

***Patent Term Adjustment:
Rules and Practical Considerations***

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I. Scope note

This article provides a broad overview of patent term adjustment (PTA), its purpose, and its implications. The article sets forth the rules for determining PTA and provides concerns and practical considerations for understanding, monitoring, and correcting PTA calculations.

II. What is PTA

Patent term adjustment (PTA) is a process carried out by the United States Patent and Trademark Office (USPTO) for adding day-for-day credits to the normal twenty year term from filing of a patent based on delays in prosecution at the USPTO. Any USPTO delays occurring during prosecution of an application are offset by delays caused by applicants. However, PTA cannot be less than zero; applicant delays can only be deducted from USPTO delays that have accrued.

III. Purpose of PTA

The law controlling PTA was created as the Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act. The law was implemented as a consequence of the change in patent term from 17 years from issuance to 20 years from filing. The concern was that delays in prosecution (*i.e.*, longer than three years) would result in patents having less term than they would have had before the new law went into effect. PTA was created to help maintain a minimum of 17 years of actual patent term even if the PTO is slow in prosecution. The rules controlling PTA are codified at 35 U.S.C. § 154 and 37 C.F.R. §§ 702-705.

IV. PTA is not PTE

One important note is that PTA is different from patent term extension (PTE). PTE is a separate law (35 U.S.C. § 154) that is applicable to a very limited situation for extending patent term for drugs and devices that must go through regulatory (FDA) approval before they can be sold. The PTE statute allows a certain period of patent term extension (maximum 5 years) to make up for patent term lost while the drug/device was going through the approval process and could not be sold.

V. Applicability of PTA

The PTA rules only apply to original applications (*e.g.*, US utility applications including continuations, divisionals and continuations-in part) **actually** filed on or after May 29, 2000. A request for continued examination (RCE) is not an original application and therefore is not affected by PTA in the same way. Priority claims to provisional, earlier-filed non-provisional or PCT applications are not considered when determining eligibility. PTA does not apply to PCT applications filed in the US Receiving Office because it is not considered the actual filing of a US application. However, PTA does apply to US national stage applications as of the date of entry into the national stage. Reissue patents are not eligible for PTA because their term is fixed by the term of the original patent. Similarly, design patents are not eligible for PTA as they have a fixed 14 year term from issue. Importantly, PTA cannot extend the term of a patent beyond the date established by a terminal disclaimer filed in that patent.

VI. PTA Rules

A. The first section of the PTA rules pertains to USPTO delays. There are three different bases under which delays can occur. These are (1) failure to act; (2) extensions for interferences, successful appeals, and secrecy orders; and (3) three year pendency term.

1. Failure to act

The first basis is failure to act by the USPTO, also known as the 14-4-4-4 rule. Under this rule, the USPTO is required to carry out certain acts during processing and examination within a given time frame. If the USPTO fails to act within the time limit, the patent term is

extended one day for every day past the time limit until the USPTO acts. There are four different time frames the USPTO is required to meet.

a. Fourteen months after filing

The first time frame is mailing an action not later than 14 months after the filing date of the application. For national stage applications, the filing date is considered to be the date applicant has met all of the requirements of 35 U.S.C. § 371(c). The adjustment period is the number of days beginning on the day after the day that is 14 months from the date on which the application was filed and ending on the date of mailing of an action. The following actions are considered under the 14 month rule.

- Action on the merits
- Written restriction requirement
- Written election of species requirement
- Requirement for information under 37 C.F.R. § 1.105
- Action under *Ex parte Quayle*
- Notice of allowance
- Written requirement for drawings

Office notices relating to pre-examination processing do not qualify as an action under the 14 month rule. This includes the following notices.

- Notice of incomplete nonprovisional application
- Notice of omitted item(s) in a nonprovisional application
- Notice to file missing parts of application
- Notice of informal application
- Notice to file corrected application papers filing date granted
- Notice to comply with requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures

b. Four months after a reply or appeal brief

The second time frame is mailing an action within four months after a reply or appeal brief is filed by the applicant. This time frame includes responding to a reply to a restriction

requirement or election of species requirement, even though this type of a reply does not require a response from the USPTO. For an appeal, the date for calculating adjustment is the date the appeal brief is actually filed, not the date the Notice of Appeal is filed. For a reply, the period of adjustment is the period beginning on the day after the date that is four months after the date a reply was filed and ending on the date of mailing of an action on the merits or a notice of allowance. For an appeal brief, the period of adjustment is the period beginning on the day after the date that is four months after the date an appeal brief was filed and ending on the date of mailing of an examiner's answer, an action on the merits, or a notice of allowance.

c. Four months after a decision by the Board of Patent Appeals and Interferences (BPAI) or a Federal court

The third time frame is mailing an action within four months after a decision of the BPAI or a Federal court. The decision must be a final decision of the BPAI or a final judgment of the Federal court and there must be at least one allowable claim remaining in the application. The period of adjustment is the period beginning on the day after the date that is four months after the date of the final decision and ending on the mailing date of either an action on the merits or a notice of allowance.

d. Four months to issue date after issue fee payment

The fourth time frame is issuance of a patent within four months after the issue fee is paid and all outstanding requirements are satisfied. The adjustment period is the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied and ending on the date the patent was issued. The filing of a priority document is not considered to be an outstanding requirement and will not affect the adjustment period. If prosecution is reopened after allowance, all outstanding requirements are not satisfied until the application is again in condition for allowance as indicated by the issuance of a new notice of allowance.

2. Interferences, successful appeals, secrecy orders

The second basis for USPTO delays is the occurrence during prosecution of interferences, successful appeals, and secrecy orders. The patent term is extended for each day

of pendency of the interference proceeding, secrecy order, or appellate review. For interferences, the pendency is counted from the date the interference is declared through the date of the final decision of the BPAI or a Federal court. For appeals, the pendency is counted from the date the notice of appeal is filed through the date of the final decision of the BPAI or a Federal court. For secrecy orders, the pendency is counted from the date the secrecy order is signed through the date the order is rescinded.

3. Three year pendency from filing to issuance

The third basis for USPTO delays is the requirement for a three year pendency from filing of an application until the date it issues as a patent. The period of adjustment under this time frame is the number of days in the period beginning on the day after the date that is three years after the actual filing date of the application and ending on the date a patent was issued. There are several prosecution activities that are excluded from the calculation of the adjustment period, including the following.

- Period consumed by continued examination of the application
(the number of days in the period beginning on the date on which a request for continued examination (RCE) was filed and ending on the date the patent was issued)
- Period consumed by interference proceedings
(the number of days in the period beginning on the date an interference was declared to involve the application and ending on the date that the interference was terminated with respect to the application; or beginning on the date prosecution in the application was suspended by the USPTO due to an interference proceeding not involving the application and ending on the date of the termination of the suspension)
- Period consumed by imposition of a secrecy order
(the number of days the application was maintained in a sealed condition)
- Period consumed by appellate review, whether successful or unsuccessful
(the number of days in the period beginning on the date on which a notice of appeal was filed and ending on the date of the last decision by the Board or by a Federal court or on the date of mailing of either an action on the merits or a notice

of allowance, whichever occurs first, if the appeal did not result in a decision by the Board)

- Period consumed by delays requested by the applicant

4. Calculating total USPTO delay

According to the rules, the total adjustment period based on USPTO delays is the sum of all of the delays described above, minus any overlap between the adjustment periods. In other words, the total period of adjustment cannot exceed the actual number of days the issuance of the patent was delayed.

While the rule for calculating total USPTO delay seems straightforward, the USPTO uses an odd interpretation of the rules when combining 14-4-4-4 delays and 3-year pendency delays. This interpretation appears to have the effect of denying applicants the full term adjustment an application may deserve. The USPTO has declared that the three year pendency delay starts from the day the application is filed and includes the entire prosecution period, but only if there is also a 14-4-4-4 delay. Therefore, the 14-4-4-4 delay and three year pendency delay necessarily overlap and an applicant cannot get credit for both delays. The USPTO gives applicants the longer of the two delays (with the three year pendency delay calculated starting from the date three years after the filing date).

In September 2008 the District Court for the District of Columbia handed down a decision (*Wyeth v. Dudas*, Civ. Action No. 1:07-cv-1492-JR, 2008 WL 4445642 (D.D.C. September 30, 2008)) holding that the USPTO had misconstrued the PTA law by including the entire prosecution period as part of the three year pendency delay and was improperly calculating the adjustment period. The court found that applicants are entitled to the sum of the 14-4-4-4 delay (which the court called the “A delay”) and the three year pendency delay (which the court called the “B delay”), minus any overlap, not just the longer of the two delays.

Since the *Wyeth* decision was announced, many patentees have filed suit in the DC District Court for correction of PTA. To date, none of these cases have been decided. While the ruling in *Wyeth* should be considered the current law for PTA calculation, the USPTO has yet to announce any changes in their procedure based on the decision. Furthermore, the USPTO has filed an appeal in the *Wyeth* case, so this matter is still up in the air.

B. The second section of the PTA rules pertains to applicant delays, otherwise known as required reduction bases. As stated above, there cannot be a negative PTA that shortens patent term. If there is no USPTO delay, there is no need to calculate applicant delay as there is no adjustment period from which to subtract the applicant delay.

The rules for reduction of PTA state that the period of adjustment will be reduced for periods of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application. Certain circumstances are listed in the rules that constitute failure by applicants. However, the USPTO has the authority to find unlisted activities to be a failure to reasonably conclude prosecution. Thus, this rule is open to interpretation by the USPTO.

1. Three month grace period for reply

Applicants are required to reply within three months to any notice or action by the USPTO making any rejection, objection, argument or other request. The adjustment period is calculated beginning on the day after the date that is three months after the date of mailing or transmission of the USPTO communication and ending on the date the reply is filed. The three month grace period is independent of the time actually given to respond. For example, a restriction requirement gives a one month period to respond, but a reply is not late for PTA purposes until three months. The grace period applies to pre-exam notices that are themselves excluded from the USPTO 14 month requirement. One notice that is excluded from this requirement is the Notice of omitted items in a nonprovisional application, as no response is required to this notice.

One exception exists for the three month grace period. An applicant's failure to respond to an office action within 3 months will be waived by the USPTO if the applicant's delay was "in spite of all due care." The USPTO will reinstate the adjustment, but for no more than a period of three months. Examples of excusable delays include the following.

- Natural disaster
- Illness or death of a sole practitioner of record
- Required testing that took longer than 3 months (*e.g.*, for a Rule 1.132 declaration)

Examples of delays that are not excusable include the following.

- Applicant's or representative's preoccupation with other matters that are given priority over the application
- Illness or death of the practitioner in charge of the application if the practitioner is associated with other practitioners
- Time consumed with communications between the applicant and his or her representative, regardless of whether the applicant resides in the United States or chooses to communicate with the United States representative via a foreign representative
- Vacation or other non-attention to an application
- Applicant filing a reply on or near the last day of the three-month period using first class mail with a certificate of mailing and the reply is not received in the USPTO until after the three-month period
- Failure of clerical employees of applicant or applicant's representative to properly docket the office action or notice for reply or perform other tasks necessary for reply within the three-month period

2. Further defined circumstances

The PTA rules list eleven specific circumstances that are considered to be a failure by applicants to conclude prosecution and occur with sufficient frequency to be explicitly set forth in the rules.

a. Suspension of action under 37 C.F.R. § 1.103

A request by applicant to suspend action is deemed a failure. The patent term reduction is the number of days beginning on the date a request for suspension was filed and ending on the date the suspension is terminated.

b. Deferral of issuance of a patent under 37 C.F.R. § 1.314

Deferral of issuance of a patent by applicant is deemed a failure. The patent term reduction is the number of days beginning on the date a request for deferral of issuance of a patent was filed and ending on the issue date of the patent.

c. Abandonment of the application or late payment of the issue fee

Abandonment of the application or late payment of the issue fee by applicant constitutes a failure. The patent term reduction is equal to the number of days beginning on the date of abandonment or the date after the day the issue fee was due and ending on the earlier of (1) the mailing date of the decision reviving the application or accepting late payment of the issue fee; or (2) the date that is four months after the filing date of the grantable petition to revive the application or to accept payment of the issue fee.

d. Failure to file a petition to withdraw the holding of abandonment or to revive an application within two months from the mailing date of a notice of abandonment

Another circumstance that constitutes an applicant delay is the failure to file a petition to withdraw the holding of abandonment or to revive an application within two months from the mailing date of a notice of abandonment. The patent term reduction is the number of days beginning on the day after the date two months from the mailing date of a notice of abandonment and ending on the date a petition to withdraw the holding of abandonment or to revive the application was filed.

e. Conversion of a provisional application to a nonprovisional application

The conversion of a provisional application to a nonprovisional application is deemed a failure. The patent term reduction is equal to the number of days beginning on the date the provisional application was filed and ending on the date a request to convert the provisional application into a nonprovisional application was filed.

f. Submission of a preliminary amendment or other preliminary paper less than one month before the mailing of an office action or notice of allowance, if that submission requires the USPTO to mail either a supplemental office action or notice of allowance

The submission of a preliminary amendment or other preliminary paper less than one month before the mailing of an office action or notice of allowance is deemed a failure if that submission requires the USPTO to mail either a supplemental office action or supplemental notice of allowance. The patent term reduction is the lesser of (1) the number of days beginning on the day after the mailing date of the original office action or notice of allowance and ending on the mailing date of the subsequent office action or notice of allowance; or (2) four months.

- g. Submission of a substantially complete reply having an inadvertent omission

The submission of a substantially complete reply having an inadvertent omission is deemed a failure. The patent term reduction is the number of days beginning on the day after the date the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed.

- h. Submission of a supplemental reply or other paper after a reply has been filed

The submission of a supplemental reply or other paper after a reply has been filed is deemed a failure. This includes the filing of information disclosure statements. It does not apply to a reply that was expressly requested by the examiner. The patent term reduction is the number of days beginning on the day after the date the original reply was filed and ending on the date that the supplemental reply or other paper was filed.

- i. Submission of an amendment or other paper after a decision by the Board or a Federal court, but less than one month before the mailing of an office action or notice of allowance, that requires the mailing of a supplemental office action or supplemental notice of allowance

The submission of an amendment or other paper after a decision by the Board or a Federal court, but less than one month before the mailing of an office action or notice of allowance, that requires the mailing of a supplemental office action or supplemental notice of allowance is deemed a failure. The patent term reduction is the lesser of (1) the number of days

beginning on the day after the mailing date of the original office action or notice of allowance and ending on the mailing date of the supplemental office action or notice of allowance; or (2) four months.

j. Submission of various papers after a notice of allowance is mailed or given

The submission of a Rule 1.312 amendment or other paper after a notice of allowance is mailed or given is deemed a failure. The patent term reduction is the lesser of (1) the number of days beginning on the date of the Rule 1.312 amendment or other paper was filed and ending on the mailing date of the office action or notice in response to the amendment or other paper; or (2) four months.

The filing of the following papers after a notice of allowance is considered a failure.

- Request for refund
- Status letter
- Amendments under 37 C.F.R. § 1.312
- Late priority claims
- Certified copy of a priority document
- Drawings
- Letter related to biological deposits
- Oath or Declaration

Papers that are not considered a failure (but only if filed within three months of the mailing date of the action or notice) include the following.

- Issue fee transmittal
- Power of attorney
- Power to inspect
- Change of address
- Change of entity status
- Response to examiner's reasons for allowance or a request to correct an error or omission in a notice of allowance or notice of allowability
- Letters relating to government interests

- Request for correction of PTA

k. Further prosecution via a continuing application

Further prosecution via a continuing application is deemed a failure. This includes filing a continuation, divisional, or continuations-in-part application. The patent term reduction includes all days of ancestral application prosecution prior to the actual filing date of the application that results in the patent.

Patent term reductions under f, h, i, and j above do not apply to information disclosure statements accompanied by a statement that each listed item was cited in a paper from a foreign patent office in a counterpart application that was received no more than thirty days prior to the filing of the information disclosure statement.

3. Unspecified circumstances

As previously stated, the USPTO has the authority to find activities other than those listed above to be a failure to reasonably conclude prosecution. According to the comments in the M.P.E.P., “there are a myriad of actions or inactions [by applicant] that occur infrequently but will interfere with the Office’s ability to process or examine an application.” Thus, the USPTO is free to interpret any atypical action as an applicant delay. The commentary lists three examples of such unusual circumstances.

- Applicant files and persists in requesting reconsideration of a meritless petition under 37 C.F.R. § 1.10 (disagreement about date of entitlement for paper filed by express mail)
- Parties to an interference obtain an extension for purposes of settlement negotiations which do not result in settlement
- When the scope of the broadest claim in the application at the time an application is placed in condition for allowance is substantially the same as suggested or allowed by the examiner more than six months earlier than the date the application was placed in condition for allowance

It is noted that the USPTO uses a computer algorithm to calculate PTA based on data in the PALM and PAIR systems. There does not appear to be a mechanism by which the USPTO

can consider any unusual circumstances as in the examples above. Thus, the flexibility of the USPTO to declare any circumstance to be an applicant delay may not matter for practical purposes.

4. Calculating total applicant delay

According to the rules, the total reduction in adjustment period based on applicant delays is the sum of all of the delays described above, minus any overlap between the reduction periods. In other words, the total period of reduction cannot exceed the actual number of days of applicant delays.

VII. When PTA is determined

The USPTO sends a PTA calculation to the applicant twice during prosecution of an application. The first time is with the notice of allowance and issue fee due. The PTA calculation is performed shortly before the notice is mailed. The calculation includes an assumption that the patent will issue within four months of issue fee payment.

The USPTO performs a second PTA calculation when the patent is about to issue for inclusion on the face of the patent. The second calculation includes consideration of the time period from payment of the issue fee to issuance of the patent.

VIII. When to request correction of PTA

An applicant cannot request correction of PTA before the first PTA calculation is received with the notice of allowance. However, it is in an applicant's best interest to continually monitor PAIR for incorrect entries before the notice of allowance is mailed. Because PTA is calculated based on PAIR entries, any incorrect entries (either in date or description of action) will result in an incorrect PTA calculation. PAIR errors can be corrected free of charge simply by calling the examiner or the Technology Center's customer service representative and pointing out the error. On the other hand, a request to correct PTA requires payment of a fee.

If an error is found in the PTA calculation received with the notice of allowance, a request to correct PTA must be filed no later than the payment of the issue fee. Only one request can be made at this stage.

After issuance of a patent, the applicant can file a request for reconsideration of PTA no later than two months from the issue date of the patent. However, this second request can only be used to correct an error related to the issue date estimate. Reconsideration or initial consideration of correction requests that were, or could have been, submitted earlier will not be entertained. If the PTA is corrected after the patent issues, a certificate of correction will be used to demonstrate the correction.

IX. How to check PTA calculation

The USPTO calculates PTA using a computer algorithm based on data entered in PAIR and PALM. The calculations are not inspected by any person. Studies show a significant error rate in the USPTO calculations. (Kayton, Patent term duration and its calculation, Release No. 3, 2008, pp. 54-55, available at www.patentterm.com). Moreover, improperly overstated PTA by the USPTO that is not rejected by the applicant can be deemed to be inequitable conduct on the part of the applicant. Thus, it can be important to check PTA on all allowed applications.

The USPTO provides a tab in PAIR to show the PTA calculation in allowed applications. This tab graphically indicates both USPTO and applicant delays according to the file wrapper and provides a sum of the respective delays and of the total PTA.

Applicants can check the PTA calculations by hand, using their own file history and a calendar. Calculating PTA by hand is tricky, in part due to overlapping rules and the different beginning and ending dates for different time periods. However, calculation by hand may be sufficient to determine if the USPTO calculation appears to be correct or is obviously wrong.

For a more specific calculation of PTA, an online calculator can be used. One such site is provided by PatentTerm® Online, LLC (www.patentterm.com). This site, which currently charges \$200 per application, downloads file history information from PAIR and provides the ability to perform multiple PTA calculations based on file history information as entered into PAIR and as it should be with any errors corrected. The site also provides detailed descriptions of the actual PTA calculations for the application.

X. When to check PTA calculation

Typically, the PTA calculation received with the notice of allowance is reported to the client together with the notice of allowance. This reporting letter explains what PTA is in

general, states the calculated PTA for the application being reported and requests the client's authorization to review the PTA calculation if desired.

In addition to consulting with the client about authorization to review the PTA calculated by the USPTO, the attorney should consider looking up the application in PAIR when a notice of allowance is received, to evaluate the status of the PTA calculation and notify the client of any readily identifiable errors.

XI. How to request PTA correction

Requests for reconsideration of the PTA and requests for reinstatement of all or part of the term reduced for applicant delay are by way of an application for patent term adjustment. The application must include a statement of facts showing:

- (i) the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
- (ii) the relevant dates as specified in 37 C.F.R. § 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
- (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
- (iv) any circumstance during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 1. 37 C.F.R. § 704 or a statement that there were no such circumstances.

Filing a request to correct PTA requires payment of the fee under 37 C.F.R. § 1.18(e). However, a request to correct PTA based on unjustified reduction for failure to reply despite all due care, requires payment of two fees (37 C.F.R. §§ 1.18(e) and (f)), as well as a showing that the applicant did exercise all due care.

If the PTA is thought to be less than indicated by the USPTO, an applicant need not file a application for term adjustment. The applicant can file a letter with the issue fee payment or after issuance of the patent indicating that the PTA appears to be longer than appropriate.

XII. Appeal to District Court

An applicant dissatisfied with the USPTO calculation of PTA has a judicial remedy by civil action in the U.S. District Court for the District of Columbia. The action must be filed within 180 days of issuance of the patent. The court has no jurisdiction to take the appeal unless the appellant perfected its administrative remedies before the USPTO – *i.e.*, the appellant must have attempted to seek PTA correction unsuccessfully from the USPTO.