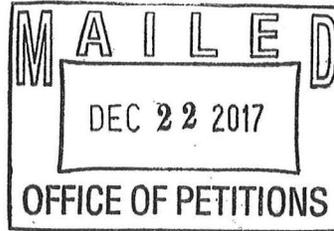




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In re Patent No. 8,526,738 :  
Issued: December 27, 2016 : DECISION ON  
Application No. 13/256,928 : PATENT TERM ADJUSTMENT  
Filing or 371(c) Date: October 4, 2011 :  
Dkt. No.: 9729-9X :

This decision is a response to patentee's "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705" filed February 27, 2017, requesting that the Office correct the patent term adjustment (PTA) from 379 days to 693 days.

This decision 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 December 27, 2016, the Office determined that patentees were entitled to 379 days of PTA.

On February 27, 2017, patentees timely filed the instant request for redetermination of PTA under 37 CFR 1.705(b), seeking an adjustment of the determination to 693 days.

**DECISION**

Upon review, the Office finds that patentees remain entitled to 379 days of PTA.

Patentees and the Office are in agreement regarding 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.

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

**"A Delay"**

The "A" delays include the following:

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(1) 5 days under 37 CFR 1.702(a)(2) beginning on November 16, 2013 (day after the date that is four months from patentee's response to non-final rejection) and ending on November 20, 2013 (date of mailing the non-final rejection);

(2) 5 days under 37 CFR 1.702(a)(2) beginning on July 18, 2015 (day after the date that is four months from the patentee's response to the non-final rejection) and ending on July 22, 2015 (date of mailing of the non-final rejection).

Patentees, however, assert that the patent is entitled to an additional "A" delay is 155 days pursuant to 37 CFR 1.703(a)(1). Patentees' assert that the Office used the incorrect commencement date. Patentees argue that the national stage commenced on September 15, 2011 and a non-final Office action was mailed on April 19, 2013.

The Office properly calculated the 37 CFR 1.702(a) (1) delay as zero days based on a national stage commencement date of February 21, 2012.

With respect to the "A" delay, patentees' calculations are based on an incorrect commencement date. Section 1(h)(1) of the AIA Technical Corrections Act revised the patent law to provide that the fourteen-month patent term adjustment period is measured from the date of commencement of the national stage under 35 U.S.C. 371 in an international application.

However, this change does not affect the Office's interpretation of the "actual filing date" of an international application. Since the patent term adjustment provisions of 35 U.S.C. 154(b) were implemented in September 2000, the Office has interpreted the phrase "actual filing date of application in the United States" in 35 U.S.C. 154(b)(1)(B) as the date of commencement of the national stage under 35 U.S.C. 371 in an international application. See, Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56382-84 (Sept. 18, 2000) (explaining why the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) must mean the date the national stage commenced under 35 U.S.C.371(b) or (f) in the case of an international application).

While papers were received in this application on September 15, 2011, the commencement date of this application is actually February 21, 2012. Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1) (a). See, 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Hence, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(f) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with, the applicable requirements under 35 U.S.C. 371(c).

Herein, an express request for early processing was not made. The patentee did not check box 3 in the Transmittal Letter filed September 15, 2011 to expressly request to begin national stage examination nor did patentee provide any other clear and unambiguous statement elsewhere in the

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filing to signal an express request for early examination. Accordingly, the 30-month period expired February 21, 2012, thirty months after the priority date of the international application (August 21, 2009). Accordingly, when the Office mailed the non-final rejection on April 19, 2013, the Office did not delay in meeting the requirement of 37 CFR 1.702(a)(1).

Accordingly, the correct amount of "A" delay is (5 + 5) is 10 days.

#### "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.<sup>1</sup>

The length of time between commencement and issuance is 1772 days, which is the number of days beginning on the commencement date of the application (February 21, 2012) and ending on the date the patent issued (December 27, 2016).

The time consumed by continued examination is 94 days. The period begins on May 17, 2016 (filing date of the "RCE") and ends on August 18, 2016 (Mail date of the notice of allowance).

The number of days beginning on the commencement date of application (February 21, 2012) and ending on the date three years after the filing date of the application (February 21, 2015) is 1097 days.

The result of subtracting the time consumed by continued examination (94 days) from the length of time between the application's commencement date and issuance (1772 days) is 1678 days, which exceeds three years (1097 days) by 581 days. Therefore, the period of "B" delay is **581 days**.

Patentees assert that the "B" delay is 740 days. Patentees also base this calculation on a commencement date of September 15, 2011. The Office properly calculates the 37 CFR 1.702(b) delay as 581 days based on a national stage commencement date of February 21, 2012. See discussion on national stage commencement *supra*.

#### "C" Delay

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<sup>1</sup> *Novartis*, 740 F.3d at 601.

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The Office and applicant are in agreement that the correct amount of overlap is zero days.

#### “Overlap”

In *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the Court of Appeals for the Federal Circuit determined that overlap occurs when the calendar days overlap between the “A” and “B” delays. Under this interpretation, the Office finds that the overlapping period of “A” delay and “B” delay is **five (5) days**. The specific period of overlap begins on July 18, 2015 and ending on July 22, 2015. During this period, Office delay was accruing concurrently under both the “A” delay and “B” delay provisions.

#### “Applicant” Delay

The patentee and the Office are in agreement as to the amount of applicant delay. The applicant delay includes the following periods:

- (1) 93 days under 37 CFR 1.704(c)(8) beginning on February 12, 2014 (day after the date of filing of the response to non-final rejection) and ending on May 15, 2014 (date of filing of the “IDS”);
- (2) 32 days under 37 CFR 1.704(b) beginning on October 23, 2015 (day after the date that is three months from the mailing of the non-final rejection) and ending on November 23, 2015 (date of filing the response to the non-final rejection); and
- (3) 82 days under 37 CFR 1.704(c) (12) beginning on February 26, 2016 (day after the mail date of the notice of allowance) and ending on May 17, 2016 (date of filing of the “RCE”).

### OVERALL PTA CALCULATION

Formula:

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

USPTO's Calculation:

$10 + 581 + 0 - 5 - 207 = 379$  days

Patentee's Calculation:

$165 + 740 + 0 - 5 - 207 = 693$  days

### CONCLUSION

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The patent term adjustment (PTA) remains 379 days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as follows:  $10 + 581 + 0 - 5 - 207 = 379$  days.

As the patent issued with 379 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, Alesia M. Brown at (571) 272-3205.

/ROBERT CLARKE/

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