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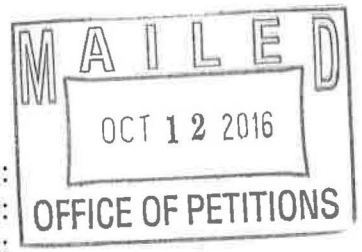

In re Application of
Arnold et al.
Application No. 13/300,877
Filed: November 21, 2011
Patent No. 9,029,381
Issue Date: May 12, 2015
Attorney Docket No.: 110421-0041-102
Title: CYCLOPROPYL AMIDE DERIVATIVES

DECISION ON REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

This is a response to Patentee's "request for reconsideration of patent term adjustment" filed December 8, 2015, 0 days to 217 days. The Office has found that the patent term adjustment remains 0 days.

The Office acknowledges the submission of both the $200.00 fee set forth in 37 C.F.R. § 1.18(e) and a five-month extension of time so as to make timely this petition. No additional fees are required.

This is the Director's decision on the applicant's request for reconsideration for purposes of seeking judicial review under 35 U.S.C. § 154(b)(4).

Relevant Procedural History

On January 15, 2014, the Federal Circuit issued a decision regarding the calculation of "B" delay after an applicant files a request for continued examination (RCE). *See Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

On May 12, 2015, the Office determined that applicant was entitled to zero days of PTA.

On December 8, 2015, Patentee filed a request for redetermination of patent term adjustment requesting a PTA of 217 days, pursuant to 37 C.F.R. § 1.705(b).

Decision

Upon review, the USPTO finds that Patentee is entitled to zero (0) days of PTA. Patentee and the Office are in agreement regarding the amount of "B" delay under 35 U.S.C. 154(b)(1)(B) , "C" delay under 35 U.S.C. § 154(b)(1)(C), overlap under 35 U.S.C. § 154(b)(2)(A), and reduction of

PTA under 35 U.S.C. § 154(b)(2)(C)(iii) and 37 C.F.R. § 1.704. At issue is the amount of "A" delay under 35 § U.S.C. § 154(b)(1)(A).

"A" Delay

A timeline of the relevant events is as follows:

- On November 2, 2012, a first notice of allowance was mailed.
- On February 4, 2013, a RCE was filed.
- On September 17, 2013, a second notice of allowance was mailed. The USPTO found this mailing warrants a 105-day adjustment under 37 C.F.R. § 1.703(a)(3) , beginning on June 5, 2013 (the day after the date that is four months after the date a reply in compliance with §1.113(c) was filed) and ending on September 17, 2013 (the date of mailing of a notice of allowance).
- On September 30, 2013, a "notice of withdrawal from issue under 37 CFR 1.313(b)" was mailed, which indicates, *in pertinent part*: "[t]he application is being withdrawn to permit reopening of prosecution. The reasons therefore will be communicated to you by the examiner."
- On June 5, 2014, a non-final Office action was mailed.

With this petition, Patentee argues the period of examination delay under 37 C.F.R. § 1.703(a)(3) should end not with the second notice of allowance which was mailed on September 17, 2013, but rather with the non-final Office action that was mailed on June 5, 2014. Patentee argues a 366-day "A" delay adjustment is warranted under 37 C.F.R. § 1.703(a)(3) beginning on June 5, 2013 (the day after the date that is four months after the date a reply in compliance with §1.113(c) was filed) and ending on June 5, 2014 (the date that Patentee argues an action under 35 U.S.C. § 132 was mailed).

Relevant Rules

37 C.F.R. § 1.702(a)(2) provides that:

> Failure to take certain actions within specified time frames. 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:
>
> Respond to a reply under 35 U.S.C. 132 or to an appeal taken under 35 U.S.C. 134 not later than four months after the date on which the reply was filed or the appeal was taken

37 C.F.R. § 1.703(a)(3) provides that:

> The period of adjustment under § 1.702(a) is the sum of the following periods:
>
> The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply in compliance with §1.113(c) was filed and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first

Relevant Statutes

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).

35 U.S.C. § 154(b)(1)(A)(ii), provides that:

> Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—
>
> respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;
>
> the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

Patentee argues that the Office communication of September 30, 2013[1] "vacated" the second notice of allowance of September 17, 2013, and as such the second notice of allowance of September 17, 2013 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 a notice of allowance within four months after the date a reply in compliance with 37 C.F.R. §1.113(c) was filed. Patentee's arguments have been carefully considered but have not been found to be persuasive.

Pursuant to 35 U.S.C. § 154(b)(1)(A) (ii), Patentee is entitled to day-to-day adjustment if the USPTO fails to respond to a reply under section 132, or to an appeal taken under section 134,

[1] The second page of this petition contains the language "the September 17, 2013 Notice of Allowance was later withdrawn on September 26, 2013..." However, it is noted that although the PTA Calculations show three entries on this date ("Withdrawal of Notice of Allowance," "Date Forwarded to Examiner," and "Miscellaneous Communication to Applicant - No Action Count") the resulting document was mailed on September 30, 2013.

within 4 months after the date on which the reply was filed. The record of the above-identified patent indisputably indicates that the USPTO entered a response to a reply under 35 U.S.C. § 132, specifically a notice of allowance, on September 17, 2013, which is four months and 105 days after the day after the date on which the RCE was filed on February 4, 2013.

In view of *Pfizer v. Lee*, 117 USPQ2d 1781, 811 F.3d 466 (Fed. Cir. 2016), and further review of the record, the Office finds that the second notice of allowance was sufficient to meet the notification requirement under 35 USC 132 to stop the accrual of A delay. In *Pfizer*, the Federal Circuit held that such notification under Section 132 merely requires that an applicant "at least be informed of the broad statutory basis for [the rejection] of his claims, so that he may determine what the issues are on which he can or should produce evidence." *Id.* at 471-472. Similarly, a notification that informs the applicant/patentee of the lack of statutory basis of rejection (i.e., notice of allowance) would be sufficient under 37 CFR 1.703(a)(3) to stop the clock.

The record reflects that Office mailed a notice of allowance on November 2, 2012 and patentee responded on February 4, 2013 by the filing a "RCE" that included an IDS submission. The IDS submission provided notice of Office actions in application 12/708,550. On September 17, 2013 in response to the IDS submission, the examiner again allowed the application and stated that the reference Office actions cited by patentee did not affect the patentability of the claims. Subsequent to the second notice of allowance, on June 5, 2014, the Office withdrew the application from issue and mailed an Office action rejecting the claims under 37 CFR 102(e) over newly cited prior art references, patent number 7,446,199 and US patent publication 2005/0137201.

Under 35 U.S.C. § 154(b)(1)(A) (ii), "A" delay is calculated based on the time that passes between the filing of a reply under 35 U.S.C. § 132 and a response to that reply. The statute does not require the response to be correct. The statute does not require that the response ultimately, stand, either completely unaltered or with only minor tweaks. The statute does not award additional "A" delay if an applicant successfully convinces the PTO that the response was erroneous. And the statue does not provide, either explicitly or implicitly, that a response, once taken, can be rendered a nullity.

What the statute does require is that at least patentee be informed of the broad statutory basis of the rejection or be notified that the application is allowed.

> [I]f issue of an original patent is delayed due to the failure of the Patent and Trademark Office to... *respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken*... the term of the patent shall be extended 1 day for each day after the end of the period specified...
>
> 35 U.S.C. § 154(b)(1)(A)(ii)(emphasis added).

Patentee cannot dispute that a response to a reply under section 132 occurred with the mailing of the second notice of allowance on September 17, 2013. The fact that the Office *sua sponte* withdrew the notice of allowance mailed on September 17, 2013 is not dispositive of whether the Office met the requirement to "stop the clock" under 35 U.S.C. § 154(b)(1)(A)(ii).

"B" Delay

The Patentee and the Office agree that the amount of "B" delay under 35 U.S.C. 154(b)(1)(B) is zero days.

The *Novartis* decision includes "instructions" for calculating the period of "B" delay. Specifically, the decision states,

> The better reading of the language is that the patent term adjustment time [for "B" delay] should be calculated by determining the length of the time between application and patent issuance, then subtracting any continued examination time (and other time identified in (i), (ii), and (iii) of (b)(1)(B)) and determining the extent to which the result exceeds three years.[2]

The length of time between application and issuance is 1269 days, which is the number of days beginning on the filing date of the application (November 21, 2011) and ending on the date the patent issued (May 12, 2015).

The time consumed by continued examination is 226 days.

The number of days beginning on the filing date of application (November 21, 2011) and ending on the date three years after the filing date of the application (November 21, 2014) is 1097 days.

The result of subtracting the time consumed by continued examination (226 days) from the length of time between the application's filing date and issuance (1269 days) is 1043 days, which exceeds three years (1097 days) by negative 54 days; however, the "B" delay cannot be negative as the Office does not accord negative "B" delay, and therefore negative 54 days corresponds to zero days of "B" delay.[3] In other words, considering the time consumed by continued examination, this application was not pending beyond the 3-year period. Therefore, the period of "B" delay is zero days.

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[2] *Novartis* at 601.

[3] 35 U.S.C. § 154(b)(1)(B) provides that if the pendency of an application is more than three years from the actual filing date of the application, the term of the patent issuing from the application shall be extended one day for each day after the end of the three-year period, but that certain time periods are excluded from the three-year period. However, if the sum of the excluded time periods exceed the over-three years period, the "B" delay will not be reduced past zero, as this would result in a reduction to the term of the patent.

Put another way, the Office's calculation of "B" delay reflects that the RCE was filed prior to the three year pendency date of the application. Considering time consumed by continued examination (and appellate review, which in this case is not applicable), this application was not pending for more than three years. As of the filing of the RCE on February 4, 2013, this application which was filed on November 21, 2011 had been pending 441 days (which is the period beginning on the filing date of the application and ending on the day before the RCE was filed). The RCE period is not included in counting the three-year pendency period.

Accordingly, prior to "B" delay accruing for the Office taking in excess of three years to issue the patent, this application had to be pending for an additional 656 (1097 – 441) days after the mailing of the second notice of allowance on September 17, 2013. As this application was only pending for an additional 602 days after the mailing of the second notice of allowance (the period beginning on the day after the mailing of the second notice of allowance – September 18, 2013 - and ending with the issuance of the patent on May 12, 2015), "B" delay is zero days.

"C" Delay

The Patentee and the Office agree that the amount of "C" delay under 37 C.F.R. § 1.703(e) is zero days.

Overlap

The Patentee and the Office agree that the amount of overlap under 35 U.S.C. § 154(b)(2)(A) is zero days.

Reduction under 35 U.S.C. § 154(b)(2)(C)(iii) & 37 CFR 1.704 [Applicant Delay]

The Patentee and Office agree that, under 37 C.F.R. § 1.704, the amount of PTA should be reduced by 149 days. The Office has determined that the Patentee failed to engage in reasonable efforts to conclude processing or examination of its application during the two following periods.

(1) A 62-day period pursuant to 37 C.F.R. § 1.704(b) from July 27, 2012 until September 26, 2012 because the Office mailed a non-final Office action on April 26, 2012. Accordingly, the three-month response date was July 26, 2012. However, the Patentee did not file its amendments to the specification and claims along with remarks until September 26, 2012.

(2) An 87-day period pursuant to 37 C.F.R. § 1.704(b) from September 6, 2014 until December 1, 2014 because the Office mailed a non-final Office action on June 5, 2014. Accordingly, the three-month response date was September 5, 2014. However, the Patentee did not file its amendment to the claims and remarks until December 1, 2014.

Overall PTA Calculation

Formula:

"A" delay + "B" delay + "C" delay - overlap - applicant delay = X.

USPTO's Calculation:

105 + 0 (1269 – 226 – 1097= 0) + 0 – 0 – 149 (62 + 87) = 0

Patentee's Calculation:

366 + 0 (1269 – 226 – 1097= 0) + 0 – 0 – 149 (62 + 87) = 217.

Conclusion

Patentee is entitled to PTA of zero (0) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: 105 + 0 + 0 – 0 – 149 = 0.

In view thereof, no adjustment to the patent term will be made. It follows that a certificate of correction is not required. Telephone inquiries specific to this matter should be directed to Attorney Advisor Paul Shanoski at (571) 272-3225.

/Kery A. Fries/

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