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In re Application of :  
Chen :  
Application No. 12/347,492 :  
Filed: December 31, 2008 : DECISION ON REQUEST  
Patent No. 9,062,112 : FOR RECONSIDERATION OF  
Issue Date: June 23, 2015 : PATENT TERM ADJUSTMENT  
Attorney Docket No.: 07039-1449002 :  
Title: B7-H1, A NOVEL :  
IMMUNOREGULATORY MOLECULE :

This is a response to Patentee's "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT" filed pursuant to 37 C.F.R. § 1.705(b) filed on September 11, 2017, requesting that the Office adjust the patent term adjustment from five hundred and twenty-six (526) days to eight hundred and twenty-six (826) days.

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 five hundred and twenty-six (526) 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 June 23, 2015, the Office determined that applicant was entitled to 557 days of PTA.

On September 17, 2015, Patentee filed a request for redetermination of patent term adjustment requesting a PTA of 750 days, pursuant to 37 C.F.R. § 1.705(b), along with the \$200 fee set forth in 37 C.F.R. § 1.18(e).

On October 7, 2016, the Office mailed an "on redetermination of patent term adjustment," indicating the Office has re-determined the patent term adjustment to be 626 days.

On December 7, 2016, Patentee filed a request for redetermination of patent term adjustment requesting a PTA of 826 days.

Art Unit: OPET

On July 19, 2017, the Office mailed an "on redetermination of patent term adjustment," indicating the Office has re-determined the patent term adjustment to be 526 days.

### **Decision**

Upon review, the USPTO finds that Patentee is entitled to five hundred and twenty-six (526) 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 770 days. The period of "A" delay is 770 days under 37 C.F.R. § 1.703(a)(2) beginning on May 31, 2012 (the day after the date that is four months after the date a reply was filed) and ending on July 9, 2014 (the date of mailing of the non-final Office action).

#### **"B" Delay**

The Office finds there are 47 days of "B" delay.

The Novartis<sup>1</sup> 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 2366 days, which is the number of days beginning on the filing date of the application (December 31, 2008) and ending on the date the patent issued (June 23, 2015).

On October 14, 2011, a request for continued examination (RCE) was filed. On April 4, 2012, an interference involving this application was declared. On April 5, 2012, a further interference involving this application was declared. On June 14, 2012, a further interference involving this

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<sup>1</sup> *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

Art Unit: OPET

application was declared. On April 30, 2013, an interference involving this application was redeclared. 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 time consumed by continued examination under 1.703(b)(1) is 1223 days beginning on the date of the filing of the RCE on October 14, 2011 and ending on February 17, 2015 (the date of the mailing of the notice of allowance). There is no additional reduction under 37 C.F.R. § 1.703(b)(2) for interference or derivation proceeding because the period of interference which begins on April 4, 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 (December 31, 2008) and ending on the date three years after the filing date of the application (December 31, 2011) is 1096 days.

The result of subtracting the time consumed by continued examination (1223 days) from the length of time between the application's filing date and issuance (2366 days) is 1143 days, which exceeds three years (1096 days) by 47 days. Therefore, the period of "B" delay is **47 days**.

The decision mailed on July 19, 2017 set forth on pages 3-5:

In *Novartis*, the Federal Circuit found the language of "examination" used in 35 U.S.C. § 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. 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 47 days.

The time consumed by continued examination is 473 days. The time consumed by continued examination includes the following two periods:

- A first period of 173 days, beginning on the filing date of the RCE (October 14, 2011) and ending on the day before a declaration of interference was issued on April 3, 2012, and;

Art Unit: OPET

- A second period of 300 days, beginning on the day after the termination of the interference proceeding on April 24, 2014 and ending on the mailing date of the notice of allowance on February 17, 2015.

The time consumed by the interference proceeding is 750 days, and constitutes the period beginning on the date an interference was declared (April 4, 2012) and ending on the date that the interference proceeding was terminated with respect to the application (April 23, 2014).

Accordingly, the B delay =  $2366 - (173 + 300) - 750 - 1096 = 47$ .

Patentee calculates the period of "B" delay to total 347 days and arrives at this number by taking the 1270-day period beginning on the day after the date that is three years after the filing date of the application (January 1, 2012) and ending with the issuance of the patent (June 23, 2015), and subtracting both the first RCE period (which totals 173 days) and the alleged 750 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 (300 days), and argues there should be no second RCE period, since

the continued examination of the application that had been requested by the applicant via the request for continued examination filed on October 14, 2011, was necessarily completed when the interference was declared on April 4, 2012. As such, the declaration of interference marked the end of the continued examination of the application requested by the applicant under section 132(b) and the end of the B Delay exclusion under 35 U.S.C. § 154(b)(1)(B)(i).

Petition submitted on December 7, 2016, page 3.

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 (February 17, 2015).

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 July 9, 2014), the period subsequent to the termination of the interference proceeding does not constitute continued examination.

Patentee further argues on page 3 of the petition submitted on December 7, 2016 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*:

Art Unit: OPET

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
  - (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.

With the petition filed on September 11, 2017, Patentee again argues the post-interference RCE period should not be deducted from the B-delay, on the following basis:

An examiner cannot pass an application on for an interference unless and until he/she has completed examination and finds no further basis to reject the claims. In such situations, just as for a notice of allowance, the declaration of an interference marks the end of applicant-requested continued examination.

Petition of September 11, 2017, page 3.

Patentee's argument has been given careful consideration and has been deemed to be unpersuasive. An interference does not necessarily mean that prosecution is closed: the interference might just refer to certain claims. This is what distinguishes interference practice from notice of allowance practice discussed in *Novartis*, and what differentiates interference status from notice of allowance status.

It is noted with interest MPEP § 2303 sets forth, *in pertinent part*:

37 CFR 41.102 Completion of examination.

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
  - (2) Would be involved in the contested case.

Art Unit: OPET

An interference should (emphasis added) rarely be suggested until examination is completed on all other issues. Each pending claim must be allowed, finally rejected, or canceled. Any appeal from a final rejection must be completed, including any judicial review. Any petition must be decided.

#### Example 1

An applicant has one allowed claim directed to invention A, which is the same invention of another inventor within the meaning of 35 U.S.C. 102(g)(1), and has rejected claims directed to different invention B. If the rejection is contested, the application is not yet ready for an interference. Restriction of the application to invention A, followed by cancellation of the claims directed to invention B would remove this impediment to declaring an interference.

#### Example 2

A patent has a claim to a species. An applicant has claims to the species and to a genus that includes the species. The examiner has allowed the species claim, but rejected the genus claim. The applicant suggests an interference with the patent. The interference will generally not be declared until the applicant resolves the status of the genus claim by, for example, appealing the rejection or canceling the rejected claim. An applicant may expedite the process of having the interference declared by canceling the genus claim from the application.

#### **“C” Delay**

The Patentee and Office agree the amount of “C” delay under 35 U.S.C. § 154(b)(1)(C) is 750 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 April 4, 2012 with the filing of a suggestion of an interference. 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 April 4, 2012 and ending on April 23, 2014 totals 750 days.

#### **Overlap**

The Patentee and Office agree the amount of overlap under 35 U.S.C. § 154(b)(2)(A) is 693 days.

As set forth above, the Office finds the period of "C" delay is the period beginning on April 4, 2012 and ending on April 23, 2014, and totals 750 days.

Art Unit: OPET

The Office finds that the 693-day period beginning on May 31, 2012 and ending on April 23, 2014 overlaps with 693 of 770-day period of "A" delay under 37 C.F.R. § 1.703 (a)(3) beginning on May 31, 2012 (the day after the date that is four months after the date the reply was filed) and ending on July 9, 2014 with the mailing of the non-final Office action. As such, the overlap totals 693 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 348 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 112-day period pursuant to 37 C.F.R. § 1.704(c)(7) from March 28, 2009 until July 17, 2009 because the Office mailed a notice to file missing parts on January 27, 2009 requiring, *inter alia*, a properly signed oath or declaration and the surcharge associated with the late submission of the same, a first response was received on March 27, 2009 that did not include a properly signed oath or declaration and the surcharge associated with the late submission of the same, a notice of incomplete reply was mailed on April 20, 2009 repeating the requirement for a properly signed oath or declaration and the surcharge associated with the late submission of the same, and a properly signed oath or declaration and the surcharge associated with the late submission of the same were received on July 17, 2009.
- (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 22-day period pursuant to 37 C.F.R. § 1.704(b) from August 6, 2010 until August 27, 2010 because the Office mailed a non-final Office action on May 5, 2010. Accordingly, the three-month response date was August 5, 2010. However, the Patentee did not file its amendment to the claims and remarks until August 27, 2010.
- (4) 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.
- (5) A 91-day period pursuant to 37 C.F.R. § 1.704(b) from October 10, 2014 until January 8, 2015 because the Office mailed a non-final Office action on July 9, 2014. Accordingly,

Art Unit: OPET

the three-month response date was October 9, 2014, 2010. However, the Patentee did not file its amendment to the claims and remarks until January 8, 2015.

- (6) A 4-day reduction pursuant to 37 C.F.R. § 1.704(c)(10) from May 18, 2015 until May 21, 2015 because the Patentee filed drawings on May 18, 2015 after the mailing of a notice of allowance on February 17, 2015 and the Office mailed a "Response to Rule 312 Communication" on May 21, 2015.

**Overall PTA Calculation**

Formula:

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

USPTO's Calculation:

$$770 + 47 (2366 - 473 - 750 - 1096) + 750 - 693 - 348 (112 + 29 + 22 + 90 + 91 + 4) = 526$$

Patentee's Calculation:

$$770 + 347 (1270 - 173 - 750) + 750 - 693 - 348 (112 + 29 + 22 + 90 + 91 + 4) = 826$$

**Conclusion**

Patentee is entitled to PTA of five hundred and twenty-six (526) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following:  $770 + 47 + 750 - 693 - 348 = 526$  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 five hundred and twenty-six (526) 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

Art Unit: OPET

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UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT : 9,062,112 B2  
DATED : Jun. 23, 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 626 days.

Delete the phrase "by 626 days" and insert – by 526 days--