# **Patent Term Adjustment**

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In 1999, Congress created a system of patent term adjustment (PTA) that adds additional time to patent terms to remedy certain delays caused by the U.S. Patent and Trademark Office (PTO) in issuing a patent.

### Why Review PTA?

More than half of all patents granted in December 2019 were entitled to PTA, with an average PTA of about 142 days. <u>https://www.uspto.gov/dashboards/patents/main.dashxml</u>.

#### **PTA: The Basics**

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- Available for utility or plant applications, not reissue or design applications.
  - <u>35 U.S.C. § 154(b)(1)(A)</u> PTA granted if any of the following occur ("A delay")
    - » PTO issues an office action or notice of allowance more than 14 months after the application is filed.
    - » PTO acts more than four months after applicants file a reply to office action.
    - » PTO acts more than four months after a decision on appeal or decision by a federal court finding at least one claim allowable.
    - » PTO issues a patent more than four months after payment of the issue fee.
- <u>35 U.S.C. § 154(b)(1)(B)</u> PTA granted if the application is pending for more than three years, excluding time consumed by the following (**"B delay"**).
  - ♦ Continued examination.
  - ♦ Interference or derivation proceeding.
  - Imposition of a secrecy order.
  - ♦ Review by PTO on appeal or by federal court.
  - ♦ Delays in processing requested by the applicant.
- <u>35 U.S.C. § 154(b)(1)(C)</u> PTA granted if issuance was delayed due to interference or derivation proceeding, imposition of a secrecy order, or appellate review by PTO or federal court that reversed an adverse determination of patentability ("C delay").
- PTA is the sum of A, B and C delays, excluding the following periods of time:
  - Overlap between A, B and C delays
  - ◊ Patent term specified in a terminal or statutory disclaimer
  - ♦ Applicant-caused delays such as:
    - » Taking longer than three months to reply to a PTO notice or office action.
    - » Abandonment of the application or late payment of the issue fee.
    - » Failing to file a petition to withdraw abandonment or revive an application within two months from issuance of a notice of abandonment.
    - » Converting a provisional application to a nonprovisional application.
    - » Submitting a preliminary amendment or other preliminary paper less than one month before issuance of an office action or notice of allowance that requires the issuance of a supplemental office action or notice of allowance.
    - » Submitting a reply having an omission.
    - » Submitting a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the PTO, after a reply has been filed.
    - » Submitting an amendment or other paper after a notice of allowance.

### Challenging the PTO's Calculation of PTA

File a request for reconsideration of PTA at the PTO.

- Due **two months after patent issuance**, with extensions of time available for up to five additional months.
- However, a request to reinstate PTA deducted for periods of time in excess of three months taken to reply to a PTO notice or office action must be filed **prior to issuance**, with no extensions of time available.
- File a civil action within 180 days after issuance?
  - Applicants dissatisfied with the PTO's decision on a request for reconsideration have an "exclusive remedy" by civil action within 180 days after the date of the PTO's decision. 78 Fed. Reg. 19416; *Daiichi v. Lee* (Fed. Cir. 2015).
  - **Ordinary tolling** of the 180-day deadline is allowed while awaiting the PTO's decision on a request for reconsideration of PTA. *Novartis v. Lee* (D.D.C. 2012); *Bristol-Myers Squibb v. Kappos* (D.D.C. 2012).
  - But, courts have not allowed equitable tolling of the 180-day deadline, *e.g.*, when a significant new PTA decision is issued. *Novartis v. Lee* (Fed. Cir. 2014); *Actelion v. Kappos* (D.D.C. 2013); *Daiichi v. Rea* (D.D.C. 2013).

## **Best Practices and Other Tips**

- Independently carry out a PTA calculation according to the current rules and regulations, and if there is an error, file a petition with the PTO to challenge the PTA calculation.
- Patentees can request reconsideration of PTA based on a deduction for "applicant delay" during a period of time when "there was no identifiable effort" the patentee could have taken to avoid the delay. *Supernus vs. lancu* (Fed. Cir. 2019).
- Ensure responses to a final office action are proper.
  - Reply including "the same arguments that were previously found unpersuasive" for an obviousness rejection and claim amendments related to a different rejection was deemed a failure to engage in reasonable efforts to conclude processing or examination. *Mayo v. lancu* (Fed. Cir. 2019).
- Avoid filing a paper containing only an information disclosure statement (IDS) after a reply has been filed.
  - IDS filed after a reply to a restriction requirement and before examination is considered applicant delay. *Gilead v.* Lee (Fed. Cir. 2015).
  - Review patent office communications from counterpart applications as soon as they are received, and instruct international associates to report such communications as quickly as possible.
    - Paper containing only an IDS will <u>not</u> be considered applicant delay if, *e.g.*, the documents cited in the IDS were first cited in a communication that was not received more than <u>30 days</u> prior to the filing of the IDS. 37 C.F.R. § 1.704(d).
- When multiple inventions are claimed, consider making an oral election of species to the examiner.
  - Issuance of a written restriction requirement will likely end the period of A delay sooner than it would have ended if the first PTO action is a substantive office action.
- To maximize A and/or B delay, consider taking a one-month extension of time and replying to a pre-examination notice or restriction requirement at the three-month deadline.
- To maximize B delay, pay the issue fee on the deadline rather than before the deadline.
- Carefully consider the consequences of filing a terminal disclaimer.
  - ♦ May or may not negatively affect PTA.
  - Does not affect patent term extension granted for delays related to regulatory review by the U.S. Food and Drug Administration. *Merck v. Hi-Tech* (Fed. Cir. 2007).
  - Preserve the largest possible PTA in parent applications in the event a terminal disclaimer is filed in later child applications.
- Avoid filing a request for continued examination (RCE).
  - Time in "continued examination" is excluded from B delay, but only for the time before allowance. Novartis v. Lee (Fed. Cir. 2014).
  - The RCE period is not ended by an interference proceeding. *Mayo v. Iancu* (Fed. Cir. 2019).
  - May still be entitled to PTA for A or C delays.
  - ◊ Consider filing an appeal instead of an RCE to preserve B delay.
- Avoid filing a supplemental amendment or an amendment after allowance.
  - ♦ Considered applicant delay.
  - ◊ If possible, correct problems in the next reply or with an examiner's amendment.
  - Challenge PTA detracted for such amendments when made in reply to a PTO notice or request.

## PTA Around the World

In addition to the U.S., the following countries also grant PTA for patent office delays.

Country	Requirements
Chile	• Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.
Colombia	<ul> <li>Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.</li> <li>Request must be filed within 2 months of grant.</li> <li>Does not apply to pharmaceutical patents.</li> <li>No fee is required.</li> </ul>
Costa Rica	<ul> <li>Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.</li> <li>Maximum of 18 months granted.</li> </ul>
Dominican Republic	<ul> <li>Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.</li> <li>Does not apply to applications filed before March 1, 2008.</li> </ul>
El Salvador	<ul> <li>Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.</li> <li>Maximum of 550 days granted.</li> </ul>
Guatemala	• Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.
Honduras	• Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.
Nicaragua	<ul> <li>Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.</li> <li>Maximum of 550 days granted.</li> </ul>
Singapore	<ul> <li>Available for "unreasonable" delay by Intellectual Property Office of Singapore in granting a Singapore patent or by a "prescribed" foreign patent office in granting a foreign patent on which a Singapore patent is based.</li> <li>Available if grant of a patent is delayed more than 4 years from the application filing date or 2 years after the request for examination, whichever is later.</li> <li>Subject to delays caused by the applicant (<i>e.g.</i>, extensions of time).</li> <li>Request must be filed within 6 months of grant and include documentary evidence to support the application and an official fee.</li> <li>Maximum of 5 years granted.</li> <li>Does not apply to applications filed before July 1, 2004.</li> </ul>
South Korea	<ul> <li>Available if grant of a patent is delayed more than 4 years from the application filing date or 3 years after the request for examination, whichever is later.</li> <li>Subject to delays caused by the applicant (<i>e.g.</i>, extensions of time).</li> <li>Request must be filed within 3 months of grant.</li> </ul>