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MAR 16 2010

CENTRAL REEXAMINATION UNIT

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In re Prickett *et al.*
Inter Partes Reexamination Proceeding
Control No. 95/000,276
Filed: July 9, 2007
For: U.S. Patent No. 6,924,264

: **DECISION ON PETITION**
: **TO CONTINUE**
: **INTER PARTES**
: **REEXAMINATION**
: **PROCEEDINGS**

This is a decision on the January 6, 2010 patent owner renewed petition entitled "PETITION UNDER 37 CFR 1.182 REQUESTING CONTINUED REEXAMINATION."

The patent owner petition is before the Office of Patent Legal Administration.

The petition is **granted**.

FEES

The fee set forth in 37 CFR 1.17(f) for the patent owner petition under 37 CFR 1.182 is \$400, and it was charged to Patent Owner's credit card on January 6, 2010 pursuant to the authorization for same in Patent Owner's EFS-WEB fee transmittal.

BACKGROUND

1. On August 2, 2005 the Office issued U.S. Patent No. 6,924,264 (the '264 patent) to Prickett *et al.* The '264 patent issued with a total of twenty-three claims.
2. On July 9, 2007, a request for *inter partes* reexamination was filed by the third party requester, and assigned control number 95/000,276 ("the '276 proceeding"). The request asserted that a substantial new question of patentability existed regarding claims 1-8, 10, and 12-23 of the '264 patent.
3. On October 3, 2007, the Office issued an order granting the request for reexamination in the '276 proceeding, concluding that a substantial new question of patentability was raised by the request regarding claims 1-8, 10, and 12-23. An Office action on the merits

was not concurrently issued with the order, but the order stated it would be issued in due course.

4. On January 17, 2008, the Office issued a first Office action on the merits rejecting claims 1-8, 10, 12-23.
5. On April 16, 2008, patent owner timely filed a response that included an amendment canceling all the originally issued twenty-three claims and adding new claims 24-38.¹
6. On May 15, 2008, third party requester timely submitted comments and declarations.²
7. The proceeding progressed until, on March 5, 2009, an Action Closing Prosecution (ACP) was issued.
8. On May 5, 2009, patent owner timely filed a response after ACP including an amendment, three affidavits and remarks.³ Concurrently patent owner filed a petition entitled "PETITION UNDER 37 CFR 1.182 REQUESTING CONTINUED REEXAMINATION," requesting entry of an amendment, remarks and affidavits filed with the petition.
9. On June 3, 2009, third party requester timely submitted comments.
10. On June 8, 2009, the Office issued a decision dismissing the May 5, 2009 patent owner petition as premature.
11. On December 17, 2009, the Office issued a Right of Appeal Notice (RAN) denying entry of patent owner's May 5, 2009 amendments, remarks and affidavits filed in response to the March 5, 2009 ACP.
12. On January 6, 2010, patent owner filed a renewed petition entitled "PETITION UNDER 37 CFR 1.182 REQUESTING CONTINUED REEXAMINATION," requesting entry of an amendment, remarks and affidavits. Concurrently, patent owner filed a petition entitled, "PETITION UNDER 37 CFR § 1.183 REQUESTING WAIVER OF THE PROHIBITION OF AN EXTENSION OF TIME FOR FILING AN APPEAL BRIEF AND FOR AN EXTENSION OF TIME FOR FILING AN APPEAL BRIEF."
13. On February 4, 2010, the third party requester filed an opposition to patent owner's January 6, 2010 petition requesting continued reexamination, which is being addressed by a decision mailed concurrently with this decision.

¹ Patent owner was granted an extension of time to file a response to the January 17, 2008 Office action until 17 April 2008.

² A third declaration executed by Mark J. Poznansky and a second declaration executed by Omar Quraishi.

³ Patent owner was granted an extension of time to file a red for response to the March 5, 2009 ACP until May 5, 2009.

14. On February 22, 2010, the Office issued a decision granting patent owner's request for waiver of 37 CFR 41.46 and granted patent owner an extension of time to file an appeal brief.
15. This decision addresses patent owner request for continued reexamination under 37 CFR 1.182 and entry of amendment, remarks and affidavits concurrently filed with the petition.

STATUTES, REGULATIONS, AND PATENT EXAMINING PROCEDURES

37 CFR 1.182 provides:

All **situations not specifically provided** for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Director, subject to such other requirements as may be imposed, and such decision will be communicated to the interested parties in writing. Any petition seeking a decision under this section must be accompanied by the petition fee set forth in § 1.17(f). (emphasis added)

37 CFR 1.951(a) provides:

After an Office action closing prosecution in an inter partes reexamination, the patent owner may once file comments limited to the issues raised in the Office action closing prosecution. The comments can include a proposed amendment to the claims, which amendment will be subject to the criteria of § 1.116 as to whether or not it shall be admitted. The comments must be filed within the time set for response in the Office action closing prosecution.

DECISION ON PETITION UNDER 37 CFR 1.182

In the present petition, it is requested that the Office continue the prosecution of the instant reexamination proceeding to provide consideration of the Amendment after ACP received in the Office on May 5, 2009 along with other after-final communications submitted in response to the March 5, 2009 ACP.

In March of 2005, the Office issued a Notice titled⁴ "Notice of Changes in Requirement for a Substantial New Question of Patentability for a Second or Subsequent Request for Reexamination While an Earlier Filed Reexamination is Pending." Notice was provided therein that a second (or subsequent) reexamination would no longer be ordered on the basis of a "substantial new question of patentability" (SNQ) that is the same as a SNQ raised in an earlier pending reexamination. Notice was also provided therein that a patent owner could file a petition under 37 CFR 1.182 requesting continued prosecution on the merits in the reexamination proceeding to seek entry of an amendment and/or evidence that was denied entry after a final rejection in an *ex parte* reexamination proceeding, or after an action closing prosecution in an

⁴ 1292 Off. Gaz. Pat. Office 20, March 1, 2005.

inter partes reexamination proceeding. By filing such a petition, the patent owner could obtain continued prosecution on the merits in the reexamination proceeding, including entry of the amendment and/or evidence that was denied entry after a final rejection in an *ex parte* reexamination proceeding, or after an action closing prosecution in an *inter partes* reexamination proceeding. Accordingly, relief in the form of a continuation of the reexamination prosecution (after a final Office action) was made available by the Office via a 37 CFR 1.182 petition, in appropriate circumstances. This petition will be referred to herein as “the § 1.182 petition.”

The § 1.182 petition must further the prosecution of the reexamination proceeding, rather than delay it, and must provide a submission toward that end. This is critical in the reexamination setting, where 35 U.S.C. 305 (for *ex parte* reexamination) and 35 U.S.C. 314 (for *inter partes* reexamination) mandate that reexamination proceedings must be conducted “with special dispatch within the Office.” Accordingly, the patent owner must make a *bona fide* effort, in the submission accompanying the § 1.182 petition, to define the issues for appeal, or the issuance of a reexamination certificate, because this is a key factor in reducing pendency of a reexamination proceeding. Stated another way, the § 1.182 petition practice includes a requirement that the filing of the § 1.182 petition be accompanied by a submission that provides a *bona fide* effort to advance the prosecution toward appeal, or toward the issuance of a reexamination certificate.

Based on the facts and circumstances of the present case, petitioner patent owner’s response in the form of a request to enter an amendment, remarks and evidence after final rejection, i.e., the May 9, 2009 response to ACP, constitutes a *bona fide* effort to advance prosecution and as such, the granting of the present petition is consistent with the requirement of 35 USC 314(c) to conduct an *inter partes* reexamination proceeding “with special dispatch within the Office.”

On March 5, 2009, the examiner issued an ACP with eight different new grounds of rejection. The first ground of rejection was a statutory non-art rejection of all the claims under 35 U.S.C. 305. The second to the eight grounds of rejection, all utilized newly submitted declarations filed by the third party requester on May 15, 2008 to evidence or support the rationale of the grounds of rejection. The sixth through eighth grounds of rejection improvidently used the third Poznansky declaration as part of the combination of references that serve as a basis of the rejection. Patent owner has never had a fair opportunity to respond to the grounds of rejection that either utilize newly cited declarations to support the rationale of the new grounds of rejection or improvidently serve as part of the basis for the new grounds of rejection, nor could patent owner have reasonably foreseen that third party requester’s newly submitted declarations would be used in this manner.

Furthermore, patent owner’s amendment is a reasonable advancement of prosecution on the merits. On page 13 of the March 5, 2009 ACP, the examiner addressed claim 28, a dependent claim that included the limitations of originally issued independent claim 23, plus the limitations of claim 13 with the limitation drawn to the exendin-4 “linked to the one or more polymers at the N or C terminal residue, or the N or C termini of a side chain of one or more amino acids of the exendin-4 or agonist analog of exendin-4, wherein the amino acid is selected from the group consisting of lysine, aspartic acid, glutamic acid and cysteine.” The examiner stated the second grounds of rejection that claim 28 was rejected under 35 USC 102(a) as anticipated by or, in the alternative, under 35 USC 103(a) as being unpatentable over Edwards, relying on Poznansky I,

Harlow & Lane declaration and a newly submitted third declaration of Mark Poznansky for evidence of inherency or in the alternative evidence of obviousness. The examiner stated that Edwards discloses exendin-4 cross-linked with glutaraldehyde to bovine serum albumin and that Poznansky I evidenced the inherent property of glutaraldehyde as a cross-linking agent that cross links peptides at the epsilon amino group of a lysine side chain or free amino group of the amino terminus. The examiner further stated that Poznansky I evidences the form of the exendin-4-BSA molecules cross-linked with glutaraldehyde as polymers linked through an epsilon amino group on a lysine amino acid, at an amino, carboxyl or thiol group, at the N or C terminal residue, or the N or C termini of a side chain, of lysine, aspartic acid, glutamic acid or cysteine, at one or more amino acid side chain moieties, or one or more amine or carboxylic groups as particularly recited in claims 26-29. The examiner went on to cite as support for a rationale of inherency or obviousness for the first time in prosecution the third Poznansky declaration, which was submitted by with third party requester's responsive comments to the January 17, 2008 Office action.

The post ACP amendment submitted by patent owner presents new claims 24-39, and specifically new claim 24 in reliance upon the examiner's statements regarding the inherency arguments as evidenced by Poznansky I and now claims exendin-4 "linked through the C-terminal amino acid to one polymer selected from the group consisting of polyethylene glycol, a polyamino acid, albumin, gelatin, succinyl-gelatin and (hydroxypropyl)-methacrylamide." Therefore, the amendment by patent owner is advancing prosecution by further amending claim 24 to include a specific location of chemical bond linkage between exendin-4 and one polymer. This further amending of claim 24 is also submitted for the purpose of obviating all other rejections of record.

Finally, patent owner submitted three affidavits to provide additional evidence in respond to the new grounds of rejection. Patent owner has good and sufficient reason for not being able to submit the affidavits early. Specifically because it was not reasonably foreseeable that they would be necessary to respond to the grounds of rejection asserted in the ACP all utilized newly submitted declarations filed by the third party requester, wherein three of the newly asserted grounds of rejection improvidently used the third Poznansky declaration as part of the combination of references to serve as a basis of the rejection. The RAN dated December 17, 2009 stated that entry of the May 9, 2009 response after ACP was denied, because the proposed amendment introduces new claim limitations not previously considered during the reexamination proceeding; the changes were not limited to cancelling claims, adopting examiner's suggestions, and the changes do not remove issues for appeal; and the proposed amendment required more than a cursory review by the examiner and it's entry would require consideration of the new grounds for rejection.

Based upon the facts and circumstances of the present case, the post ACP amendment, remarks and declarations presented by Petitioner/patent owner, consistent with and limited by patent owner to a response to the reasonably unforeseeable new asserted grounds of rejection and based upon the reasonable reliance of the actions taken by the examiner in the ACP, is deemed a *bona fide* attempt to advance the prosecution toward the issuance of a reexamination certificate. As such, the granting of the present petition is consistent with the requirements of 35 USC 314(c) to conduct an *inter partes* reexamination proceeding "with special dispatch within the Office."

In view of the above and the fact situation presented by the record, the petition is granted, and the prosecution in the above-noted reexamination proceeding is hereby continued. Prosecution is reopened for consideration of the amendment, affidavits and remarks submitted after ACP on May 5, 2009. The May 5, 2009 response to ACP will be entered in the reexamination proceeding, and the proceeding will be forwarded to the CRU to await submission of any third party comments under 37 CFR 1.947 after the May 5, 2009 patent owner response. Following the submission of third party requester comments or the lapse of the time period for third party comment, the proceeding will be forwarded to the examiner for action consistent with this decision. The examiner will consider the May 5, 2009 patent owner response and any third party comments. The Examiner will then issue an Office action treating the May 5, 2009 patent owner papers as a response and third party comments received after a first Office action.

CONCLUSION

1. The petition under 37 CFR 1.182 is granted.
2. The prosecution of the '276 *inter-partes* reexamination proceeding is continued. No further continuation of the present reexamination proceeding will be granted absent a showing of extraordinary circumstances.
3. The closing of prosecution rendered via the Office action mailed March 5, 2009 is withdrawn, and prosecution of the proceeding is reopened. The amendment will be treated as a response by patent owner received **after** a first Office action.
4. Third party requester has thirty (30) days from the date of mailing of this decision to submit comments pursuant to 37 CFR 1.947.
5. The Amendment After ACP received May 5, 2009⁵ will be entered by the Central Examination Unit, await submission of third party comments and then be forwarded to the examiner for consideration of both the amendment and any third party comments.
6. Jurisdiction for the '276 reexamination proceeding is returned to the Central Reexamination Unit (CRU).
7. Telephone inquiries related to this decision should be directed to Joseph F. Weiss, Jr., Legal Advisor, at (571) 272-7759, or in his absence, the undersigned at (571) 272-7710.



Kenneth M. Schor
Senior Legal Advisor
Office of Patent Legal Administration

Kenpet8/RCR/IP 3-11-10

⁵ This decision takes no position on the propriety of the amendment or whether it introduces new matter. Any issues raised by the amendment will be addressed by the Examiner in the next Office action.