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In re Patent No. 8,114,874 : DECISION ON REQUEST
Zou et al. : FOR RECONSIDERATION OF
Issue Date: February 14, 2012 : DECISION UPON REMAND
Application No. 11/644,849 :
Filing Date: December 22, 2006 :
Attorney Docket No. 432B US :
For: SUSSTITUTED ACETYLENIC :
IMIDAZO[1,2-B]PYRIDAZINE :
COMPOUNDS AS KINASE INHIBITORS :

This is a decision on the "REQUEST FOR RECONSIDERATION OF DECISION ON PATENT TERM ADJUSTMENT-POST-GRANT," filed on June 9, 2016. The request is treated as a request for reconsideration of the decision upon remand mailed April 19, 2016, in which the Office determined that patentee is entitled to zero (0) days of patent term adjustment. Patentee requests that the patent term adjustment be corrected from zero (0) days to thirty-five (35) days, or, in the alternative, to thirty-three (33) days.

The request for reconsideration is granted to the extent that the decision upon remand has been reconsidered; however, the request for reconsideration of patent term adjustment is DENIED with respect to making any change in the patent adjustment determination under 35 U.S.C. 154(b) of 0 days.

RELEVANT PROCEDURAL HISTORY

On February 14, 2012, the Office determined that patentee was entitled to 0 days of PTA.

On April 11, 2012, an application for patent term adjustment was filed, seeking a patent term adjustment of fifty-six (56) days.

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On May 14, 2012, a decision on application for patent term adjustment was mailed, stating that the Office had re-determined the PTA to be zero (0) days.

On August 9, 2012, patentee filed a civil action in the United States District Court for the Eastern District of Virginia, seeking review of the patent term adjustment granted in this patent.

On January 28, 2016, a petition under 37 CFR 1.182 was filed, requesting that the Office comply with the remand order issued by the United States District Court for the Eastern District of Virginia in *Ariad Pharmaceuticals, Inc., v. Lee*, Civ. Action No. 1:12cv-886-TSE-TRJ regarding the patent term adjustment.

On April 19, 2016, a decision upon remand on patent term adjustment was mailed, stating that the patent term adjustment is 0 days.

On June 9, 2016, patentee filed the instant request for reconsideration of decision upon remand on patent term adjustment, seeking an adjustment of the determination to 35 days, or in the alternative, 33 days.

DECISION

Upon review, the Office finds that patentee remains entitled to zero (0) days of PTA.

Patentee and the Office are in agreement regarding the amount of "A" delay under 35 U.S.C. 154(b)(1)(A), the amount of "C" delay under 35 U.S.C. 154(b)(1)(C), the amount of overlap under 35 U.S.C. 154(b)(2)(A), and the amount of PTA reduction due to applicant delay under 35 U.S.C. 154(b)(2)(C)(iii) and 37 CFR 1.704.

Patentee and the Office are in disagreement regarding the amount of "B" delay under 35 U.S.C. 154(b)(1)(B).

"A" Delay

Patentee and the Office agree that there are 203 days of "A" delay.

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"B" Delay

The Office has determined that there are 175 days of "B" delay.

Patentee contends that there are 295 days of "B" delay.

Patentee's calculation of "B" day increasing from 175 days to 295 days is based on their argument that 120 days consumed by the Office's erroneous abandonment is to be excluded from "time consumed by continued examination." Per this argument, "B" delay would 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 35 U.S.C. 154(b)(1)(B)), then subtracting any time the application was held abandoned during the period of continued examination, and determining the extent to which the result exceeds three years.

The Office's calculation of "B" delay is in accordance with the decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). Patentee's calculation is not.

Pursuant to *Novartis*, the amount of "B" delay is 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 35 U.S.C. 154(b)(1)(B)) and determining the extent to which the result exceeds three years. *Novartis*, 740 F.3d at 601.

The length of time between application and issuance is 1,881 days, which is the number of days beginning on the December 22, 2006 filing date and ending on the February 14, 2012 date of patent issuance.

The time consumed by continued examination is 609 days. The time consumed by continued examination includes the following period(s):

- A period of 609 days, beginning on February 12, 2010 (the filing date of the RCE) and ending on October 13, 2011 (the mailing date of the notice of allowance).

The number of days beginning on the filing date (December 22, 2006) and ending on the date three years after the filing date (December 22, 2009) is 1097 days.

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The result of subtracting the time consumed by continued examination (609 days) from the length of time between the filing date and issuance (1881 days) is 1272 days, which exceeds three years (1097 days) by 175 days.

Therefore, the period of "B" delay is 175 days.

Patentee arrives at a period of "B" delay of 295 days by not including as time consumed by continued examination a period of time of 120 days patentee articulates as "time (120 days) ... consumed by absence of examination due to the Office's mistaken abandonment of the application." First, of all, this calculation is inconsistent with the decision in *Novartis*. *Novartis* defined the period of time consumed by continued examination as the period beginning on the filing date of a RCE and ending on the date of mailing of a notice of allowance. Patentee's attention is further directed to *Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee*, 80 FR 1346 (January 9, 2015), which provides:

If a first request for continued examination is filed before a notice of allowance has been mailed and a second request for continued examination is filed after a notice of allowance has been mailed, the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days in the period beginning on the date on which the first request for continued examination was filed and ending on the date of mailing of the notice of allowance following the first request for continued examination, plus the number of days in the period beginning on the date on which the second request for continued examination was filed and ending on the date of mailing of the notice of allowance following the second request for continued examination. If a second request for continued examination is filed without a notice of allowance having been mailed between the filing of the first and second requests for continued examination and a notice of allowance is mailed after the second request for continued examination, the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days in the period beginning on the date on which the first request for continued examination was filed and ending on the date of mailing of the notice of allowance.

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It is acknowledged that a period of abandonment was not expressly at issue in calculating time consumed by continued examination in either *Novartis* or the companion case *Exelixis*. But to that point, neither is a period of abandonment at issue here. What patentee's argument fails to acknowledge is that by virtue of the holding of abandonment being withdrawn, there is no period of abandonment in this application. Thus, even if their argument were persuasive that the "time consumed by continued examination" should not include any period of abandonment, such argument is not relevant to the determination of patent term adjustment in this patent.

Further, based on a determination that the abandonment was improper and thus, should be withdrawn, appropriate Office delay was accorded pursuant to 35 U.S.C. 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(3). That is, the RCE and submission filed February 12, 2010 were treated as a proper and timely reply to the final Office action mailed August 3, 2009. Pursuant to 35 U.S.C. 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(3), Office delay was calculated as 123 days, beginning on June 13, 2010 and ending on October 13, 2010¹. This reflects the time period (beyond the four month period) in which the Office considering the application as abandonment failed to reply to the RCE and submission filed February 12, 2010. (This was reflected in the original determination of patent term adjustment indicated on the patent).

Consistent with there being no period of abandonment in this application, neither in the original determination of patent term adjustment nor in the redetermination was a period of applicant delay entered for a period of abandonment of the application as provided for in 1.704(c)(3)².

¹ 37 CFR 1.703(a)(3) also pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(ii) and specifies that the period is the number of days, if any, beginning on the day after the date that is four months after the date a reply in compliance with 37 CFR 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.

² Pursuant to 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b), the Office's redetermination of patent term adjustment mailed May 14, 2012 added an applicant delay of 101 days for the period, beginning on November 4, 2009 (the day after the date four months after the mailing of the final Office action) and ending on February 12, 2010 (the date the reply in compliance with 37 CFR 1.113(c) was filed).

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"C" Delay

Patentee and the Office agree that there are 0 days of "C" delay.

Overlap

Patentee and the Office agree that the total number of overlapping days of Office delay is 0 days.

The Office finds that "B" delay includes the following period(s):

- (1) A period of 51 days, beginning on December 23, 2009 (the day after the date that is the three year anniversary of the filing date) and ending on February 11, 2010 (the day before the RCE was filed); and
- (2) A period of 124 days, beginning on October 14, 2011 (the day after the notice of allowance was mailed) and ending on February 14, 2012 (the date of patent issuance).

None of the 203 days of "A" delay occur on the same calendar days as the "B" delay.

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

Patentee and the Office agree that, under 37 CFR 1.704, the amount of PTA should be reduced by 463 days.

OVERALL PTA CALCULATION

Formula:

"A" delay + "B" delay + "C" delay - Overlap - Applicant delay = X days of PTA

USPTO's Calculation:

203 (i.e., 80 + 123) + 175 (i.e., 1881 - 609 - 1097) + 0 - 0 - 463 (i.e., 97 + 96 + 101 + 45 + 95 + 29) = 0 days

Patentee's Calculation:

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$203 + 295 + 0 - 0 - 463 = 35$ days

or

$203 + 295 + 0 - 0 - 463 = 35$ days

CONCLUSION

The patent term adjustment (PTA) remains zero (0) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as follows:
 $203 + 175 + 0 - 0 - 463 = 0$ days.

As the patent issued with 0 days of PTA, no further action will be undertaken by the Office with respect to the patent term adjustment.

Telephone inquiries specific to this matter should be directed to Attorney Advisor, Nancy Johnson at (571) 272-3219.

/ROBERT CLARKE/
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