

Patent Term Adjustment for Fun and Profit*

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Patent term adjustment (“PTA”) is a powerful provision for extending the term of a patent and, consequently, increasing its value. Even a few days of extra patent term can provide enormous financial benefits to a patentee whose patent covers a blockbuster drug or other commercially successful invention. This article identifies common pitfalls to avoid before, during, and after patent prosecution to help ensure that a patentee receives the most PTA it can.

The American Inventor’s Protection Act of 1999² created the framework for positively adjusting patent term³ as a result of delays caused by the U.S. Patent and Trademark Office (“PTO”) during routine prosecution.⁴ PTA is available for original (i.e., not reissue) utility and plant patents, but not for design patents.⁵

While PTO delays may increase the

PTA a patent receives, delays and certain other actions by the applicant may decrease the PTA. Accordingly, the patentee can maximize the term adjustment to which it is entitled by adopting several strategies, which are outlined below.

Before filing the patent application:

1. Know the rules for patent term adjustment.

The PTO lays out and comments upon the complex PTA calculation rules in Chapter 2700 of the Manual of Patent Examining Procedure.⁶ Practitioners having thorough knowledge of these rules can avoid actions or inactions that reduce PTA. A full analysis of the rules is beyond the scope of this article, but some of the basic elements of PTA are:

a. PTO examination delays increase PTA.

35 U.S.C. § 154(b)(1)(A)-(C) set out a series of guarantees of examination and pendency timeliness. Any delays caused by the PTO that result in failure to meet these guarantees contribute to PTA. These guarantees include: (1) first action⁷ within fourteen months after filing;⁸ (2) action following an applicant’s responsive filing or an appellate decision within four months; (3) issuance of the patent within four months of the issue fee payment; and (4) issuance of patent within three years of filing.⁹ The PTO will also grant PTA for

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² Pub. L. 106-113, 113 Stat. 1501A-557.

³ *Id.* at §§4402, 4504, 113 Stat. at 564.

⁴ Patent term adjustment is codified at 35 U.S.C. § 154(b). Other mechanisms for extending or restoring patent term, not treated here, are codified at §§ 155, 155A, and 156.

⁵ 37 C.F.R. § 1.702(f). Plant patents are eligible for PTA because no part of 35 U.S.C. provides otherwise. *See* 35 U.S.C. § 161, second paragraph. Design patents are ineligible because the statute specifies that they are granted for a fixed term of fourteen years from the issue date. *See* 35 U.S.C. § 173.

⁶ United States Patent and Trademark Office, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2730-2736 (8th ed., rev. 4 2005).

⁷ Actions include a written restriction or election requirement, a requirement for information, an office action on the merits, an *Ex parte Quayle* action, and a notice of allowability. 37 C.F.R. § 1.703(a)(1); M.P.E.P. § 2731.

⁸ or after fulfilling the requirements of 35 U.S.C. § 371 for U.S. national stage entry.

⁹ PTA accorded under the three-year guarantee

(5) delay caused by secrecy order, interference, or successful appellate review. If delays attributable to different grounds overlap, the PTA will not exceed the actual number of days that issuance was delayed.¹⁰

b. Applicant delays decrease PTA.

35 U.S.C. § 154(b)(2)(B) states that PTA will not extend the patent term beyond an expiration date specified in a disclaimer. A terminal disclaimer filed to overcome a non-statutory double patenting rejection and that identifies a prior patent or patent application is considered to “specify” an expiration date, even though it does not expressly set forth that date.¹¹

35 U.S.C. § 154(b)(2)(C) provides that PTA will be reduced if an applicant fails “to engage in reasonable efforts to conclude prosecution of the application.” An applicant is deemed to have “failed to engage” if it takes more than three months to respond to a rejection, objection, argument, or other request from the PTO.¹² The PTO, with the rulemaking authority conferred by 35 U.S.C. § 154(b)(2)(C)(iii), has defined several other situations that constitute failure to engage in reasonable efforts. These are set out at 37 C.F.R. § 1.704 and include (among others) suspension requests, revival of an abandoned application, converting a provisional application to a nonprovisional application under 35 U.S.C. § 111(b)(5) and 37 C.F.R. § 1.53(c)(3), filing a preliminary amendment or a post-appeal paper that interferes with the preparation of an office action, filing a defective response or a

supplemental response, and filing an amendment after allowance or formal drawings after allowance.

2. Consider filing a continuation-in-part instead of a continuation.

As stated at M.P.E.P. § 708, a continuation-in-part (CIP) application is docketed for examination based on its actual, not effective, filing date. Consequently, the pendency to first action in a CIP application is typically longer than that for a continuation application and is thus more likely to violate the fourteen-month-to-first-action guarantee. For example, a continuation application that receives a first action one year after filing would qualify for no PTA under the fourteen-month guarantee, while a CIP application that receives a first action three years after filing would qualify for twenty two months’ PTA under that guarantee.

During pendency:

3. Avoid extensions beyond three months, supplemental responses, noncompliant responses, and requests for continued examination.

Any response filed more than three months after the mailing of the Office action that necessitated the response will reduce PTA. For office actions that set a three-month period for response, this means avoid taking any extensions of time. For actions that set a one- or two-month period for response,¹³ taking a two- or one-month extension, respectively, will

typically results from the issuance of a string of non-final office actions.

¹⁰ 35 U.S.C. § 154(b)(2)(A).

¹¹ PTO Office of Patent Legal Administration, Personal Communication, May 22, 2006.

¹² 35 U.S.C. § 154(b)(2)(C)(ii).

¹³ These include a requirement for restriction/election (1 month), a notice to comply with sequence listing requirements (1 month), a notice to file missing parts or missing requirements (2 months), an *Ex Parte Quayle* action (2 months), and a requirement for information under 37 C.F.R. § 1.105 (2 months).

not reduce PTA.

Supplemental responses (unless expressly requested by an examiner) and papers that do not comply with the amendment practice rules listed at 37 C.F.R. § 1.121 will reduce PTA by the number of days from the initial reply to the filing of the supplemental or corrected reply, so avoid them. Supplemental replies are now entered as a matter of right only in the limited circumstances set forth in 37 C.F.R. § 1.111(a)(2)(A)-(F), but even a supplemental reply denied entry may reduce PTA, so consider carefully whether a supplemental reply is merited. An Information Disclosure Statement (IDS) filed by itself is treated as a supplemental reply, so try to file the IDS with a reply or before the first action.¹⁴

Any prosecution time after the filing of a request for continued examination (RCE) will not count toward the three-year total pendency guarantee,¹⁵ so consider alternatives to filing an RCE. These include (a) filing a response to a final office action that prompts the examiner to issue a new office action (discussed at M.P.E.P. § 706.07(e)) or a notice of allowance; (b) requesting or petitioning to have the finality of an office action withdrawn (M.P.E.P. § 706.07(d)); and (c) appealing the rejection (discussed below). Another alternative to an RCE is filing a continuation application, but

doing so will eliminate any PTA accumulated in the parent application.¹⁶

4. File formal drawings with the initial application or during examination, not with the issue fee payment.

PTA loss due to late formal drawings submission is a common pitfall because the first indication that formal drawings are required may come with the notice of allowance, or worse yet, with a Notice of Drawing Inconsistency or other amendment requirement mailed by the Office of Patent Publications after the issue fee has been paid.

Formal drawings filed with an issue fee payment will reduce the PTA by the number of days from the filing of the formal drawings to the date of an Office action or notice in response to them, or four months, whichever is less.¹⁷ Avoid this problem by filing drawings that meet the requirements of 37 C.F.R. § 1.84 with the initial patent application, with a preliminary amendment before examination, or with an otherwise responsive filing (such as a response to a notice to file missing parts or a response to an office action).

5. Make telephone invention restrictions and elections of species.

The fourteen-month-to-first-action guarantee is tolled by the issuance of a restriction or election requirement.¹⁸ Consequently, if an examiner calls with a request to make a telephonic restriction or election, try to respond rather than force the examiner to issue a paper requirement. It is likely that the examiner will take longer to prepare and issue a first action on the merits than to issue a restriction requirement, so more PTA will probably

¹⁴ 37 C.F.R. § 1.704(d) sets a special rule for an IDS that lists only items first cited in a foreign patent office communication for a counterpart application and is filed with 30 days of receipt. The filing of such an IDS by itself will not reduce PTA.

¹⁵ For example, filing an RCE at month 40 of prosecution will limit the three-year guarantee to 4 months, regardless of how much longer prosecution lasts. Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34284 (Jun. 21, 2004), 1284 Off. Gaz. 56 (Jul. 13, 2004).

¹⁶ 37 C.F.R. 1.704(c)(11).

¹⁷ 37 C.F.R. § 1.704(c)(10); M.P.E.P. § 2732.

¹⁸ M.P.E.P. § 2731.

result from a telephone election than from a paper election.

6. File papers by Express Mail, with the electronic filing system, or by fax, instead of by first class mail.

Papers filed by Express Mail and complying with the other requirements of 37 C.F.R. § 1.10 will be considered filed on their date of mailing for purposes of calculating PTA.¹⁹ Papers filed using the electronic filing system will be accorded the date of receipt as the filing date.²⁰

Papers filed by facsimile will be considered filed on their date of complete receipt by the PTO only if the PTO is open for business on that day. Otherwise, the transmission will be deemed received on the next day that is not a weekend or federal holiday within the District of Columbia.²¹ While this practice does not affect meeting a deadline that falls on a weekend or holiday (because such deadlines are automatically extended to the next PTO business day), it will reduce PTA. So avoid filing papers by facsimile on days that the PTO is closed.

Papers filed by first-class mail are considered for PTA purposes as having been filed on the day that they are received by the PTO, *even if the paper includes a certificate of first-class mailing.*²² Since mail delays can amount to a week or more, PTA is maximized by avoiding first-class mailing.

Papers may also be filed during business hours by hand delivery to the

Customer Service Window (currently in the Randolph Building at 401 Dulany Street, Alexandria VA 22314).

7. Avoid terminal disclaimers.

As mentioned above, the PTO Office of Patent Legal Administration takes the view that the disclaimer provision of 35 U.S.C. § 154(b)(2)(B) applies to terminal disclaimers that do not expressly state an expiration date but instead specify only another patent or patent application as the measuring stick. This makes sense because the statutory term of a given patent may be readily determined, and because one purpose of the terminal disclaimer is to prevent unfair time-wise extension of patent rights. However, the PTO acknowledges that the question is ultimately one of statutory interpretation that will be decided by the courts.²³

A terminally-disclaimed patent may, however, be eligible for PTA that does not extend its term beyond the earlier patent's expiration date. This may happen, for example, if the earlier patent itself is entitled to PTA or some other form of patent term extension. Suppose the earlier patent is entitled to 40 days' PTA. If the later patent accumulated a calculated 100 days of delay, it would be entitled to PTA for 40 of those days. Note that the PTO does not adjust the PTA to take terminal disclaimers into account; instead, it lists the calculated PTA on the face of the patent with a caveat that the PTA is subject to any disclaimer of patent term. So in the present hypothetical case, the later patent would issue with a PTA of 100 days listed on its face; it is the patentee's responsibility to determine the effect of any disclaimer on PTA.

Nevertheless, practitioners should reconsider the near-automatic practice of

¹⁹ *Id.*; M.P.E.P. § 2733.

²⁰ "Legal Framework for EFS-Web." <URL: <http://www.uspto.gov/efc/portal/efs/legal.htm>>. The date of receipt is reckoned based on the time at the PTO, not the local time of the sender. Hence, a paper filed at 23:00 Pacific Time will be deemed filed the following day for PTA purposes.

²¹ 37 C.F.R. §§ 1.6(a)(3), (d).

²² M.P.E.P. § 2731.

²³ PTO Office of Patent Legal Administration, Personal Communication, May 22, 2006.

filing terminal disclaimers to obviate non-statutory double patenting rejections in related applications if PTA may be affected. Although attacking a double patenting rejection may require critiquing the claim scope of the applicant's earlier patent or application on which the rejection is based, the potential PTA boon may justify the risk of estoppel or prosecution disclaimer.

8. Fix errors in PAIR before allowance.

The PTO calculates PTA using a computer algorithm that bases its calculations on the submission filing dates recorded in the PAIR system.²⁴ Hence, errors in PAIR may contribute to errors in the PTA calculation. A PAIR error may be an error in a submission filing date or an action mailing date, an error in the description of a submission or action (such as listing comments on a statement of reasons for allowance as a "miscellaneous incoming paper"), an omission of a paper that was actually filed or mailed, or the inclusion of a paper never actually filed or mailed. M.P.E.P. § 2731 specifically advises practitioners to call to the PTO's attention any PAIR errors prior to allowance of an application, because PAIR corrections before allowance can be requested and made informally, while PTA corrections after allowance will require the filing of a formal, detailed request to correct the PTA.

9. Appeal rejections.

Time spent in an ultimately successful review will count toward PTA, from the day a Notice of Appeal is filed to the day a decision is issued by the Board of Patent Appeals and Interferences or a Federal

court that reverses an adverse determination of patentability, provided the patent issues "under" that decision.²⁵ A patent issues "under" a decision when it includes at least one claim for which the appellate decision reverses all rejections and does not impose any new grounds of rejection.²⁶ A remand by a panel of the Board of Patent Appeals and Interferences to the examiner (not an administrative remand) may also be considered such a "decision" under certain circumstances, even though the panel does not formally reverse a rejection.²⁷ Although pendency times at the Board have been greatly shortened and are now measured in months rather than years for most appeals, an appeal can still consume a year or more in briefing and consideration, and the entire time for a successful appeal adds to PTA.

One especially noteworthy feature in appeals is that taking extensions of time to file an Appeal Brief is *not* considered "failure to engage in reasonable efforts" to advance prosecution and will not result in PTA reduction under 37 C.F.R. § 1.704(b), because an Appeal Brief is filed following a Notice of Appeal and not directly in response to any "rejection, objection, argument or other request" by the PTO.²⁸ An applicant seeking to increase PTA may therefore consider taking a full five month extension of time before filing an appeal brief.²⁹

²⁴ PAIR is the "Patent Application Information Retrieval" System and is accessible through the PTO website <URL: www.uspto.gov>.

²⁵ 35 U.S.C. § 154(b)(1)(C)(iii); 37 C.F.R. § 1.702(e).

²⁶ Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term, 65 Fed. Reg. 56,363, 56,369-70 (Sept. 18, 2000), 1239 Off. Gaz. 14 (Oct. 3, 2000).

²⁷ 37 C.F.R. § 1.702(e); Revision of Patent Term Extension and Patent Term Adjustment Provisions, 69 Fed. Reg. 21,704 (Apr. 22, 2004), 1282 Off. Gaz. 100 (May 18, 2004).

²⁸ PTO Office of Patent Legal Administration, Personal Communication, May 22, 2006.

²⁹ This exception does not apply to the filing of a

Time spent in a pre-appeal brief request for review does not count toward PTA, even if the request is successful, because the decision of the pre-appeal review panel is not a decision of the Board or of a Federal court.³⁰

Upon allowance:

10. Do not file papers after allowance.

Most papers filed after allowance are deemed to represent failure of the applicant to engage in reasonable efforts to conclude prosecution, because they interfere with the preparation of the application for issuance.³¹ Common after-allowance papers that reduce PTA include amendments under 37 C.F.R. § 1.312, certified copies of priority documents, drawings (discussed above), supplemental declarations, and status inquiries.³² Exceptions include timely issue fee payments (of course), comments on an examiner's statement of reasons for allowance, and change of small entity status, among others.³³ The PTA will be reduced by the lesser of four months or the number of days from the filing of the after-allowance paper to the mailing date of a PTO reply or notice in response to the paper.³⁴

11. Independently confirm the PTO's calculation of PTA.

The notice of allowance will include a

Reply Brief, because the rules specifically exclude reply briefs from eligibility for extensions of time, 37 C.F.R. § 1.136(a)(1)(ii), and because a Reply Brief is filed in response to an Examiner's Answer or Supplemental Answer.

³⁰ "Pre-Appeal Brief Conference Pilot Program." 1296 Off. Gaz. 67 (July 12, 2005).

³¹ M.P.E.P. § 2732.

³² *Id.*

³³ *Id.*

³⁴ 37 C.F.R. § 1.704(c)(10).

page setting forth the calculated PTA. As discussed above, this calculated value may be wrong, especially if there are errors in the PAIR records for the application. Practitioners can offer clients independent confirmation of the PTA calculation on a case-by-case basis or perform it as a matter of routine.

12. Request correction diligently, even for favorable errors.

A correction in the PTA reported in the notice of allowance must be requested by filing a request for reconsideration of PTA under 37 C.F.R. § 1.705(b) *before payment of the issue fee*. Such a request requires a detailed factual statement laying out all pertinent dates, the correct PTA, the bases for the correct PTA, and any delays caused by the applicant that will reduce the PTA, as well as a \$200 processing fee (even for errors caused by the PTO).³⁵

If the request for reconsideration of the PTA includes a request to reinstate a portion of PTA reduced for failure to reply to an Office action within three months, the request must also be accompanied by a \$400 processing fee and a showing that, despite all due care, the applicant was unable to reply within three months.³⁶ M.P.E.P. § 2734 sets out several examples of showings that may or may not satisfy this requirement.

Upon issuance:

13. Re-calculate the PTA.

The Issue Notification and the issued patent will include a second statement of PTA, which will reflect any changes to PTA resulting from events following mailing of the notice of allowance.³⁷ Any request for reconsideration of the PTA

³⁵ 37 C.F.R. § 1.705(b).

³⁶ 37 C.F.R. § 1.705(c).

³⁷ 37 C.F.R. § 1.705(d); M.P.E.P. § 2735.

indicated in the patent must be filed under 37 C.F.R. § 1.705(d) *within two months of issuance* and must include a detailed factual statement as described above. Such a request cannot request PTA correction on the basis of issues that could have been raised in response to the notice of allowance, and any request under 37 C.F.R. § 1.705(d) will be dismissed as to those issues.³⁸

Even PTA errors in the patentee's favor (i.e., indicating a longer PTA than that to which the patentee is entitled) should be corrected, lest the patentee unwittingly attempt to enforce the patent during the period of unearned PTA. If the time period for correcting PTA has passed, a patentee considering enforcing its patent during the PTA period should still independently confirm that it is entitled to the PTA period to be enforced. Unearned PTA may be surrendered by filing a disclaimer under 35 U.S.C. § 253, second paragraph and 37 C.F.R. § 1.321(b).

At any time:

14. Ask questions.

The laws and rules defining PTA are among the most complicated in patent practice, and their many nuances are not treated in this article. Accordingly, practitioners are well advised to study 35 U.S.C. § 154(b), 37 CFR §§ 1.701-705, and M.P.E.P. §§ 2730-2736 to become knowledgeable in this subject. In addition, practitioners with PTA questions concerning specific applications may contact the PTO's PTA help line at 571-272-7702. The help line is staffed by attorneys in the Office of Patent Legal Administration.

³⁸ *Id.*