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In re Application of	:	
Chen	:	
Application No. 12/421,310	:	
Filed: April 9, 2009	:	DECISION ON REQUEST
Patent No. 8,981,063	:	FOR RECONSIDERATION OF
Issue Date: March 17, 2015	:	PATENT TERM ADJUSTMENT
Attorney Docket No.: 07039-1449003	:	
Title: B7-H1 ANTIBODIES	:	

This is a response to Patentee's "request for reconsideration of the patent term adjustment" filed pursuant to 37 C.F.R. § 1.705(b) filed on October 26, 2016, requesting that the Office adjust the patent term adjustment from six hundred and four (604) days to seven hundred and twenty-three (723) days.

The Office acknowledges the submission of a three-month extension of time so as to make timely this petition. No additional fees are required.

The request for reconsideration is granted to the extent that the determination 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 six hundred and four (604) days.

This is the Director's decision on the applicant's request for reconsideration under 35 USC 154(b)(3)(B)(ii). Any appeal from this decision is pursuant to 35 U.S.C. § 154(b)(4)(A).

Relevant Procedural History

On March 17, 2015, the Office determined that applicant was entitled to 621 days of PTA.

On September 17, 2015, Patentee filed a request for redetermination of patent term adjustment requesting a PTA of either 685 or 655 days, pursuant to 37 C.F.R. § 1.705(b), along with both the $200 fee set forth in 37 C.F.R. § 1.18(e) and a four-month extension of time so as to make timely the petition.

On May 26, 2016, the Office mailed an "on redetermination of patent term adjustment," indicating the Office has re-determined the patent term adjustment to be 604 days.

Decision

Upon review, the USPTO finds that Patentee is entitled to six hundred and four (604) 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 reduction of PTA under 35 U.S.C. § 154(b)(2)(C)(iii) and 37 C.F.R. § 1.704.

The sole item in dispute is the amount of "B" delay under 35 U.S.C. § 154(b)(1)(B).

"A" Delay

The Patentee and Office agree the amount of "A" delay under 35 § U.S.C. § 154(b)(1)(A) is 898 days. The period of "A" delay is 898 days under 37 C.F.R. § 1.703(a)(3) beginning on January 15, 2012 (the day after the date that is four months after the date the RCE was filed) and ending on June 30, 2014 with the mailing of the non-final Office action.

"B" Delay

The Office finds there are zero days of "B" delay.

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.

The length of time between application and issuance is 2169 days, which is the number of days beginning on the filing date of the application (April 9, 2009) and ending on the date the patent issued (March 17, 2015).

The time consumed by continued examination under 1.703(b)(1) is 1147 days beginning on the date of the filing of the RCE on September 14, 2011 and ending on November 3, 2014 the date of the mailing of the notice of allowance. There is no additional reduction under 1.703(b)(2) for interference or derivation proceeding because the period of interference which begins on February 9, 2012 (date of declaration of interference) and ending on termination of interference proceeding (April 23, 2014) completely overlaps with the period of continued examination.

The number of days beginning on the filing date of application (April 9, 2009) and ending on the date three years after the filing date of the application (April 9, 2012) is 1097 days.

The result of subtracting the time consumed by continued examination (1147 days) from the length of time between the application's commencement date and issuance (2169 days) is 1022 days, which exceeds three years (1097 days) by 0 days. Therefore, the period of "B" delay is **0 days**.

In Novartis, the Federal Circuit found the language of "examination" used in § 154(b)(1)(B) to presumptively end at allowance, when prosecution is closed and there is no further examination on the merits in the absence of a special reopening. *See Novartis AG v. Lee* 740 F. 3d 593(Fed Cir. 2014). Accordingly, Novartis provides guidance that continued examination period begins on filing of the request for continued examination and only ends on the mailing of a notice of allowance; accordingly if an interference was filed within such time period, the interference proceeding would not end examination. Unlike a Notice of Allowance, an interference proceeding would merit further examination after ending the interference proceeding.

Assuming arguendo that the continued examination would pause during the interference proceeding, there would be three separate periods that include pre-interference RCE period, the interference period, and the post-interference RCE period. However the post-interference RCE period is considered examination time, since after the termination of the interference proceeding, the Examiner performs an updated search and reviews the relevant art so as to make a determination regarding patentability. *See* MPEP 2308.01. As such, the Office finds that each of the three periods: (1) pre-interference RCE period, (2) the interference period, and (3) the post-interference RCE period until Notice of Allowance, is excluded from B-Delay time under the regulations and plain language of 35 U.S.C. §§ 154(b)(1)(B)(I)&(ii). Under this analysis, the amount of "B" delay would remain zero.

The time consumed by continued examination includes the following two periods:

- A first period of 148 days, beginning on the filing date of the RCE (September 14, 2011) and ending on the day before a declaration of interference was issued on February 9, 2012 (February 8, 2012), and;

- A second period of 194 days, beginning on the day after the termination of the interference proceeding on April 23, 2014 (April 24, 2014) and ending on the mailing date of the notice of allowance (November 3, 2014).

The time consumed by interference would be 805 five days and constitutes the period beginning on the date an interference was declared (February 9, 2012) and ending on the date that the interference proceeding was terminated with respect to the application (April 23, 2014).

Accordingly, the B" Delay = 2169 - (148 + 194) - 805 -1097 = 0.

Patentee calculates the period of "B" delay to total 120 days and arrives at this number by taking the 1072 day period beginning on the day after the date that is three years after the filing date of the application (April 10, 2012) and ending with the issuance of the patent (March 17, 2015), and subtracting both the first RCE period (which totals 148 days) and the alleged 804 day period this application was under an interference proceeding. Patentee's calculations do not recognize the post-interference RCE period, since Patentee argues that terminating the RCE period on the day before the declaration of interference is consistent with considerations present within *Changes to the Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee*, however as set forth on page 1348 thereof,

> Section 1.703(b)(1) is amended to provide that the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days, if any, in the period beginning on the date on which any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151.

Patentee disputes the post-interference RCE period (194 days), and argues there should be no second RCE period, since "the continued examination that was requested by the applicant on September 14, 2011, ended when the interference was declared by the Board – and that 148 days should be the sole exclusion under 35 U.S.C. § 154(b)(1)(B)(i)."[1] In other words, the declaration of interference terminated the RCE period, which did not resume on the day after the termination of the interference proceeding on April 23, 2014 (April 24, 2014) and run until the mailing date of the notice of allowance (November 3, 2014).

Patentee argues that despite the fact that prior to the declaration of interference no indication was made by the Examiner that all claims were allowable, that prosecution was closed and all claims were allowable. Patentee adds that since it was the Examiner who reopened prosecution after the termination of the interference proceeding (which appears to be a reference to a non-final Office action mailed on June 30, 2014), the period subsequent to the termination of the interference proceeding does not constitute continued examination.

Patentee further argues that "[b]efore an interference may be declared, examination of the application must be completed, and cites to 37 C.F.R. § 41.02(a). This appears to be a typographical error, as Rule 41.02(a) does not exist. Patentee appears to be referring to 37 C.F.R. § 41.102(a), which states, *in toto:*

> Before a contested case is initiated, except as the Board may otherwise authorize, for each involved application and patent:
>
> (a) Examination or reexamination must be completed, and
>
> (b) There must be at least one claim that:
>
> > (1) Is patentable but for a judgment in the contested case, and

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[1] Petition submitted on October 26, 2016, page 2.

(2) Would be involved in the contested case.

As noted in MPEP 2308.01, an interference judgment simply resolves any question of priority between the two parties to the interference. The judgment does not prevent the examiner from making a rejection in further examination in the same application or a different application. If a party loses on an issue in the interference, the examiner should reject any claim for which allowance would be inconsistent with the interference judgment. Accordingly, after conclusion of interference proceeding, the examiner still must determine whether to make additional rejections which would be continued examination.

"C" Delay

The Patentee and Office agree the amount of "C" delay under 35 U.S.C. § 154(b)(1)(C) is 805 days.

As set forth above, an interference proceeding was instituted to involve the application in the interference under 35 U.S.C. 135(a) on September 14, 2011 with the filing of a suggestion of an interference. On February 9, 2012, a declaration of interference was issued by the Patent Trial and Appeal Board. The Patent Trial and Appeal Board issued a judgement on February 19, 2014, and the period for seeking judicial review expired 63 days later on April 23, 2014, per 37 C.F.R. § 90.3.

The period beginning on February 9, 2012 and ending on April 23, 2014 totals 805 days.

Overlap

The Patentee and Office agree the amount of overlap under 35 U.S.C. § 154(b)(2)(A) is 805 days.

Since there is no "B" delay, there is no overlap between "A" delay and "B" delay.

As set forth above, the Office finds the period of "C" delay is the period beginning on February 9, 2012 and ending on April 23, 2014, and totals 805 days.

The Office finds that this entire 805-day period beginning on February 9, 2012 and ending on April 23, 2014 overlaps with the 898-day period of "A" delay under 37 C.F.R. § 1.703(a)(3) beginning on January 15, 2012 (the day after the date that is four months after the date the RCE was filed) and ending on June 30, 2014 with the mailing of the non-final Office action. As such, the overlap totals 805 days.

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

The Patentee and Office agree the amount of reduction under 35 U.S.C. § 154(b)(2)(C)(iii) & 37 CFR 1.704 is 294 days. The Office has determined that the Patentee failed to engage in

reasonable efforts to conclude processing or examination of its application during the following periods.

(1) A 46-day period pursuant to 37 C.F.R. § 1.704(c)(7) from July 18, 2009 until September 1, 2009 because the Office mailed a notice to file missing parts on May 1, 2009 requiring, *inter alia*, replacement drawings, a first response was received on July 17, 2009 that did not include replacement drawings, a notice of incomplete reply was mailed on July 29, 2009 repeating the requirement for replacement drawings, replacement drawings of a quality low enough to prevent their entry were received on August 3, 2009, a notice of incomplete reply was mailed on August 11, 2009 indicating that electronically reproducible replacement drawings were required, and electronically reproducible replacement drawings were received on September 1, 2009.

The Office entered a 29-day reduction pursuant to 37 C.F.R. § 1.704(b), and the Office agrees[2] that a 46-day reduction is warranted pursuant to 37 C.F.R. § 1.704(c)(7). As set forth in the redetermination mailed on May 26, 2016, the 29-day reduction has been removed and a 46-day reduction has been entered.

(2) A 29-day reduction pursuant to 37 C.F.R. § 1.704(c)(8) from February 12, 2010 until March 12, 2010 because the Patentee filed an IDS document on March 12, 2010 after Patentee had filed a reply on February 11, 2010. *See Gilead Sciences Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015). The Patentee did not submit a statement under 37 C.F.R. § 1.704(d) along with the IDS document. Consequently, a reduction of 29 days was entered.

(3) A 90-day period pursuant to 37 C.F.R. § 1.704(b) from January 15, 2011 until April 14, 2011 because the Office mailed a final Office action on October 14, 2010. Accordingly, the three-month response date was January 14, 2011. However, the Patentee did not file its notice of appeal until April 14, 2011.

(4) A 105-day reduction pursuant to 37 C.F.R. § 1.704(c)(8) from September 15, 2011 until December 28, 2011 because the Patentee filed IDS documents on October 7, 2011 and December 28, 2011 after Patentee had filed a reply on September 14, 2011.[3] *See Gilead Sciences Inc. v. Lee*. The Patentee did not submit a statement under 37 C.F.R. § 1.704(d) along with either of these IDS documents. Consequently, a reduction of 105 days was entered.

(5) A 24-day period pursuant to 37 C.F.R. § 1.704(b) from October 1, 2014 until October 24, 2014 because the Office mailed a non-final Office action on June 30, 2014. Accordingly, the three-month response date was September 30, 2014. However, the Patentee did not file its remarks until October 24, 2014.

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[2] *See* petition, pages seven through eight.

[3] It is noted these periods of reduction consist of 23 days and 105 days, respectively. However, since the 23-day period falls within the 105-day period, a single reduction of 105 days is warranted.

Overall PTA Calculation

Formula:

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

USPTO's Calculation:

898 + zero (2169 – 1147) + 805 – 805 – 294 (46 + 29 + 90 + 105 + 24) = 604.

Patentee's Calculation:

898 + 120 (2169 – 148 – 805) + 805 – 805 – 294 (46 + 29 + 90 + 105 + 24) = 724.

Conclusion

Patentee is entitled to PTA of six hundred and four (604) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: 898 + 0 + 805 – 805 – 294 = 604 days.

The Certificates of Correction Branch will be made aware of this decision, and the Office will *sua sponte* issue a certificate of correction in the amount of six hundred and four (604) days.

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

/ROBERT CLARKE/
Robert A. Clarke
Patent Attorney
Office of the Deputy Commissioner
for Patent Examination Policy

Encl. Adjusted PTA calculation
Certificate of Correction

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT : 8,981,063 B2
DATED : Mar. 17, 2015
INVENTOR(S) : Chen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by 621 days.

Delete the phrase “by 621 days” and insert -- by 604 days--