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AUG 25 2011

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In re Patent of Collins : FINAL AGENCY DECISION
Patent No. 7,875,453 : ON
Issue Date: January 25, 2011 : REQUEST FOR RECONSIDERATION
Application No. 11/452,502 : OF
Filed: June 14, 2006 : DECISION ON APPLICATION
Attorney docket: 10847-044001 : FOR
For: DIFFERENTIATION OF MULTI- : PATENT TERM ADJUSTMENT
LINEAGE PROGENITOR CELLS TO
HEPATOCYTES

This is a decision on the "RESPONSE TO DECISION ON APPLICATION FOR PATENT TERM ADJUSTMENT" filed June 23, 2011, requesting reconsideration of the decision of April 25, 2011, and requesting that the patent term adjustment determination under 35 U.S.C. § 154(b) in the decision of April 25, 2011, be changed from 118 days to 246 days.

Patentee requests that the decision on this renewed request for reconsideration of patent term adjustment be deferred or delayed until a final decision has been rendered in Abbott Biotherapeutics Corp. v. Kappos. There is no specific regulatory provision for requesting that a petition under 37 CFR 1.705(d) be held in abeyance.

The request for reconsideration of the decision of April 25, 2011, is granted to the extent that the decision of April 25, 2011, 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) of 118 days indicated in the decision of April 25, 2011. 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 January 25, 2011, the above-identified application matured into U.S. Patent No. 7,875,453, with a revised patent term adjustment of 118 days. On March 24, 2011, Patentee timely submitted a petition for reconsideration of patent term adjustment (with required fee), asserting that the correct number of days of Patent Term Adjustment is 246 days. On April 25, 2011, the Office mailed a decision indicating the patent term adjustment is 118 days and affording Patentee with a 30 day/1 month period to contest the decision. Patentee timely filed the present petition on June 23, 2011. Patentee maintains that the Office incorrectly calculated Office delay pursuant to 37 CFR 1.702(b). Patentee contends that the Office erred in subtracting from the "B delay" a period of time that was not "consumed by continued examination of the application." Specifically, Patentee argues that (after the filing of a request for continued examination) the Office mailed a Notice of Allowance on September 20, 2010, thereby closing examination of the application on that date. Thus, Patentee argues no continued examination took place during the 128 day period from September 20, 2010 (the mailing date of the Notice of Allowance) until January 25, 2011 (the date the patent was issued). As such, Patentee maintains that the "B delay" should include the 128 days and be increased from 0 to 128 days. Patentee concludes that the correct patent term adjustment is 246 days (the sum of 240 days of "A delay" and 128 days of "B delay" minus 122 days of Applicant delay).

RELEVANT STATUTE AND REGULATIONS

The statutory basis for calculation of "B delay" is 35 U.S.C. 154(b)(1)(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY, which provides that:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including -

- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);
- (ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the

Board of Patent Appeals and Interferences or by a Federal court;
or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

The implementing regulation, 37 CFR 1.702(b) provides that:

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 issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including:

- (1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b);
- (2) Any time consumed by an interference proceeding under 35 U.S.C. 135(a);
- (3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181;
- (4) Any time consumed by review by the Board of Patent Appeals and Interferences or a Federal court; or
- (5) Any delay in the processing of the application by the Office that was requested by the applicant.

OPINION

Patentee's arguments have been considered, but not found persuasive. The Office calculated the period of "B delay" pursuant to 35 U.S.C. 154(b)(1)(B)(i) and 37 CFR 1.702(b)(1) as 0 days based on the application having been filed under 35 U.S.C. 111(a) on June 14, 2006 and the patent not having issued as of the day after the three year date, June 15, 2009, and a request for continued examination being filed on April 14, 2009. In other words, the 128-day period beginning on the date of mailing of the notice of allowance to the date of issuance of the patent was considered time consumed by continued examination of an application under 35 U.S.C. 132(b) and was not included in the "B delay."

The Office's calculation of "B delay" is correct. The "B delay" is an adjustment entered if the issuance of the patent was delayed due to the failure of the Office to issue a patent

within three years after the date on which the application was filed. However, the adjustment does not include, among other things, any time consumed by continued examination of the application at the request of the applicant under 35 U.S.C. 132(b)¹. So, with respect to calculating the "B delay" where applicant has filed a request for continued examination, the period of adjustment is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the number of days in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued.

Further, counting the period of time excluded from the "B delay" for the filing of a request for continued examination under 35 U.S.C. 132(b), from the date on which the request for continued examination is filed to the date the patent is issued is proper. Patentee does not dispute that time consumed by continued examination of an application under 35 U.S.C. 132(b) is properly excluded and that the calculation of the excluded period begins on the date of filing of the request for continued examination. At issue is what further processing or examination beyond the date of filing of the request for continued examination is not any time consumed by continued examination of the application under 35 U.S.C. 132(b). The USPTO indicated in September of 2000 in the final rule to implement the patent term adjustment provisions of the AIPA that once a request for continued

¹ Pursuant to 35 U.S.C. 132(b) , 37 CFR 1.114 provides for continued examination of an application, as follows:

(a) If prosecution in an application is closed, an applicant may request continued examination of the application by filing a submission and the fee set forth in § 1.17(e) prior to the earliest of:

(1) Payment of the issue fee, unless a petition under § 1.313 is granted;

(2) Abandonment of the application; or

(3) The filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. 141, or the commencement of a civil action under 35 U.S.C. 145 or 146, unless the appeal or civil action is terminated.

(b) Prosecution in an application is closed as used in this section means that the application is under appeal, or that the last Office action is a final action (§ 1.113), a notice of allowance (§ 1.311), or an action that otherwise closes prosecution in the application.

examination under 35 U.S.C. 132(b) and 37 CFR 1.114 is filed in an application, any further processing or examination of the application, including granting of a patent, is by virtue of the continued examination given to the application under 35 U.S.C. 132(b) and CFR 1.114. See Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term, 65 Fed. Reg. 56366, 56376 (Sept. 18, 2000) (response to comment 8). Thus, the excluded period begins with the filing of the request for continued examination and ends with the issuance of the patent.

Patentee's argument that the period of time after the issuance of a notice of allowance on a request for continued examination is not "any time consumed by continued examination requested by the applicant under section 132(b)" within the meaning of 35 U.S.C. 154(b)(1)(B)(i) is not availing. This limitation is not supported by the statutory language. Garcia v. United States, 469 U.S. 70, 75 (1984) ("only the most extraordinary showing of contrary intentions from [legislative history] would justify a limitation on the 'plain meaning' of the statutory language"). BP Am. Prod. Co. v. Burton, 549 U.S. 84, 91 (2006) ("Unless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning"). The statute provides for a guarantee of no more than 3-year application pendency, by providing for an adjustment in the patent term.

First, "Subject to the limitations of paragraph (2)," means that the limitations of paragraph 2 apply to this paragraph's adjustment of patent term. That is, the day-to-day extension of patent term for pendency beyond the 3 year period is restricted as follows: 1) "B delay" cannot accrue for days of "A delay" that overlap, 2) the patent term cannot be extended beyond disclaimed term, and 3) the period of adjustment, including accrued "B delay," will be reduced for applicant delay.

Second, "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States," meaning that the condition must first occur that the issuance of an original patent (35 U.S.C. 153), not merely the issuance of a notice of allowance, is delayed due to the Office's failure to issue a patent (sign and record a patent grant in the name of the United States), not merely mail a notice of allowance, within 3 years after the actual filing date of the application in the United States. This provision gives the Office a three-year period to issue a patent (sign and record a patent grant in the name of

the United States) after the application filing date before an adjustment will accrue for "B delay."

Third, "not including- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b); (ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or (iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), meaning that the three-year period does not include "any time consumed by" or "any delay in processing," as specified in clauses (i)-(iii). This language correlates to 35 U.S.C. 154(b)(1)(A) which likewise provides the basis for determining the period given the Office to take the specified actions before an adjustment will accrue for "A delay" (e.g., extended for 1 day after the day after the period specified in clauses (i)-(iv)).

Furthermore, these clauses are interpreted using their ordinary meanings. Nonetheless, the context of the legislation should be considered. As stated in Wyeth v. Dudas, 580 F.Supp.2d 138 (D.D.C., September 30, 2008), because the clock for calculating the 20-year patent term begins to run on the filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate this effect, the statute, *inter alia*, grants adjustments of patent term whenever the patent prosecution takes more than three years, regardless of the reason. The time consumed by prosecution of the application includes every day the application is pending before the Office from the actual filing date of the application in the United States until the date of issuance of the patent. The time it takes to prosecute the application ends not with the mailing of the notice of allowance, but with the issuance of the patent.

Thus, not including "any time consumed by" means not including any days used to prosecute the application as specified in clauses (i)-(ii)². Clause (i) specifies "any time consumed by

² Clause (iii) provides for not including (iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued. It is noted that paragraph (3)(C) allows with an adequate showing by applicant for reinstatement of no

continued examination of the application requested by the applicant under section 132(b)." Clause (ii) specifies "any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court." "Time" in the context of this legislation throughout refers to days.

"Consumed by" means used by or used in the course of. *Websters Collegiate Dictionary*, (11th ed.). The "any" signifies that the days consumed by are "any" of the days in the pendency of the application, and not just days that occur after the application has been pending for 3 years. As such, "any time consumed by" refers to any days used in the course of 1) continued examination of the application under section 132(b) (the filing of a request for continued examination), 2) interference proceedings, 3) secrecy orders, and 4) appellate review. Thus, that 3-year period given to the Office to issue a patent before an adjustment will accrue for "B delay" does not include any days used in the course of or any time consumed by clauses (i)-(ii), including any time consumed by the filing of a request for continued examination.

Fourth, "the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued" meaning that the consequence of this failure is that after "the end of that 3-year period" an additional 1 day of patent term will accrue for each day that the application is pending until the day the patent is issued.

The "time consumed by" or used in the course of the continued examination of the application requested by the applicant under section 132(b) does not end until issuance of the patent. 35 U.S.C. 132(b) was enacted under the same title, the "American Inventors Protection Act of 1999," as 35 U.S.C. 154(b). Section 4403 of the AIPA amended 35 U.S.C. § 132 to provide, at the request of the applicant, for continued examination of an application for a fee (request for continued examination or RCE practice), without requiring the applicant to file a continuing application under 37 CFR 1.53(b) or a continued prosecution application (CPA) under 37 CFR 1.53(d). Thus, clause (i) is different from clause (ii) in that clause (i) refers to an examination process whereas clause (ii) refers to time consumed by proceedings (interferences, secrecy orders and appeals) in an application.

more than 3 months of the patent term reduced for applicant delay in taking in excess of three months to respond.

By nature, the time used in the course of the examination process continues to issuance of the patent. The examination process involves examining the application to ascertain whether it appears that the applicant is entitled to a patent under the law. See 35 U.S.C. 131 ("[t]he 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"). If on examination it appears that the applicant is entitled to a patent, the USPTO issues a notice of allowance. See 35 U.S.C. 151 ("[i]f it appears that applicant is entitled to a patent under the law, a written notice of allowance of the application shall be given or mailed to the applicant"). If on examination it appears that the applicant is not entitled to a patent, the USPTO issues a notice (an Office action) stating the applicable rejection, objection, or other requirement, with the reasons therefor. See 35 U.S.C. 132 ("[w]henver, 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"). Neither the issuance of a notice of allowance nor the insurance of an Office action terminates the examination process. If after the issuance of an Office action under 35 U.S.C. 132 it subsequently appears that the applicant is entitled to a patent (e.g., in response to an argument or amendment by the applicant), the USPTO will issue a notice of allowance. Conversely, if after the issuance of a notice of allowance under 35 U.S.C. 151 it subsequently appears that the applicant is not entitled to a patent (e.g., in response to information provided by the applicant or uncovered by the USPTO), the USPTO will withdraw the application from issuance and issue an Office action under 35 U.S.C. 132 stating the applicable rejection, objection, or other requirement, with the reasons therefor.

As held in Blacklight Power, the USPTO's responsibility to issue a patent containing only patentable claims does not end with the issuance of a notice of allowance under 35 U.S.C. 151. See BlackLight Power, Inc. v. Rogan, 295 F.3d 1269, 1273 (Fed. Cir. 2002). Rather, if there is any substantial, reasonable ground within the knowledge or cognizance of the Director as to why an application should not issue, it is the USPTO's duty to refuse to issue the patent even if a notice of allowance has previously

been issued for the application. See In re Drawbaugh, 9 App. D.C. 219, 240 (D.C. Cir 1896).

Moreover, the applicant continues to be engaged in the examination process after the mailing of the notice of allowance. 37 CFR 1.56 makes clear that the applicant has a duty to disclose information material to patentability as long as the application is pending before the USPTO (i.e., until a patent is granted or the application is abandoned). See 37 CFR 1.56(a) ("[t]he duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned"). 37 CFR 1.97 and 1.98 provide for the consideration of information submitted by the applicant after a notice of allowance has been mailed. See 37 CFR 1.97(d). In addition, 37 CFR 1.312 provides for the amendment of an application after a notice of allowance has been mailed. In fact, the request for examination procedures³ permit the filing of a request for continued examination under 37 CFR 1.114 even after the issuance of a notice of allowance under 35 U.S.C. 151. See 37 CFR 1.114(a)(1).

As the examination process does not terminate with the mailing of the notice of allowance, the time consumed by continued examination requested by the applicant under section 132(b) does not terminate with the mailing of the notice of allowance. All the time the application is pending from the date of filing of the request for continued examination to the mailing of the notice of allowance through issuance of the patent is a consequence of the filing of the request for continued examination. Further action by the Office is pursuant to that request. Applicant has gotten further prosecution of the application without having to file a continuing application under 37 CFR 1.53(b).

All of the continued examination pursuant to the filing of the request by the applicant is properly excluded from the delay attributed to the Office. 35 U.S.C. 154(b)(1)(B)'s guarantee of a total application pendency of no more than three years provides for adjustment of the patent term for delay due to the Office's failure to issue the patent within three years, but does not include "any time consumed by continued examination requested by the applicant under 35 U.S.C. 132(b)." It is not necessary to mitigate the effect on the 20-year term to the extent that applicant has requested that the Office continue to

³ Thus, on occasion, even where a request for continued examination has already been filed and a notice of allowance issued pursuant to that request, applicant may file a further request for continued examination.

examine the application via a request for continued examination, in lieu of, the filing of a continuing application under 37 CFR 1.53(b).

In this instance, a request for continued examination was filed on April 14, 2009, and the patent issued by virtue of that request on January 25, 2011. Pursuant to 35 U.S.C. 154(b)(1)(B)(i), the period beginning on September 20, 2010 and ending on January 25, 2011 is not included in calculating Office delay.

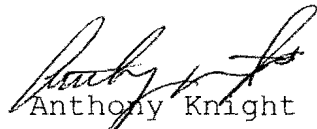
CONCLUSION

Accordingly, the decision on application for patent term adjustment has been reconsidered and the request for additional patent term is **DENIED**.

The patent term adjustment remains 118 days, as indicated in the decision of April 25, 2011.

Deposit account no. 06-1050 will be refunded the \$200.00 petition fee submitted with the instant petition, as Patentee has previously paid the \$200.00 petition fee on March 24, 2011.

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