clearly stating the reasons in support thereof.

(c) Reply to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim. If any claim stands allowed, the reply to a final rejection or action must comply with any requirements or objections as to form.

37 CFR 1.116 states:

(b) After a final rejection or other final action (§ 1.113) in an application or in an ex parte reexamination filed under § 1.510, or an action closing prosecution (§ 1.949) in an inter partes reexamination filed under § 1.913, amendments may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action. Amendments presenting rejected claims in better form for consideration on appeal may be admitted. The admission of, or refusal to admit, any amendment after a final rejection, a final action, an action closing prosecution, or any related proceedings will not operate to relieve the application or patent under reexamination from its condition as subject to appeal or to save the application from abandonment under § 1.135, or the reexamination from termination. No amendment can be made in an inter partes reexamination proceeding after the right of appeal notice under § 1.953 except as provided for in paragraph (d) of this section.

(c) If amendments touching the merits of the application or patent under reexamination are presented after final rejection, or after appeal has been taken, or when such amendment might not otherwise be proper, they may be admitted upon a showing of good and sufficient reasons why they are necessary and were not earlier presented.

37 CFR 41.33 states in pertinent part:

(a) Amendments filed after the date of filing an appeal pursuant to § 41.31(a)(1) through (a)(3) and prior to the date a brief is filed pursuant to § 41.37 may be admitted as provided in § 1.116 of this title.

(d)(1) An affidavit or other evidence filed after the date of filing an appeal pursuant to § 41.31(a)(1) through (a)(3) and prior to the date of filing a brief pursuant to § 41.37 may be admitted if the examiner determines that the affidavit or other evidence overcomes all rejections under appeal and that a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented has been made.

MPEP 706.07 states:

Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection. Switching from one subject matter to another in the claims presented by applicant in successive amendments, or from one set of references to

another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application or a final rejection.

While the rules no longer give to an applicant the right to "amend as often as the examiner presents new references or reasons for rejection," present practice does not sanction hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application. But the applicant who dallies in the prosecution of his or her application, resorting to technical or other obvious subterfuges in order to keep the application pending before the primary examiner, can no longer find a refuge in the rules to ward off a final rejection.

The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal. However, it is to the interest of the applicants as a class as well as to that of the public that prosecution of an application be confined to as few actions as is consistent with a thorough consideration of its merits. Neither the statutes nor the Rules of Practice confer any right on an applicant to an extended prosecution; *Ex parte Hoogendam*, 1939 C.D. 3, 499 O.G.3, 40 USPQ 389 (Comm'r Pat. 1939).

STATEMENT OF GROUNDS

In making the final rejection, all outstanding grounds of rejection of record should be carefully reviewed, and any such grounds relied on in the final rejection should be reiterated. They must also be clearly developed to such an extent that applicant may readily judge the advisability of an appeal unless a single previous Office action contains a complete statement supporting the rejection.

However, where a single previous Office action contains a complete statement of a ground of rejection, the final rejection may refer to such a statement and also should include a rebuttal of any arguments raised in the applicant's reply. If appeal is taken in such a case, the examiner's answer should contain a complete statement of the examiner's position. The final rejection letter should conclude with Form Paragraph 7.39.

MPEP 714.12 states:

Once a final rejection that is not premature has been entered in an application, applicant or patent owner no longer has any right to unrestricted further prosecution. This does not mean that no further amendment or argument will be considered. Any amendment that will place the application either in condition for allowance or in better form for appeal may be entered. Also, amendments complying with objections or requirements as to form are to be permitted after final action in accordance with 37 CFR 1.116(b). Ordinarily, amendments filed after the final action are not entered unless approved by the examiner. See MPEP § 706.07(f), § 714.13 and § 1207.

MPEP 714.13 states:

It should be kept in mind that applicant cannot, as a matter of right, amend any finally rejected claims, add new claims after a final rejection (see 37 CFR 1.116) or reinstate previously canceled claims.

MPEP 1206 states:

A new amendment must be submitted in a separate paper. Entry of a new amendment in an application on appeal is not a matter of right. The entry of an amendment (which may not include a new affidavit, declaration, exhibit or other evidence) submitted in an application on appeal is governed by 37 CFR 41.33, not 37 CFR 1.116.

OPINION

Petitioner seeks reversal of the Technology Center Director's decision of October 12, 2006, on the grounds that the Office action of January 16, 2004, was improperly made final, and relies *inter alia* on MPEP § 706.07 in support of his contention that a clear issue must be developed between the examiner and applicant before finality is properly invoked. Accordingly, petitioner further contends that the amendment June 16, 2004 and the affidavit and amendment filed February 21, 2005 should be entered.

Petitioner argues that the final Office action mailed January 16, 2004 introduces the concepts of: (1) "automatic" or "inherently" to support an obviousness-type double patenting rejection; and (2) a new legal authority of *prima facie* obviousness. Thus, petitioner contends the finality of the Office action is improper, as petitioner had no opportunity to respond to the rejection.

MPEP 706.07 stated, at the time of the action complained of: (1) any such grounds relied on in the final rejection should be reiterated and they must also be clearly

developed to such an extent that applicant may readily judge the advisability of an appeal unless a single previous Office action contains a complete statement supporting the rejection; and (2) the final rejection may refer to such a statement and also should include a rebuttal of any arguments raised in the applicant's reply.

As stated in the Technology Center Director's decision, the examiner's rejection in the final Office action merely developed the grounds of rejection to such an extent that applicant may readily judge the advisability of an appeal in response to petitioner's remarks. The Technology Center Director correctly noted: (1) claims 142-154 remain rejected under the judicially created doctrine of obviousness-type double patenting; (2) the terms "automatically" or "inherently" did not introduce a new grounds of rejection as they were utilized to provide further explanation of the outstanding obviousness-type double patenting rejection in response to petitioner's arguments; and (3) the statement "...narrower claims will not be patentable, *prima facie*, absent a proper terminal disclaimer" is not a new grounds of rejection or new legal theory as the statement merely reiterated that the claims were obvious over claim 23 of U.S. Patent No. 4,399,216.

It follows that the Technology Center Director did not clearly err in upholding the finality of the Office action. Petitioner's contention that the requirement in MPEP § 706.07 for the development of a clear issue as a condition of a proper finality was not here satisfied, is simply without merit. To the contrary, it is difficult to see how the issue could have been more clearly developed by the final Office action.

Petitioner complains that the examiner has erred in the analysis used to support the obviousness-type double patenting rejection. A rejection, or the continuation of a rejection, of a claim(s) cannot be reviewed on petition; rather, as explained in MPEP 1201, the mechanism for having the propriety of a given rejection reviewed is by way of appeal before the Board of Patent Appeals and Interferences under 35 U.S.C. § 134 and 37 CFR 41.31. The issues of whether e.g., the examiner properly analyzed the claims in light of the specification disclosure before making the rejection(s), or whether the rejections over prior art were properly maintained relate to the merits of those rejections and such can only be considered on appeal and will not be considered on petition. See 37 CFR 1.181(a); see also *Boundy v. U.S. Patent & Trademark Office*, 73 USPQ2d 1468 (DC Eva 2004), appeal dismissed, 2004 U.S. App. LEXIS 26384 (Fed. Cir. 2004). It is well settled that the Director will not, on petition, usurp the functions or impinge upon the jurisdiction of the Board of Patent Appeals and Interferences. See *In re Dickerson*, 299 F.2d 954, 958, 133 USPQ 39, 43 (CCPA 1962); *Baylev's Restaurant v. Bailev's of Boston, Inc.*, 170 USPQ 43, 44 (Comm'r Pat. 1971).

Given that the Office action was properly made final, 37 CFR 1.116 is controlling on entry *vel non* of the amendment after final filed June 16, 2004 and further, given that a Notice of Appeal was filed July 19, 2004, 37 CFR 41.33 is controlling on entry *vel non*

of the amendment and affidavit filed February 21, 2005. As explained MPEP §§ 714.12, 714.13, 1206 entry of either amendment or the affidavit was not a matter of right and, as here, could properly be refused entry by the examiner, for various reasons, including that a proposed amendment raises the issue of new matter or raises new issues that would require further consideration or search. In the Advisory Action of December 1, 2004, the examiner noted that the proposed amendment, filed June 16, 2004, did not clearly place the application in condition for allowance and that said proposed amendment raised the issue of new matter. In the Advisory Action of September 23, 2005, the examiner noted that the proposed amendment, filed February 21, 2005, did not clearly place the application in condition for allowance and that the claims as proposed to be amended required further consideration or search, and that the affidavit was not entered as there was no showing of good and sufficient reasons why it is necessary and not earlier presented.

Furthermore, the Technology Center Director noted petitioner's contention that the amendment of June 16, 2004 did not raise the issue of new matter as the phrase "a proteinaceous material which is a precursor," was supported by Figure 1, page 6, lines 13-16; page 11, line 28, page 17, lines 1-20, and page 4, line 34 to page 5, line 7. However, the Technology Center Director correctly noted: (1) there is no support for "a proteinaceous material which is a precursor," in Figure 1, page 6, lines 13-16; page 11, line 28, and page 17, lines 1-20; and (2) page 4, line 34 to page 5, line 7 only addresses the general background of the invention. Clearly, since a careful determination of whether or not this material constitutes new matter will have to be made the issue of new matter is raised. Accordingly, the Technology Center Director did not clearly err in upholding the examiner's refusal to enter the amendment of June 16, 2004 as raising the issue of new matter.

Additionally, the Technology Center Director noted petitioner's contentions that: (1) the amendment of February 21, 2005 should be entered because it presents the rejected claims in better form for appeal; and (2) the Declaration of Francis H. Ruddle, Ph.D., should be entered under 37 CFR 1.116(b)(3) which provides that an "amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and presented earlier." With respect to the contention that amendment of February 21, 2005 placed the claims in better form for appeal, the Technology Center Director noted that the amended claims contained changes which raise new issues and that three new claims were presented without the cancellation of any other claims. Therefore, the Technology Center Director's decision correctly analyzed petitioner's amendment in view of the fact that the examiner's final Office action did not raise any new issues and merely further developed the record in response to petitioner's arguments. Furthermore, with respect to entry *vel non* of the Declaration of Francis H. Ruddle, Ph.D., petitioner argues that the Technology Center Director failed to consider that petitioners were responding to a new reasons for rejection. The Technology Center

Director correctly noted in a petition decision mailed October 12, 2006 that the examiner has not provided new reasons for rejection and merely further developed the record in response to petitioner's arguments. As the Technology Center Director noted in a petition decision mailed October 12, 2006 petitioner has failed to provide good and sufficient reasons why the testimony and statements of researchers were not presented earlier in prosecution because: (1) the submission of the testimony and statements of research did not occur until over six months after August, 2004; (2) petitioner has had over eight years from the date of the first obviousness-type double patenting rejection made over U.S. Patent No. 4,399,216 in this case to submit any and all necessary evidence to rebut this rejection; and (3) petitioner has had over two years to provide rebuttal evidence against the obviousness-type double patenting rejection over U.S. Patent No. 4,399,216 from the date of mailing of the first Office action April 23, 2003, in this latest continuation under 37 CFR 1.129(a). Therefore, the Technology Center Director did not clearly err in upholding the examiner's refusal to enter the amendment and affidavit of February 21, 2005.

For the reasons set forth above, the Technology Center Director's decision to refuse petitioners' requests to withdraw the finality of the Office action mailed January 16, 2004, or compel the entry of the amendment after final filed June 16, 2004 and the affidavit and amendment after final filed February 21, 2005 are not shown to be in clear error.

DECISION

A review of the record indicates that the Technology Center Director did not abuse his discretion or act in an arbitrary and capricious manner in the petition decisions of October 12, 2006. The record establishes that the Technology Center Director had a reasonable basis to support his findings and conclusions.

The petition is granted to the extent that the decisions of the Technology Center Director of October 12, 2006 have been reviewed, but is denied with respect to making any change therein. As such, the decisions of October 12, 2006 will not be disturbed. The finality of the Office action of January 16, 2004, and the refusal to enter the amendment of June 16, 2004 and the amendment and affidavit of February 21, 2005, will not be disturbed. The petition is **denied**.

This application file is being forwarded to Technology Center 1600 for further processing.

Telephone inquiries concerning this decision should be directed to David A. Bucci at (571) 272-7099.



Andrew Hirshfeld
Acting Deputy Commissioner for
Patent Examination Policy

Cp

¹ This decision may be viewed as a final agency action within the meaning of 5 U.S.C. § 704 for purposes of seeking judicial review. See MPEP 1002.02