

Patent Term Adjustment (Bio/Chem. Partnership)



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Patent Term Adjustment (PTA)

- The patent term adjustment (PTA) provisions of the AIPA are effective May 29, 2000 and apply to utility and plant applications filed on or after May 29, 2000
- The patent term extension (PTE) provisions of Public Law 103-465 (URAA) apply to utility and plant applications filed before May 29, 2000 but on or after June 8, 1995
- Patent term adjustment or extension under 35 U.S.C. § 154(b) does not apply to design applications or to any application filed before June 8, 1995



Patent Term Adjustment (PTA)

- Provides three (3) bases for adjustment under 35 U.S.C. § 154(b)(1):
 - USPTO failure to take certain actions within specified time frames “A” delay (35 U.S.C. § 154(b)(1)(A))
 - USPTO failure to issue a patent within three years of the filing date under 111(a) or commencement date “B” delay(35 U.S.C. § 154(b)(1)(B))
 - Delays due to interference, secrecy order, or successful appellate review “C” delay(35 U.S.C. § 154(b)(1)(C))
- Provides day-for-day adjustment for each failure or delay resulting in adjustment



Patent Term Adjustment (PTA)

Failure to take certain actions within specified time frames (14-4-4-4):

- Failure to initially act on the application within fourteen (14) months after filing date/commencement (patents with issue date January 14, 2013 to present). Prior to January 14, 2013, patents that issued from international applications measured the start date from date that 35 USC 371(c) requirements were fulfilled.
- Failure to act on a reply or act on an appeal brief within four (4) months after date the reply or appeal brief is filed
- Failure to act on an application within four (4) months after a PTAB or court decision if allowable claims remain in the application
- Failure to issue the patent within four (4) months of the date the issue fee was paid and all outstanding requirements were satisfied



Patent Term Adjustment (PTA)

USPTO failure to issue a patent within three years pendency:

- In an international (PCT) application, “date of commencement of the national stage under 371” is start date for the application
- In an application filed under 111(a), the filing date is start date for the application
- The three-year period does not include time consumed by any of:
 - Continued examination (RCE) under 35 U.S.C. § 132(b)
 - Secrecy order, interference, or any appellate review
 - Applicant-requested delays



Patent Term Adjustment (PTA)

- Delays caused by an interference proceeding (35 U.S.C. § 135(a))
- Delays caused by imposition of a secrecy order (35 U.S.C. § 181)
- Delays caused by **successful** appellate review (requires a PTAB/court decision reversing an adverse patentability determination)
 - all rejections of at least one claim must be reversed
 - In some instances, a remand shall be considered a decision reversing an adverse patentability determination
- These delays are the bases for patent term extension under Public Law 103-465 (URAA)



Patent Term Adjustment (PTA)

Novartis v. Lee, 740 F. 3d 593 (Fed. Cir. 2014).

Mandate issued March 10, 2014

- The Federal Circuit in *Novartis* reviewed the statutory interpretation of 35 U.S.C. § 154(b)(1)(B)(i) and issued decision regarding effects of filing an RCE on “B” Delay.
- The Federal Circuit ruled that the no “B” Delay adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application’s filing.
- The Federal Circuit further ruled 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 as “B” Delay but should be counted as “B” Delay.



Patent Term Adjustment (PTA)

- USPTO FINAL RULES (Novartis)
- 80 Fed. Reg. 1346-57 (January 9, 2015)
- Implemented in the USPTO algorithm on October 7, 2014.
- Changes to 37 C.F.R. 1.703 apply to any patent granted before, on, or after January 9, 2015.
- Changes to 37 C.F.R. 1.704(c)(12) for RCE filed on or after March 10, 2015.



Patent Term Adjustment (PTA)

- Amended 37 CFR 1.703(b)(1) provides that the time consumed by continued examination of the application under 35 U.S.C. 132(b) is “[t]he 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.”
- Applicable to any patent that issued before, on or after January 9, 2015.



Patent Term Adjustment (PTA)

- 37 CFR 1.704(c)(12) is a new rule that provides: “[s]ubmission of a request for continued examination under 35 U.S.C. 132(b) after any notice of allowance under 35 U.S.C. 151 has been mailed” constitutes a failure of applicant to engage in reasonable efforts to conclude processing or examination of an application, “in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed.”
- 37 CFR 1.704(c)(12) is applicable to any application in which an RCE is filed on or after March 10, 2015.



Patent Term Adjustment (PTA)

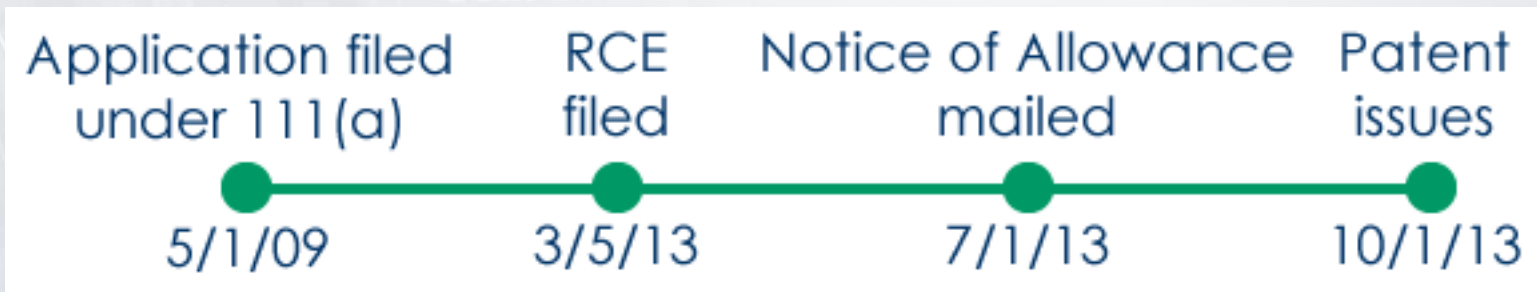
- 37 CFR 1.704(d) is amended to provide that a request of continued examination in compliance with § 1.114 with no submission other than an information statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution of the application under 1.704(c)(12), if the request for continued examination under 35 U.S.C. 132(b) is accompanied by the statement provided for in 1.704(d).
- This section is applicable as of March 10, 2015.



Patent Term Adjustment (PTA)

Example 1(facts)

- Application filed under 111(a) on 5/1/09
- RCE filed on 3/5/13
- Notice of Allowance mailed on 7/1/13
- Patent issues on 10/1/13
- There were no “A” Delays or “C Delays”
- No Applicant delays under 37 CFR 1.704(b) and (c)





Patent Term Adjustment (PTA)

Example 1 (Calculation)

- Days from filing to issue is $(5/1/09 - 10/1/13) = 1615$
- Days RCE to NOA is $(3/5/13 - 7/1/13) = 119$
- Days considered as “B” days = $1615 - 119 = 1496$
- Overall “B delay” = $1496 - 1097 = 399$
- Overall PTA = $A + B + C - \text{overlap} - \text{applicant delay}$
- $PTA = 0 + 399 + 0 - 0 - 0 = 399$ days



Patent Term Adjustment (PTA)

Example 2 (facts)

- Application filed on 5/1/2009
- RCE filed on 6/1/2011
- Notice of Allowance mailed on 10/12/2012
- Patent issued on 3/10/13
- There were no “A” delays or “C” delays
- No applicant delays under 37 CFR 1.704(b) and (c)



Patent Term Adjustment (PTA)

Example 2 (calculation)

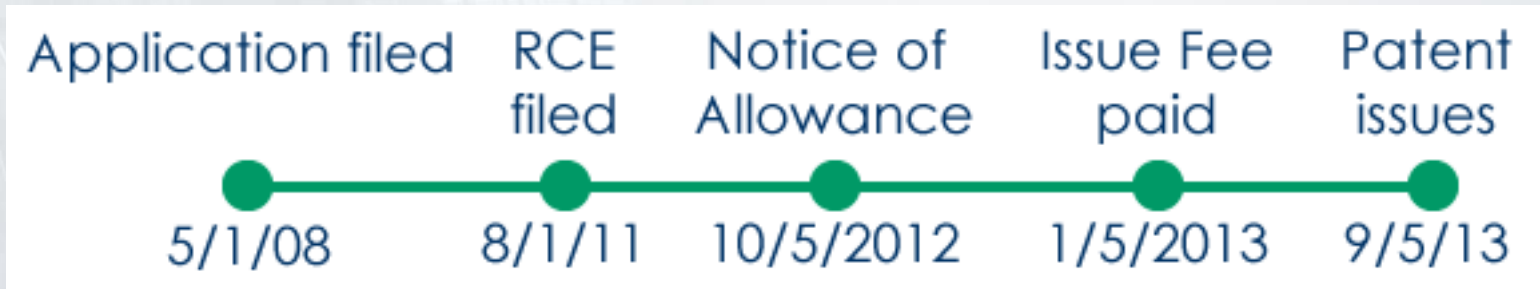
- Days from filing to issue is $(5/1/09 - 3/10/13) = 1410$
- Days from RCE to NOA is $(6/1/11 - 10/12/12) = 500$
- Days considered as “B” days is $1410 - 500 = 910$
- Overall “B” delay is $910 - 1097 = 0$
- $PTA = A + B + C - \text{Overlap} - \text{Applicant delay}$
- $PTA = 0 + 0 + 0 - 0 = 0$



Patent Term Adjustment (PTA)

Example (3) facts

- Application filed 5/1/2008
- RCE filed 8/1/11
- Notice of Allowance 10/5/2012
- Issue fee paid 1/5/2013
- Patent issues 9/5/2013





Patent Term Adjustment (PTA)

Example (3) calculation

- Filing to issue date (5/1/2008 – 9/5/2013) = 1954
- Days from RCE to NOA (8/1/2011- 10/5/2012) = 432
- Days considered as “B” days is $1954 - 432 = 1522$
- “B delay” is $1522 - 1096 = 426$
- “A delay” (issue more than 4 months after (IFEE) is $5/6/2013 - 9/5/2013 = 123$
- Overlap is $5/6/2013 - 9/5/2013 = 123$
- No “C” delays or Applicant Delays
- $PTA = A + B + C - \text{Overlap} - \text{Applicant Delay}$
- $PTA = 123 + 426 + 0 - 123 - 0 = 426$



Patent Term Adjustment (PTA)

Clarification of 37 CFR 1.704(c)(10)- No reductions for paper filed after notice of allowance including

- 1) an Issue Fee(s) Transmittal (PTOL-85B);
- 2) a power of attorney;
- 3) a power to inspect;
- 4) a change of address;
- 5) a change of entity status (micro, small, non-small);
- 6) a response to the examiner's reasons for allowance or a request to correct an error or omission in the ``Notice of Allowance" or ``Notice of Allowability";
- 7) status letters;



Patent Term Adjustment (PTA)

Clarification of 37 CFR 1.704(c)(10)- No reductions for paper filed after notice of allowance including (cont'd):

- 8) requests for a refund;
- 9) an inventor's oath or declaration;
- 10) an information disclosure statement with a statement in compliance with Sec. 1.704(d);
- 11) the resubmission by applicant of unlocatable paper(s) previously filed in the application (Sec. 1.251);



Patent Term Adjustment (PTA)

Clarification of 37 CFR 1.704(c)(10)- No reductions for paper filed after notice of allowance including(cont'd)

12)a request for acknowledgment of an information disclosure statement in compliance with Secs. 1.97 and 1.98, provided that the applicant had requested that the examiner acknowledge the information disclosure statement prior to the notice of allowance, or the request for acknowledgement was applicant's first opportunity to request that the examiner acknowledge the information disclosure statement;



Patent Term Adjustment (PTA)

Clarification of 37 CFR 1.704(c)(10)- No reductions for paper filed after notice of allowance including(cont'd)

- 13) comments on the substance of an interview where the applicant-initiated interview resulted in a notice of allowance; and
- 14) letters related to government interests (e.g., those between NASA and the Office).



Patent Term Adjustment (PTA)

Clarification of 37 CFR 1.704(c)(10)- Reductions for paper filed after notice of allowance including:

- 1) An amendment under Sec. 1.312;
- 2) a paper containing a claim for priority or benefit or request to correct priority or benefit information (e.g., a new or supplemental application data sheet filed to correct foreign or domestic benefit information);
- 3) a request for a corrected filing receipt;
- 4) a certified copy of a priority document;
- 5) drawings;
- 6) a letter relating to biologic deposits;
- 7) a request to change or correct inventorship; and
- 8) an information disclosure statement not accompanied by a statement in compliance with Sec. 1.704(d).



Patent Term Adjustment (PTA)

Procedures for determining adjustment:

- 35 U.S.C. § 154(b)(3)(B)(i) provides that the Director shall make a determination of the period of patent term adjustment and transmit a notice of determination no later than the date of issuance of the patent
- The Office provides the calculation in the Issue Notification Letter that is mailed or given to applicant approximately three weeks before the patent issues.
- If there is any discrepancy between the amount published on the patent and the calculation in the issue notification letter, the amount on the front of the patent is the Office's official notification. See Revisions to Implement the Patent Term Adjustment Provisions of Leahy-Smith America Invents Act Technical Corrections Act, 79 Fed. Reg. 27555 (May 15, 2014).



Patent Term Adjustment (PTA)

- 35 U.S.C. § 154(b)(3)(B)(ii) provides for one request for reconsideration of USPTO's patent term adjustment determination.
- The regulation that implements this provision is 37 CFR § 1.705(b). The rule provides that any request for reconsideration must be filed within two months from the date the patent was granted. However, extensions of time under 37 CFR § 1.136(a) may be granted.



Patent Term Adjustment (PTA)

In response to the request for reconsideration by the applicant (patentee), the Office will do one of the following replies:

- 1) If the Office agrees with patentee's calculation, the Office will issue a decision granting the request and a certificate of correction indicating the revised patent term adjustment calculation;
- 2) If the Office finds the amount calculated by the Office is correct and needs no additional information from applicant, the Office will issue a denial of the request for reconsideration, and this decision is the Director's decision within the meaning of 35 USC 154(b)(4).



Patent Term Adjustment (PTA)

In response to the request for reconsideration by the applicant (patentee), the Office will do one of the following replies (cont'd)

- 3) If the PTA redetermination results in a different amount of PTA than indication on the front of the patent, the Office will issue a redetermination of the PTA and this determination is not the Director's decision within the meaning of 35 USC 154(b) that starts applicant's 180 day window to file civil action; and
- 4) If the PTA redetermination results in the same determination as on the patent but seeks additional information from the patentee, the Office will issue a request for information and applicant has two months to respond (no additional fee required) and extensions of time are available under 37 CFR 1.136.



Patent Term Adjustment (PTA)

Judicial review of USPTO determination:

- Applicant (patentee) has 180 days from patent grant to seek judicial review of the USPTO's adjustment determination for patents issuing prior to January 14, 2013
- Applicant(patentee) has 180 days from the date of the director's decision on the request for reconsideration of patent term adjustment to file the civil action for patents issuing on or after January 14, 2013.



Thank You