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Paper No.

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MAILED SEP 06 2011 OFFICE OF PETITIONS

In re Application of

Breslin et al.

DECISION ON APPLICATION

Application No. 11/079,647

Patent No. 7,741,356

PATENT TERM ADJUSTMENT

Filed: March 14, 2005 Issued: June 22, 2010

Docket No. PRD2200USNP Title: NOVEL COMPOUNDS AS OPIOID

RECEPTOR MODULATORS

This is a decision on the "REQUEST FOR RECONSIDERATION OF PETITION DECISION" filed April 15, 2011. Patentee requests that the determination of patent term adjustment under 35 U.S.C. § 154(b) be corrected from 1009 days to 1107 days. More specifically, Patentee contends that a prior decision of the Office was both erroneous and unconstitutional.

The request for reconsideration of the patent term adjustment under 37 C.F.R. § 1.705(b) is **DENIED**.

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

RELEVANT BACKGROUND

On April 9, 2007 (14 months and 330 days after the filing of this application), the United States Patent and Trademark Office (USPTO) entered an Office action under 35 U.S.C. § 132(a) (a restriction requirement). The USPTO entered a subsequent Office action under 35 U.S.C. § 132(a) (a restriction requirement) on July 16, 2007 (14 months and 428 days after the filing of this

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

application), which indicated, in pertinent part "[t]he Restriction Requirement of April 09, 2007 is rescinded and is replaced by this action." Patentee argues that the examination delay pursuant to 37 C.F.R. § 1.702(a)(1) should be 428 days, not 330 days.

Pursuant to 37 C.F.R. § 1.702(a)(1):

"Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to:
(1) Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international application;"

On January 13, 2009, Applicants filed a petition requesting, inter alia, that the aforementioned delay pursuant to 37 C.F.R. § 1.702(a)(1) should be 428 days, not 330 days. The Office dismissed this request via the mailing of a decision on May 18, 2010.

On July 19, 2010, Patentee filed a petition requesting that the aforementioned delay pursuant to 37 C.F.R. § 1.702(a)(1) should be 428 days, not 330 days. The Office dismissed this request via the mailing of a decision on March 15, 2011 which was signed by Senior Attorney Paul Shanoski.

RELEVANT STATUTES

- 35 U.S.C. §§ 3(b)(3)(A) and (B) provides that:
 - "(3) OTHER OFFICERS AND EMPLOYEES. The Director shall-
 - (A) appoint such officers, employees (including attorneys), and agents of the Office as the Director considers necessary to carry out the functions of the Office; and
 - (B) define the title, authority, and duties of such officers and employees and delegate to them such of the powers vested in the Office as the Director may determine. The Office shall not be subject to any administratively or statutorily imposed limitation on positions or personnel, and no positions or personnel of the

² Restriction requirement of July 16, 2007, page 2.

Office shall be taken into account for purposes of applying any such limitation."

35 U.S.C. § 131 provides that:

"The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor."

35 U.S.C. § 132 provides that:

"(a) Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

(b) The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title."

35 U.S.C. § 154(b)(1)(A), provides, in relevant part:

"Subject to the limitations under [35 U.S.C. § 154(b)(2)], if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to —

provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after the date on which an application was filed under section 111(a) of this title;

the term of the patent shall be extended 1 day for each day after the end of this [fourteen-month period] until [the response] is taken."

DECISION

In the petition filed on July 19, 2010, Patentee essentially argued that the restriction requirement of July 16, 2007 "vacated" the restriction requirement of April 9, 2007, and as

such the restriction requirement of April 9, 2007 should be treated as not having been issued for purposes of determining whether the issuance of the patent was delayed due to the failure of the USPTO to mail an action under 35 U.S.C. § 132 within 14 months after the date the application was filed under 35 U.S.C. § 111(a). The decision which was mailed on March 15, 2011 set forth, in pertinent part:

"The vacatur of an Office action sets aside or withdraws any rejection, objection or requirement in an Office action, as well as the requirement that the applicant timely reply to the Office action to avoid abandonment under 35 U.S.C. § 133. The vacatur of an Office action signifies that the Office action has been set aside, voided, or withdrawn as of the date of the vacating Office action or notice. The vacatur of an Office action, however, does not (emphasis included) signify that the vacated Office action is void ab initio and is to be treated as if the USPTO had never issued the Office action. The patent examination process provided for in 35 U.S.C. §§ 131 and 132 contemplates that Office actions containing rejections, objections or requirements will be issued, and that the applicant will respond to these Office action, "with or without amendment." (35 U.S.C. § 132(a)). mere fact that an examiner or other USPTO employee upon further reflection determines that an Office action, or that a rejection, objection or requirement in an Office action, is not correct and must be removed does not warrant treating the Office action as void ab initio and as if the USPTO had never issued the Office action.

The USPTO appreciates that there may be situations in which it is appropriate to treat an Office action or notice issued in an application as void ab initio and as if the USPTO had never issued the Office action. However, these would be extremely rare situations, such as the issuance of an Office action or notice by an employee who does not have the authority to issue that type of Office action or notice, the issuance of an Office action or notice in the wrong application, or the issuance of an Office action or notice containing language not appropriate for inclusion in an official document. In essence, the situations in which it is appropriate to treat an Office action or notice issued in an application as void ab initio and as if the USPTO had never issued the Office action are the situations in which it is appropriate to expunge an Office action or notice from the USPTO's record of the application. That is simply not the case in this situation.

Pursuant to 35 U.S.C. § 154(b)(1)(A)(i), patentees are entitled to day-to-day adjustment if the USPTO fails to provide a notification under section 132 of this title not later than 14 months after the date on which an application was filed under section 111(a) of this title. The record of the above-identified

patent indisputably indicates that the USPTO entered an Office action under 35 U.S.C. § 132, specifically a restriction requirement, on April 9, 2007, which is 14 months and 330 days after the date on which the application was filed under 35 U.S.C. § 111(a). The fact that the Office later set aside the restriction requirement of April 9, 2007 does not negate the fact that the Office responded within the meaning of 35 U.S.C. § 154(b)(1)(A)(i) and 37 CFR 1.702(a)(1) on April 9, 2007. Unless expunged from the record (which is not warranted in this situation), for purposes of calculating patent term adjustment, the Office action entered by the examiner on April 9, 2007 was properly used to determine whether the USPTO delayed the issuance of the above-identified patent by failing to provide a notification under 35 U.S.C. § 132 within 14 months after the date on which the application was filed under 35 U.S.C. § 111(a). See Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term, 65 Fed. Reg. 54366 (Sept. 18, 2000) (final rule)."

Decision on petition, mailed on March 15, 2011, pages 3-5.

With the petition dated April 15, 2011, Patentee makes two arguments:

- The decision dated March 15, 2011 is improper substantively, as the findings contained therein are "inconsistent with the legal authorities that the Petition Decision acknowledges to be applicable," and;
- 2. The decision dated March 15, 2011 is unconstitutional, as it was not signed by "the Director or any other Officer of the PTO." 4

Regarding the first argument, the Office holds that the vacatur of an Office action does not signify that the vacated Office action is void ab initio and is to be treated as if the USPTO had never issued the Office action, as set forth on pages 3-4 of the decision mailed on March 15, 2011, for the reasons set forth therein.

Regarding the second argument, the Office holds that the Director of the USPTO is free to delegate decision making authority as appropriate. Since the file history has been reviewed in the preparation of this decision and the decision of March 15, 2011 is hereby ratified, no issue is believed to be

³ Petition dated April 15, 2011, page 2.

^{4 &}lt;u>Id</u>.

present on the point of authority to sign the decision. Moreover, as this decision has been signed by the Director of the Office of Petitions, this issue has been rendered moot.

CONCLUSION

In view thereof, the patent term adjustment of 1009 days as set forth in the mailing of March 15, 2011 is correct.

Telephone inquiries specific to this matter should be directed to Senior Attorney Paul Shanoski at (571) 272-3225.

It is noted that the address listed on the petition differs from the address of record. The application file does not indicate a change of correspondence address has been filed in this case, although the address given on the petition differs from the address of record. If Petitioner desires to receive future correspondence regarding this patent, the change of correspondence address must be submitted.

A courtesy copy of this decision will be mailed to the address which appears on the petition. However, all future correspondence will be directed to the address of record until such time as appropriate instructions are received to the contrary. Petitioner will not receive future correspondence related to this patent unless Change of Correspondence Address, Patent Form (PTO/SB/123) is submitted for the above-identified patent.

For Petitioner's convenience, a blank Change of Correspondence Address, Patent Form (PTO/SB/123), may be found at http://www.uspto.gov/web/forms/sb0123.pdf. If appropriate, a change of fee address (form PTO/SB/47) and a request for customer number (form PTO/SB/125) should be filed in accordance with Manual of Patent Examining Procedure, section 2540. A

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blank fee address form may be found at http://www.uspto.gov/web/forms/sb0047.pdf.

Anthony Knight

Director

Office of Petitions

cc: Joseph Lucci

Woodcock Washburn LLP

Circa Centre

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