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12/532,406	02/02/2010	Thomas Schultz SR.	057977-140252 (8607USO1)	7460
89399	7590	10/23/2014	EXAMINER	
Michael Best & Friedrich LLP (AbbVie Deutschland) Two Prudential Plaza 180 N. Stetson Avenue Chicago, IL 60601			JACKSON, SHAWQUIA	
			ART UNIT	PAPER NUMBER
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			10/23/2014	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Commissioner for Patents  
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In re Patent No. 8,507,469  
Issue Date: October 4, 2013  
Application No. 12/532,406  
Filed: February 2, 2010  
Attorney Docket No. 8607USO1

REDETERMINATION  
OF PATENT TERM ADJUSTMENT  
AND  
NOTICE OF INTENT TO ISSUE  
CERTIFICATE OF CORRECTION

This is a response to applicants "LETTER REGARDING CREDIT DAYS AND DEBIT DAYS IN THE CALCULATION OF THE PATENT TERM ADJUSTMENT PERIOD AND REQUEST FOR ADJUSTMENT OF PATENT TERM EXTENSION" filed October 4, 2013 requesting that the Office adjust the PTA from 274 days to 345 days. The Office has re-determined the PTA to be 345 days.

This redetermination of patent term adjustment is not the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4) that triggers a 180-day period for applicant disagreeing with the Office redetermination to commence a civil action in the District Court for the Eastern District of Virginia.

The Office acknowledges submission of the fee set forth in 37 CFR 1.18(e). No additional fees are required. The fee set forth in 37 CFR 1.18(e) is a requirement and will not be refunded.

### **Relevant Procedural History**

On August 13, 2013, this patent issued with a patent term adjustment determination of 274 days. On October 4, 2013, patentee timely filed a "LETTER REGARDING CREDIT DAYS AND DEBIT DAYS IN THE CALCULATION OF THE PATENT TERM ADJUSTMENT PERIOD AND REQUEST FOR ADJUSTMENT OF PATENT TERM EXTENSION" seeking an adjustment of the determination to 345 days.

Patentee argues "Assuming all the above is correct, by adding a total of 70 credit days to the 343 credit days calculated by the PTO (as explained above), as well as removing 1 debit day from the 69 debit days calculated by the PTO (as explained above) to the overall calculation, Applicant submits that the PTA for the instant application is 345 days (413 total credit days, minus 68 total debit days, total to 345 overall days). This change in credit days, debit days, and overall PTA days, is accounted due to the PTO-14 month rule and the ArQule ruling."

Upon review, the USPTO finds that patentee is entitled to 345 days of PTA. The Office agrees the Office's prior calculation of A-1 Delay is incorrect. As will be discussed, the correct period of A-1 delay is 413. The Office has also revisited the amount of "B" delay

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under 35 U.S.C. § 154(b)(1)(B) and the amount of overlapping days under 35 U.S.C. § 154(b)(2)(A) pursuant to the Federal Circuit's decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

### **Background**

The instant application is the national stage of International Application No. PCT/EP2008/053389, filed March 20, 2008.

National stage papers were filed in this case on September 21, 2009.

The Office issued a Notice of Acceptance on February 23, 2010, which states the "Date of Completion of All 35 U.S.C. 371 Requirements" ("Date of Completion") is February 2, 2010.

The Office issued a Notice of Allowance and an Initial PTA Determination on March 28, 2013. The Initial PTA Determination informs Applicants of a patent term adjustment to date of 287 days, which is the number of days beginning on the day after the date fourteen months after the Date of Completion (February 2, 2010), and ending February 1, 2011, the date the Office issued the Office Action minus the Applicant Delay days.

Applicants filed the instant petition on October 4, 2013. The petition asserts the Office used an incorrect Date of Completion when calculating the period of A-1 Delay. The petition asserts the correct period of A-1 Delay is 70 days, which is the number of days beginning on the day after the date fourteen months after the *alleged* Date of Completion (September 23, 2009), and ending February 1, 2011 the date the Office issued the Office Action.

### **Discussion**

On January 14, 2003, President Obama signed into law H.R. 6621, which makes technical corrections to the Leahy-Smith America Inventors Act and title 35 of the United States Code.

H.R. 6621 amends section 154 of title 35 of the United States Code by explicitly requiring that calculation of "A" delay be based upon the date of national phase commencement rather than "the date on which an international application fulfilled the requirements of section 371," as set forth in 35 USC § 154 prior to the signing of H.R. 6621....

The Office recently amended several regulations in order to implement changes made by the AIA Technical Corrections Act (H.R. 6621). See Revisions to Patent Term Adjustment (Interim Final Rule), 78 Fed. Reg. 19416 (April 1, 2013).

The Office amended 37 C.F.R. § 1.703(a) to read as follows, with emphasis added:

The period of adjustment under § 1.702(a) is the sum of the following periods:

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- (1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application 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[.]<sup>1</sup>

The changes made to 37 C.F.R. § 1.703(a) apply to all patents issued on or after January 14, 2013, and the instant patent issued on a date after January 14, 2013. Therefore, the changes made to 37 C.F.R. § 1.703(a) apply to this case.

In view of the prior discussion, the Office agrees the period of A-1 delay should be based on the date the national stage commenced (“Commencement Date”) instead of the Date of Completion or the filing date.

As the application papers do not include a request for early processing, the national stage commenced upon the expiration of 30 months from the priority date of the international application. The date 30 months after March 23, 2007, which is the priority date of the international application is September 23, 2009, and in other words, the commencement date is September 23, 2009 and the delay pursuant to 37 C.F.R. § 1.703(a) is 70 days.

For the same reasons outlined above, the B delay is calculated three years from the anniversary of the commencement date, September 23, 2009 to August 13, 2013, the date the application issued.

Upon review, the USPTO finds that patentee is entitled to 345 days of PTA. The Office has revisited the amount of “B” delay under 35 U.S.C. § 154(b)(1)(B) and the amount of overlapping days under 35 U.S.C. § 154(b)(2)(A) pursuant to the Federal Circuit’s decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

The Office notes that the interpretation of the “B” delay was based upon rule 37 CFR 1.703(b)(1) which excluded from the amount of “B” delay the period beginning on the date of filing of the continued examination and ending on the date of the issuance of the patent. However, subsequent to the filing of this lawsuit and remand to the Office, the Federal Circuit reviewed the statutory interpretation of 35 U.S.C. § 154(b)(1)(B)(i) and issued a decision regarding the effects of a Request for Continued Examination (“RCE”) on “B” delay in the *Novartis* appeal. In *Novartis*, the Federal Circuit agreed with the Office that “no [“B” delay] adjustment time is available for any time in continued

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<sup>1</sup> See Revisions to Patent Term Adjustment (Interim Final Rule), 78 Fed. Reg. 19416, 19420 (April 1, 2013).

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examination, even if the continued examination was initiated more than three calendar years after the application's filing." *Novartis*, 740 F.3d at 601. However, the *Novartis* court found that if the Office issues a notice of allowance after an RCE is filed, the period after the notice of allowance should not be excluded from the "B" delay period but should be counted as "B" delay. *Id.* at 602. The Federal Circuit issued its mandate in the *Novartis* appeal on March 10, 2014.

Pursuant to the *Novartis* decision, the USPTO has determined that the patentee is entitled to 0 days of "B" delay. In this case, the national stage commenced ("Commencement Date") on September 23, 2009<sup>2</sup>, and the patent issued on August 13, 2013; thus, the application was pending for 1421 days. During this time, the applicant filed an RCE on December 19, 2011. Under 35 U.S.C. § 154(b)(1)(B)(i), the time period consumed by continued examination ("RCE period") was from December 19, 2011 until the notice of allowance was issued on March 28, 2013 – i.e., 466 days. Subtracting the sum of the RCE periods from the total number of days the application was pending results in  $1421 - 466 = 955$  days. Thus, for purposes of "B" delay, the application was pending for  $955 - 1097$  [i.e., 3 years from the actual filing date] = 0 days beyond the 3-year anniversary of the commencement date.

The Office has also determined that no periods of overlap exist.

### **APPLICANT DELAY**

Applicants dispute the reduction of 69 days applicant delay. "Applicant filed a response on May 25, 2011 to a Non-Final Office Action dated February 1, 2011. A period of adjustment shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed (35 U.S.C. §154(b)(2)(C)(ii); 37 C.F.R. §1.704(b)). Applicant has analyzed this rule in accordance with *ArQule vs. Kappos*, 793 F.Supp. 2d 214 (D.D.C. 2011). Per *ArQule*, since the 3-month period (February 1, 2011 to May 1, 2011) ended on a Sunday (i.e., May 1, 2011), the effective 3-month deadline is May 2, 2011 because May 1, 2011 was a Sunday (See 35 USC 21(b)). Again, Applicant filed a response on May 25, 2011. Measuring from the effective 3-month deadline of May 2, 2011 to the response filing date of May 25, 2011 total to 23 debit days. Applicant thereby requests that the 1 debit days employed by the PTO to the response filed on May 25, 2011 is in error and petitions for removal of this 1 debit day."

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<sup>2</sup> The international application did not include an express request for early commencement pursuant to 35 U.S.C. 371(f), thus the commencement date is 30 months after the priority date. The date 30 months after March 23, 2007, the priority date is September 23, 2009, and in other words, the commencement date is September 23, 2009.

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In *Arqule v. Kappos*, \_\_ F.Supp.2d \_\_ (D.D.C. 2011), the District Court of the District of Columbia ruled that the 35 U.S.C. § 21 (b) "weekend add holiday" exception applies to "any action" including the § 154(b)(2)(C). Accordingly, because May 1, 2011 was a Sunday, the time period to calculate Applicant delay commenced on May 2, 2011 rather than May 1, 2011. Therefore, a delay of 24 days was accrued, corresponding to the time period between May 1, 2011 (three months after the mailing date of the Office Action, in accordance with 37 CFR §1.704(b)) and May 25, 2011. Applicants respectfully request the Office to remove the 24 days of Applicant delay, replace with 23 days of Applicant delay and correct the total Applicant delay.

The reduction is being reconsidered and, based upon the decision in the *Arqule* case, it is determined that entry of a reduction for this reply timely filed pursuant to 35 U.S.C. §21(b) is not warranted. Accordingly, the period of reduction of 24 days is being removed. Thus, instead of a 24 day reduction for applicant delay pursuant to 37 C.F.R. §1.704(b), 23 days should have been accorded for applicant delay for response filed May 25, 2011. The total Applicant Delay therefore is 68 days, not 69 days.

### Overall PTA Calculation

#### Formula:

"A" delay + "B" delay + "C" delay - Overlap - applicant delay = X

USPTO's Calculation:

$$413 + 0 + 0 - 0 - 68 = 345$$

Patentee's Calculation

$$413 + 0 + 0 - 0 - 68 = 345$$

### Conclusion

Patentee is entitled to PTA of three hundred forty-five (345) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following:  $413 + 0 + 0 - 0 - 68 = 345$  days.

Patentee has **two (2) months** from the date of the Office's redetermination of patent term adjustment to request reconsideration of the patent term adjustment if patentee continues to disagree with this determination (no petition fee). This two month period is extendible under 37 CFR 1.136(a). The new/renewed request for reconsideration may be filed without any additional fee. However, patentee who responds more than two months after the mail date of the redetermination is required to pay the extension of time fee. After the period of time to respond has expired, the Office will *sua sponte* issue a certificate of correction adjusting the PTA to three hundred forty-five (345) days.

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Telephone inquiries specific to this decision should be directed to the undersigned Attorney at (571) 272-3212.

/Patricia Faison-Ball/

Patricia Faison-Ball  
ATTORNEY ADVISOR  
Office of Petitions

Enclosures: Copy of DRAFT Certificate of Correction  
Adjusted PTA calculation

Office of Petitions: Decision Count Sheet

Mailing Month

Application No.

12532406



For US serial numbers: enter number only, no slashes or commas. Ex: 10123456

For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official:

FAISON-BALL, PATRICIA

Count (1) - Palm Credit

12/532,406

Decision: DISMISSED

FINANCE WORK NEEDED

Select Check Box for YES



Decision Type: 551 - 37 CFR 1.705(d) - PATENT TERM ADJUSTMENT AF



Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED

Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED

Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

If more than 3 decisions, attach 2nd count sheet & mark this box

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