Patent Term Adjustments and Extensions: Leveraging Recent Decisions and USPTO Rule Changes

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Patent Term Adjustments and Extensions: Leveraging Recent Decisions and USPTO Rule Changes
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Patent Term Adjustment and AIA

- AIA SEC. 9: A patentee’s challenge to the USPTO’s PTA calculation that is filed on or after September 16, 2011, must be filed with the U.S. district court for the Eastern District of Virginia ("ED VA"), instead of the U.S. district court for the District of Columbia ("D DC").
Patents Eligible for PTA

- 37 C.F.R. §1.702 Grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

- 37 C.F.R. §1.701 Extension to patent term for examination delay for utility patent applications filed on or after June 8, 1995, and before May 29, 2000.
Importance of Patent Term Adjustment

Figure 1  The S-shape curve life cycle of patent value. Successful pharmaceutical R&D in each phase increases the potential value of a patent. In the early stages of patent licensing, the patent’s value is low because of the risks and uncertainties involved. However, in the later stages, such as phases 1–3, the value of a pharmaceutical patent grows at an accelerated pace as the potentially huge market revenues protected by the patent are realized. Data source: Ministry of Economic Affairs.

Nature Biotechnology, 29(9):298-801 (Sept. 2011)
Three Types of Patent Term Adjustment
35 U.S.C. § 154(b)(1)(A)-(C)

“A Guarantee / A Delay” – “Guarantee of prompt [PTO] responses”: 1 day of patent term extension for each day of delay due to the failure of the Patent and Trademark Office to meet specific deadlines in (i)-(iv) (“14-4-4-4”);

“B Guarantee / B Delay” – “Guarantee of no more than 3-year application pendency”: 1 day of patent term extension for each day beyond 3 years from filing until the patent issues (subject to certain exclusions);

“C Guarantee / C Delay” – “Guarantee or adjustments for delays due to interferences, secrecy orders, and appeals”: 1 day for each day of the pendency of the proceeding, order, or review.
Example of A-Delay

*Univ. of Mass. v. Kappos, 903 F.Supp.2d 77 (DDC, Nov. 9, 2012)*

- First OA was a restriction requirement.
- PTO and UMass agreed there should be new restriction requirement.
- UMass argued that PTA should include 223 days between 1st and 2nd OA because the first OA was incorrect.
- **District Court:** No.
  - A-delay clock stops when first OA issues.
  - No requirement that the first OA be correct.
  - A-delay = 465 days.
C-Delays
Delays Due To Interferences and Appeals

- **C-Delays**: §154(b)(1)(C), Issue of patent delayed due to interferences, secrecy orders, and appeals.
  - Appellate review by PTAB or a federal court “in which the...review reversed an adverse determination of patentability[.]”

- **Old**: accrues from date Notice of Appeal filed.

- **Now**: accrues from date jurisdiction over the application passes to the Board until date of a final Board /court decision in favor of the applicant.
  - Change applicable to any application in which a notice of allowance is issued after September 16, 2012, and any patent issuing thereon (and any timely reconsideration request after Sept. 16, 2012).
  - 37 C.F.R. 1.703(e)
C-Delays
Delays Due To Interferences and Appeals

• New starting point of “accrues from date jurisdiction over the application passes to the Board”
  • Defined as when reply brief is filed or time to file has expired.
  • Removes many months of PTA from C-Delay calculation.
  • Good news if B-Delay is still accruing: any loss in C-Delay will be compensated by an increase in B-Delay (resulting in net increase in PTA).
  • But if B-delay is not accruing, results in a net loss of PTA.
  • Note, failure to file an Appeal Brief within 3 months from filing of Notice of Appeal will be deemed applicant delay.
Appeal Cases

- Appeal decision successful (decision on at least one claim reversed) 05/04/2010
- Filing Date 11/05/2004
- First appeal Filed 12/06/2006
- Three Years from Filing 11/05/2007
- 3-Year Deadline for PTO Action

Notes:
- No possibility of B delay because filed appeal before 3-year clock.
- Days from PTA could be deducted for applicant delay if come under list of “no-no’s”

C Delay = 1246 days, but only get it if appeal successful.
## Appeal Cases

<table>
<thead>
<tr>
<th>Filing Date</th>
<th>Three Years + 1 day from Filing</th>
<th>First Appeal Filed</th>
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<td>05/04/2010</td>
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### Notes:
- C delay overlaps with B delay, no double-counting \((B+C)-C = 911\) days
- Days from PTA could be deducted for applicant delay if come under list of “no-no’s”
Appeal Cases

- Filing Date: 11/05/2004
- Three Years + 1 day from Filing: 11/06/2007
- First appeal Filed: 12/18/2008
- Appeal decision unsuccessful: 05/04/2010

3-Year Deadline for PTO Action

Proper B Delay = 911 days

Notes:
- No C delay because appeal unsuccessful, but get all of B delay = 911 days.
- Because you filed the appeal after three years, then B delay will accrue, irrespective of whether you win the appeal.
- Days from PTA could be deducted for applicant delay if come under list of “no-no’s”
B-Delays
More Than 3-Year Application Pendency
(Focus for Today’s Webinar)

• B-Delays: §154(b)(1)(B), Issue of an original patent is delayed due to the failure of the US PTO to issue a patent within 3 years after the actual U.S. application filing date, not including—
  • any time consumed by continued examination of the application requested by the applicant under section 132(b);
  • time consumed by an interference, imposition of a secrecy order, or time consumed by PTAB or Federal court review; and
  • any delay at the request of the applicant.
Limitations on Patent Term Adjustment


Disclaimed term applies to all of A, B and C-Delay: TERMINAL DISCLAIMER (35 U.S.C. § 154(b)(2)(B)).


• USPTO list of “no-no’s” at 37 C.F.R. §1.704
Recent Additions to USPTO List of “no-no’s” at 37 C.F.R. §1.704

- (c)(10): Submission of an amendment after a notice of allowance, adjustment reduced by lesser of number of days from when amendment filed to date of Office Action or 4 months.

- (c)(11): Failure to file an appeal brief in within 3 months after notice of appeal filed, adjustment reduced by the number of days from date 3 months from the date notice of appeal to PTAB filed until appeal brief or RCE filed.

- (c)(12): Submission of a RCE after notice of allowance mailed, adjustment reduced by the number of days from day after the date of mailing of the notice of allowance and ending on the date the RCE was filed.

- (c)(13): Failure to provide an application in condition for examination within eight months from either the date on which the application was filed/national stage commenced, adjustment reduced by the number of days date eight months from either date of filing/national stage commenced and ending on the date the application is in condition for examination.

- (c)(14): Further prosecution via a continuing application, adjustment shall not include any period that is prior to the actual filing date of the application that resulted in the patent.
Recent Additions to USPTO List of ‘no-no’s’ at 37 C.F.R. §1.704

• (d)(1): A paper or RCE containing only an IDS will not be considered a failure to engage in reasonable efforts to conclude prosecution, if the paper or RCE is accompanied by a statement that each item of information contained in the IDS was first cited by or is a communication from a foreign patent office or USPTO and was not received more than 30 days prior to filing the IDS.

• (e): request for reinstatement of reduced PTA will not be considered a failure to engage in reasonable efforts to conclude prosecution.

• (f): “condition for examination” means application includes a specification, at least one claim, an abstract, any necessary drawings, any English translation required, a sequence listing if necessary, inventor’s oath/declaration or an application data sheet, the basic filing fee, the search fee, the examination fee, any certified copy of the previously filed application, and any application size fee.
Recent Additions to USPTO List of “no-no’s” at 37 C.F.R. §1.704


Note:

• (c)(12) applicable only to applications in which a RCE is filed on or after Mar. 10, 2015.

• (c)(11), (c)(13), (c)(14) and (f) above include changes applicable only to patent applications filed/national stage commenced on or after December 18, 2013.

• (e) applicable only to applications in which a notice of allowance was mailed on or after April 1, 2013.

• (c)(10)(ii) above includes changes applicable only to patent applications in which a notice of appeal was filed on or after Sept. 17, 2012.
Calculating PTA

• 37 C.F.R. § 1.703(f):

  • PTA “will run from the expiration date of the patent[.]”

    • Sum of the A Delay, B Delay, and C Delay, “to the extent that such periods are not overlapping, less the sum of the periods [for applicant delay].”

    • Overlap is calculated by counting delays occurring on the same calendar days but only counting those days once.

      • Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010)

      • Before Wyeth, USPTO interpreted statute as only allowing greater of A-delays or B-delays, not both. Now, it is A-delays plus B-delays, minus overlapping days.
Calculating PTA: Add PTE

- 37 C.F.R. § 1.703(f):
  - Patent Term Extension ("PTE") is in addition to PTA. 35 U.S.C. §156(a): “The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b). [.]"
RCE Cases
(Pre-ExelixisI/ Novartis)

Filing Date: 11/05/2004

Three Years + 1 day from Filing: 11/06/2007

First RCE Filed: 12/18/2008

Notice of Allowance: 12/14/2009

Issue Date: 05/04/2010

PTO B Delay = 408 days

3-Year Deadline for PTO Action
RCE Cases

- US PTO Interpretation of 37 C.F.R. § 1.703(b)(1):
  - that any time consumed by an RCE is excluded from the B Delay determination, even if it occurs after the three-year window has closed; and
  - “time consumed by” an RCE extends until the issuance of the patent.

In Exelixis, Inc. v. Kappos, 2012 WL 5398876 (E.D. Va. Nov. 1, 2012) and Novartis AG v. Kappos, 2012 WL 5564736 (D.D.C. Nov. 15, 2012), patent owner argued USPTO improperly cuts off B Delay when an RCE is first filed after the PTO has failed to issue a patent within three years of the application’s filing date.
Time Between Allowance and Issuance

- Although not addressed in district court decision, in its complaint, Novartis argued that even if B-Delay stopped accruing upon filing a RCE, the PTO's calculation of B Delay still improperly excluded the time between the Notice of Allowance and Issuance.

- Continued examination of the applications corresponding to the RCE-Affected Patents concluded on the date the notices of allowance were mailed.

- B-Delay should accrue from the date the PTO mailed the notices of allowance for these patents through the date of issuance of these patents.
But Wait a Minute!

  - Judge Brinkema took a different view of the statutory language, and denied Exelixis’ motion to correct the PTO’s calculation of PTA.
RCE’s After 3-Year Deadline Should Be Treated Same as RCE’s Prior to 3-Year Deadline

Exelixis II (con’t)

at *8. With all due respect to our colleague, this Court parts ways with the reasoning in Exelixis I and declines to find that the statute’s silence as to RCEs filed after the three-year period expresses “plain and unambiguous” congressional intent on the issue. To the contrary, we find that a reasonable interpretation of the statute and its legislative history support the conclusion that there is no reason to treat RCEs differently based upon when they were filed, and that accordingly, the PTO’s regulation deserves Skidmore deference because it is a “reasonable conclusion as to the proper construction of the statute.” Cathedral Candle, 400 F.3d at
Avoids “Absurd” Result

Exelixis II (con’t)

on Patents § 13.03. Not only does an RCE permit applicants to retain their accrued PTA (unlike the filing of a CPA, see 37 C.F.R. § 1.704(c)(12)), but there is currently no limit on the number of times an applicant is permitted to file an RCE to raise “new arguments” or “new evidence” after a final notice of rejection has been issued.¹⁴ Thus, availability of unlimited RCEs creates the potential for the very abuses that spurred reform of the laws on patent terms in the first place. In light of this legislative history and legitimate, pragmatic congressional concern, the PTO’s regulation denying PTA from the time an RCE is filed comports with “a reasonable conclusion as to the proper construction of the statute” under Skidmore.
**Abraxis Follows *Exelixis II***


*Abraxis* argued either (1) **323 days**, if the end date of the Part B delay is the issuance of the notice of allowance rather than the issue fee payment date; or (2) **372 days** (A=Delay 135 days + B-Delay 365 days – 23 days overlap – 105 days applicant delay).
Abraxis Follows Exelixis II

- *Abraxis* (con’t)
  - Abraxis 2 arguments
    - PTA should include the days between the payment of the issue fee and the issuance of the patent; and
    - Part B delay accrues regardless of any RCE filing.
• **Abraxis (con’t)**

  • **District Court:**

    • “the Court cannot agree with the conclusion of the *Exelixis I* and *Novartis* courts that statutory silence about the effect of an RCE filing after the three-year statutory deadline unambiguously means that Part B delay accrues regardless of any other action taken in the post-deadline period.”

    • “In other words, if, as the Exelixis I and Novartis courts opined, RCE filings under subparagraph (B)(i) were not considered applicant delay, and applicant delay were restricted to subparagraph (B)(iii), then the limitations set out in paragraph (2)(C) reducing PTA for applicant delay should have been restricted in application to subparagraph (B)(iii), but they are not.”
Congressional Record of Technical Amendment

  - “The Committee is aware that the district court for the Eastern District of Virginia, on November 1 of this year, issued a decision in the case of Exelixis v. Kappos that appears to have adopted a highly problematic interpretation of the patent term adjustment allowed by § 154(b)(1)(B). For reasons that remain unclear, the court concluded that continuations and other events described in the “not including” clauses of that subparagraph should not be excluded from the subparagraph’s calculation of patent term adjustment, but instead must be read only to toll the three-year clock that determines when patent term adjustment begins to accrue under subparagraph (B). The district court’s interpretation of subparagraph (B) thus would allow patent term adjustment to accrue for any continued examination sought after the three-year clock has run. Such a result, of course, would allow applicants to postpone their patent’s expiration date through dilatory prosecution, the very submarine-patenting tactic that Congress sought to preclude in 1994 when it adopted a 20-year patent term that runs from an application’s effective filing date.”
“Despite the absurd and undesirable results that would appear to flow from the district court’s interpretation, the Committee declines to address this matter at this time. This case was brought to the Committee’s attention only very recently, precluding the thorough consideration and consultation that is appropriate before legislation is enacted. Moreover, Congress is not in the business of immediately amending the United States Code in response to every nonfinal legal error made by a trial court. The Committee, of course, reserves the right to address this matter in the future. In the meantime, the fact that the present bill does not amend § 154(b) to address the Exelixis decision should not be construed as congressional acquiescence in or agreement with the reasoning of that decision.”
Jan. 15, 2014
The Federal Circuit


  - Vacate and remand.

  - "We address those two interpretations in our decision today in Novartis AG v. Lee, No. 13-1160 (Fed. Cir. Jan. 15, 2014). Based on the ruling in Novartis, we vacate the judgments as to patent term adjustment for the ‘436 and ‘622 patents in this case and remand for redetermination of the proper adjustments in accordance with Novartis.”
• *Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014)*

• PTA determination (reversed-in-part)

  • “no 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 patent term adjustment time 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. Such a reading ensures that applicants recover for any ‘delay[s] due to the failure of the [PTO],’ without allowing the applicant to recover for ‘any time consumed by continued examination,’ as the statute requires. Id. § 154(b)(1)(B)(i).”
Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014)

"...the correct interpretation of the statute is the PTO’s view that time spent in a continued examination does not deplete the PTO’s allotment of three years for application processing before a resulting patent has its term extended, no matter when the continued examination begins."
Affirmed Time After Allowance Until Issuance Should Be Counted

- **Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014)**
  
  - "While we thus disagree with Novartis on its first § 154(b)(1)(B) issue, we agree with Novartis on its second § 154(b)(1)(B) issue. ...We reject the PTO’s view that the time after allowance, until issuance, is ‘time consumed by continued examination’ and so is excluded from adjustments given to the patentee. Such time from allowance to issuance undisputedly would count toward the PTO’s three-year allotment in a case not involving a continued examination. There is no basis for distinguishing a continued examination case."
  
  - "In the present case, time after allowance was not time caused by the continued examination. Because the PTO applied the contrary view in calculating the patent term adjustment for the ’155, ’518, and ’631 patents, those calculations must be corrected."
And Affirmed Tolling Decision

- Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014)
  - 180-day clock applies to challenges of final PTA determinations.
  - Novartis did not file suit within 180 days of denial of reconsideration, so Novartis’ claims for 15 patents untimely.

Federal Circuit in *Novartis*: time excluded from B-delay for filing a RCE > 3 years after filing ends at allowance, not the issue date.
  • “allowance-to-issuance time is not to be distinguished according to whether there is a continued examination in a prosecution. Either way such time is plainly attributable to the PTO.”

Where PTA did not include days between allowance and issuance, file request that the time from allowance to issue be included in B-delay.
  • As pointed out by Susan J. Mack and Azy S. Kokabi, Sughrue Mion PLLC in IPLaw 360 article, “Calculating Patent Term Adjustment Post-Novartis” (Feb. 13, 2014): for patents issuing on or after Jan. 14, 2013, all applications for PTA must be filed within seven months of the issue date (two months from the grant of the patent plus an additional five months with payment of extension of time fees).
  • Novartis decision Jan. 15, 2014, so includes any patent issuing on or after June 15, 2013.
NEW RULES


DATES: Effective date: The changes to 37 CFR 1.703 in this final rule are effective on January 9, 2015, and the changes to 37 CFR 1.704 in this final rule are effective on March 10, 2015.

Applicability date: The changes to 37 CFR 1.703 in this final rule apply to any patent granted before, on, or after January 9, 2015. 37 CFR 1.704 as adopted in this final rule applies to all original applications (other than for a design patent) filed on or after May 29, 2000, and to patents issued on such applications, except that 37 CFR 1.704(c)(12) as adopted in this final rule applies only to applications in which a request for continued examination under 35 U.S.C. 132(b) and 37 CFR 1.114 is filed on or after March 10, 2015, and 37 CFR 1.704(c)(13) as adopted in this final rule applies only to patent applications filed under 35 U.S.C. 111 on or after December 18, 2013, and international patent applications in which the national stage commenced under 35 U.S.C. 371 on or after December 18, 2013.

See slides 15-17
Gilead Sciences, Inc. v. Lee, 778 F.3d 1341 (Fed. Cir. 2015)

- Restriction requirement issued November 18, 2009
- Gilead responded on February 18, 2010
- Gilead filed a supplemental IDS on April 16, 2010 (before Office Action).
- USPTO assessed 57 days of applicant delay based on time between Gilead’s initial reply to restriction requirement and filing supplemental IDS.
- DC: Granted summary judgment in favor of USPTO.
- FC: Affirmed.
  - “this court finds that a reasonable interpretation of the statute is that Congress intended to sanction not only applicant conduct or behavior that result in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred.”
Mohsenzadeh v. Lee, 790 F.3d 1377 (Fed. Cir. 2015)

- Mohsenzadeh filed the original patent application on July 6, 2001.
- USPTO issued restriction requirement on Sept. 21, 2006 - more than 5 years later (A-delay).
- Patent issued June 2010 with PTA including 1476 days for delay in issuing restriction requirement.
- Divisionals claiming other methods filed Jan. 8, 2010, issued without PTA.
- Mohsenzadeh asked for PTA of 1476 days on each, because each claimed same priority date as the original application.
- USPTO refused.
Mohsenzadeh (con’t)

- District court: Granted summary judgment to USPTO.
- FC: Affirmed.
  - A patent is only entitled to PTA for delay in the prosecution of the application from which the patent directly issued, not the application from which it derived priority.
  - Section 154(b)(1)(A) “an application” limited to the original application.
  - “The language of the provision of the patent term adjustment statute at issue ... clearly shows that Congress intended delay in the prosecution of an application to be restored to a single patent, the patent issuing directly from that application”
RECENT FEDERAL CIRCUIT PTA DECISIONS

- *Daiichi Sankyo Co. Ltd. v. Lee*, 791 F.3d 1373 (Fed. Cir. 2015)

    - File petition for reconsideration up to 180 days after patent issuance, as long as sole basis for reconsideration was that PTA calculated pre-*Wyeth*.

  - Two Daiichi patents issued prior to Aug. 5, 2009, but Daiichi argued should be eligible for recalculation under the new standard, which it said would have added at least 321 days to both patents.

  - USPTO denied petition.

  - DC: Granted judgment to USPTO.

  - FC: Affirmed.
    - USPTO did not abuse discretion.
**RECENT FEDERAL CIRCUIT PTA DECISIONS**

- *Daiichi* (con’t)
  - DC: Agreed USPTO should recalculate PTA of the one patent eligible for Optional Interim Procedure (patent granted within 180 days of March 2, 2010).
    - Remanded optional interim procedure patent for recalculation from 86 to 503 days.
      - But this patent terminally disclaimed over the two ineligible patents.
• *Daiichi* (con’t)

• Daiichi amended complaint.
  • 35 U.S.C. §154(b)(4)(A)’s 180-day limit for judicial review does not apply to challenges of final PTA determinations (only initial determinations);
  • Even if 180-day limit applies, should be equitably tolled because Daiichi relied on USPTO 2004 Notice and if promptly sought administrative and judicial review when district court decided *Wyeth*.
  • PTO’s use of 180-day limit for administrative review violates the APA.
**Daiichi** (con’t)

- FC: Affirmed.
  - USPTO acted within its discretion to adopt 180-day limit.
  - Denying requests for reconsideration of PTA filed more than 180 days after patent issuance was not an abuse of discretion.
  - All patents issuing before Interim Procedure cutoff date treated the same.
  - Refusal to suspend the 180-day limit was not “arbitrary, capricious, and not in accordance with the law.”
PATENT TERM ADJUSTMENT – EXAMPLE 1

A-Delay - 876
B-Delay - 982
C-Delay - 0

876 + 982 - 206 = 1652 - 616 = 1036 days (2.8 years)

PTA lost post-RCE = 815 (2.2 years) (no PTA accrues after filing RCE)

Note: PTE, if any, is added to PTA.
PATENT TERM ADJUSTMENT – EXAMPLE 2

A Delay - 888  Non-overlapping USPTO delays - 1788
B Delay - 474  Applicant Delays - 13
C Delay - 675

888 + 474 + 675 - 218 = 1819 - 13 = 1806 days (4.9 years)

Note: PTE, if any, is added to PTA.
PATENT TERM ADJUSTMENT – EXAMPLE 3

A Delay - 838
B Delay - 1413
C Delay - 871

838 + 1413 + 871 - 168 = 2954 - 205 = 2749 days (7.5 years)

Prosecution by Appeal: 153 days of PTA did not accrue during first appeal; but because no RCE was filed, an additional 404 days of B-Delay did accrue.

Note: PTE, if any, is added to PTA.
PROCEDURE FOR CHALLENGING PTA

• **37 CFR § 1.705(b)**
  • A request for reconsideration must be filed no later than two months from date of issuance.* Usually (A) and (B) delay; could also be (C) delay
  • USPTO–determined-PTA is now provided “no later than date of issuance” of the patent (See §154(b)((3)(B)(i))).

• **Under 35 USC § 154(b)(4)**
  • File district court action in E.D. Va. within 180 days “after the date of the Director's decision on the applicant's request for reconsideration.”

*applicable only to patents granted on or after January 14, 2013.*
TIPS FOR TRYING TO MAXIMIZE PTA

• Review US PTO’s PTA calculation in Notice of Allowance and, if disagree, must act quickly to preserve rights.
  • Consider two-prong approach: after patent issues, request reconsideration in US PTO within 2 months and file district court case within 180 days of issuance.
  • If application falls under new guidance, may not need to file suit within 180 days, but there may be questions about which cases fall under new guidance.
  • Consider filing another case or amended complaint within 180 days of decision by PTO even if filed earlier.
    • Would not want to file too early, get dismissed and then be unable to re-file because deadline had passed.
TIPS FOR TRYING TO MAXIMIZE PTA

• Respond within 3 months of an action – don’t take extensions.
  • 37 C.F.R. §1.704(b): >3 months is “failure to engage in reasonable efforts to conclude processing or examination” and will mean deduction from PTA.
  • Respond right at end of 3 months??

• Verbally communicate election; a written restriction requirement will stop the 14-month clock.

• File electronically.
TIPS FOR TRYING TO MAXIMIZE PTA

• Try to file complete replies.
  • Ask examiner if a problem can be corrected in the next reply or by an examiner’s amendment.

• Avoid Terminal Disclaimers.

• Avoid RCE’s?
  • Be aggressive and argue against or appeal final rejections rather than use RCE.
  • Appeals?

• Once 3-year deadline has passed, consider paying the issue fee at the last possible moment to maximize (B) delay.
MAXIMIZING PTA:
AVOIDING PITFALLS

• Avoid filing papers after allowance.
  • Ask examiner to make corrections by examiner’s amendment.
  • If a problem can be corrected by certificate of correction, wait and file after patent issues.

• Consider filing a CIP rather than a continuation.
  • First action for a CIP typically takes longer than for a continuation.

• Timely file Information Disclosure Statements (IDS)
  • File an IDS before the first office action or with a reply.
    • Not considered untimely if IDS is filed within 30 days of a communication from the USPTO or a foreign patent office with a certification under 37 C.F.R. § 1.704(d).
    • Earlier rule only included foreign office communications.
    • Certification under 37 CFR § 1.97(e)(1) does not prevent loss of PTA (within 3-months).
MAXIMIZING PTA: AVOIDING PITFALLS

- File Appeals – if grounds exist and record supports.
  - Establish necessary record early in prosecution to support appeal.
  - If examiner re-opens prosecution through an office action currently no C-Delay accrues.
    - No favorable decision by the Board.
    - A-Delay from the Appeal Brief filing until examiner issues an office action to re-open prosecution (any time over 4 months).
    - But B-Delay, if available.
  - Currently, some extensions of time during the appeal process do not count against the applicant for PTA.
    - But, e.g., extension for filing an Appeal Brief = applicant delay.
CALCULATE YOUR OWN PTA

• PTA as calculated by USPTO is issued no later than issue date.

• Check USPTO’s calculation of PTA to ensure that it is correct.
  • Based on data found in “PAIR” - but not always accurate.

• Final PTA will be indicated on the face of the issued patent.
WHAT SHOULD CORPORATE COUNSEL BE DOING?

- Identify pending applications that cover inventions that are expected to retain value at end of patent term.

- Carefully analyze US PTO’s PTA calculation.
  - Make sure correct under current law.
  - Determine if law not being properly applied by US PTO.
  - If disagree, must act quickly to preserve rights.
    - After patent issues, request reconsideration in US PTO within 2 months and prepare to file district court case within 180 days of decision on request for reconsideration.
PATENT TERM EXTENSION
35 U.S.C. § 156

- 35 U.S.C. § 156 provides for patent term extensions for a patent that claims a product, a method of making a product, or a method of using a product that has been subject to premarket regulatory review before it is approved for commercial marketing in the United States.

- Extension = \( \frac{1}{2} \) (testing phase) + approval phase - any time applicant did not act with due diligence

○ Not to exceed 5 years from patent expiration, exclusive of any regulatory review period occurring before the patent issues §156(g)(6) or not to exceed 14 years from NDA approval § 156(c)(3), whichever comes first.
HOW DELAY IN PATENT ISSUANCE COSTS PTE

- How to lose some 900 days of patent term extension because of delayed issuance
- Scenario 1:
  - Day 0 - Regulatory review starts
  - Day 1 - Patent issues
  - Day 1000 - NDA filed
  - Day 1500 - FDA approval

Patent gets about 999/2 of PTE for the regulatory review to NDA period and all 500 days for the regulatory period from NDA to FDA approval, 500 + 500 = 1000 (subject to the 5/14 year caps)
How to lose some 900 days of patent term extension because of delayed issuance

Scenario 2:
- Same facts but patent issues on Day 998
- Patent gets 2/2 of PTE for the regulatory review to NDA period and all 500 days for the regulatory period, from NDA to FDA approval, 1+500 = 501 (subject to the 5/14 year caps).

Scenario 3:
- Same facts but patent issues on Day 1400
- Patent gets 0 of PTE for the regulatory review to NDA period, and only 100 days or so of PTE in the NDA approval time span, 0+100 = 100 (subject to the 5/14 year caps).
Hypothetical Example:
Patent Term Extension Timeline for U.S. 0,000,001 (broad drug substance)

13 Aug 2002
'001 Patent Grant

16 Jun 2004
IND Date

16 Jul 2004
Regulatory Review Start Date

3 Jan 2011
NDA Filed

6 Sep 2012
NDA Approval Date

6 Sep 2016
Initial ANDA Challenge Date

6 Sep 2017
NCE Expiration Date

1 Sep 2019
Original Expiration of the '001 Patent (OPFA)
(PCT filed 1 Sep 1999)

1 Sep 2024
Original Expiration + 5 years

6 Sep 2026
NDA Approval + 14 years

30 Jul 2024
Appx. Expiration of the Extended '001 Patent

Patent term (no PTA, no extension): 20 years from PCT filing, almost 7 years from NDA approval date.
Patent term with 5 year extension: 25 years from PCT filing, almost 12 years from NDA approval date.
14 year cap: 24 years from patent grant, 14 years from NDA approval date.
5 year cap is earlier, BUT eat into PTE if grant is after 16 Jul 2004 (AIA Prioritized Track I Exam: from 9/16/11 can accelerate issuance)
Hypothetical Example Showing LOSS in PTE from taking longer to get the patent
Patent Term Extension Timeline for U.S. 0,000,001
(broad drug substance)

This slide shows the actual calculations for the regulatory approval period.
Hypothetical Example:
Patent Term Extension Timeline for U.S. 0,000,002
(narrow drug substance covering approved product and bioequivalents)

Patent term (no PTA, no extension): almost 17 years from grant, some 8+ years from NDA approval date.
Patent term with 5 year extension: almost 22 years from grant, some 13+ years from NDA approval date.
14 year cap: 22 years 5 mos. from patent grant, 14 years from NDA approval date. 5 year cap is earlier.
Longer expiration than ‘001 A key: patent issued before 16 July 2004. Issuing thereafter eats into PTE.
‘002: “more enforceable” than ‘001? AIA from September 16, 2011: Track I prioritized exam
Hypothetical Example Showing LOSS in PTE from taking longer to get the patent

Patent Term Extension Timeline for U.S. 0,000,002
(narrow drug substance covering approved product and bioequivalents)

This slides shows the actual calculations for the regulatory approval period
Note that the continuation strategy cost some 2 years of PTE on perhaps the "most enforceable" of the patents '001, '002, and '003. An earlier application in the family could have helped PTE. Track I Prioritized Exam available beginning on 9/16/11 can help get patent earlier and maximize PTE.
Hypothetical Example Showing LOSS in PTE from taking longer to get the patent
Patent Term Extension Timeline for U.S. 0,000,003 (polymorphic form of the drug substance)

This slides shows the actual calculations for the regulatory approval period.
Hypothetical Example: Patent Term Extension Timeline for U.S. 0,000,004 (method of use approved by FDA)

Note that continuation strategy ate into PTE. But ‘004 may not have been the primo patent of the series because generic manufacturer might have been able to seek another indication and might have been able to skinny label.
Hypothetical Example Showing LOSS in PTE from taking longer to get the patent

Patent Term Extension Timeline for U.S. 0,000,004 (method of use approved by FDA)

½ of 1900 days (950)  
all of days (605)

22 Oct 2005  ‘004 Patent Grant  
3 Jan 2011 NDA Filed

6 Sep 2012 NDA Approval Date  
6 Sep 2017 NCE Expiration Date  
6 Sep 2016 Initial ANDA Challenge Date

18 Jul 2022 Original Expiration of the ‘004 Patent Continuation of PCT Priority  
18 Jul 2002

6 Sep 2026 NDA Approval + 14 years

18 Jul 2027 Original Expiration + 5 years

27 Apr 2025 Appx. Expiration of the Extended ‘004 Patent

This slide shows the actual calculations for the regulatory approval period
Assume Prioritized Exam was used for the ‘001; issued in a little over 9 months. ‘001 extension approximately 1460 days; expires 1-01-39, as shown. BUT subject to 14-year cap, 23-10-36, as shown which comes before 5-year cap! Why? Filing after regulatory period began, patent issued quickly.
SAMPLE PTE TIMELINE FOR THE FUTURE
(NOT TO SCALE)

1-1-10
Earliest effective non-prov. filing date

23-10-15
'001 patent grant

23-10-21
Approx. NDA Filing date

23-10-27
Approx. NCE expiration date

23-10-22
Approx. NDA Approval Date

23-10-26
Approx. Initial ANDA challenge date

1-1-30
original expiration of '001 patent + 5 years

23-10-36
approx. NDA approval + 14 years

17-11-13
Approx. IND filing date

17-12-13
Approx. regulat. review start date

‘001 extension approximately 1460 days to ~1-1-34, not shown.
BUT does not even hit 5-year cap, 1-1-35, which comes before 14-year cap! Why?
Filed patent application before regulatory period began; patent did not issue quickly.
LIMITED TIME TO MAKE REQUEST

- Deadline for filing application for PTE: non-extendible 60-day period from the date the product is approved for commercial marketing.

  - Genetics’ request for an interim extension was denied.
  - There are deadlines applying to the filing of patent term extension requests, and the request was not timely filed. See 37 CFR 1.760.
  - DC: the extensions “are not automatic.”
LIMITED TIME TO MAKE REQUESTS

- If the original term of the patent will expire before the product is approved for commercial marketing or use, application for interim PTE must be filed during the period beginning 6 months, and ending 15 days before the term is due to expire.
  - Each subsequent application for interim extension must be filed during the period beginning sixty days before and ending thirty days before the expiration of the preceding interim extension.

- PTE available even where regulatory approval occurs after the expiration date of the original patent term.
• Any patent term extension granted is for the entire patent, not individual claims.
  • “§ 156 applies to the term of the patent, not individual claim(s).” Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc., 655 F.3d 1291 (Fed. Cir. 2011)

PTE AVAILABLE FOR CLASS III MEDICAL DEVICES ALSO

- Medical devices must be approved under § 515 of the Federal Food, Drug and Cosmetic Act to be eligible for term extension. Medical devices approved under § 510(k) are not eligible.

APPLICATION FOR PTE

• Start planning early in the product approval cycle. Avoid last-minute rush.

  • File early to permit US PTO to review the application and identify any potentially fatal errors before the 60-day deadline expires.

  • And whether or not such early review occurs, file well before the non-extendible 60-day period.

  • Draft your PTE application as soon as FDA approval is obtained so you can see if you have any holes to fill.
APPLICATION FOR PTE

• **Start planning early in the product approval cycle. Avoid last-minute rush.**

  • File PTE for all Orange Book-listable patents and later elect which patent will get the PTE.

  • Hedge your bets against foreign litigation and AIA procedures of PGR and IPR.

  • Hedge your bets against possible use of Supplemental Examination.

  • Consider potential further development of approved product.
APPLICATION FOR PTE

• **Start planning early in the product approval cycle. Avoid last-minute rush.**

• Close communication with Regulatory group.
  
  • Make sure appropriate person leading PTE application is identified of approval as soon as possible.
  
  • Alert to need for documents and FDA communication logs.
PROCESSING A PTE REQUEST

• Patentee may file multiple applications for PTE based on different patents but the same regulatory approval of a product.

  • Preserve an opportunity to select an appropriate patent until the time that the Commissioner must grant a certificate of patent term extension.
  • Only one patent may be extended per regulatory review of a particular product.

• All papers are available in theory to the public on PAIR once the application for patent term extension is filed.
NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,444,673, which claims the human drug product LUNESTA® (eszopiclone), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 760 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 760 days.


\[
\text{Period of Extension} = \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase}
\]

\[= \frac{1}{2} (1,256 - 1,106) + 685\]

\[= 760 \text{ days (2.1 years)}\]

Since the regulatory review period began August 25, 1999, before the patent issued (September 3, 2002), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 25, 1999, to and including September 3, 2002, is 1,106 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.
• US PTO Explanation of the calculation:

Since the regulatory review period began August 25, 1999, before the patent issued (September 3, 2002), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 25, 1999, to and including September 3, 2002, is 1,106 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

• Patent granted Sept. 3, 2002
• NDA filed Jan. 31, 2003
• NDA approved Dec. 15, 2004
• PTE application Feb. 11, 2005
• Original expiration Jan. 16, 2012
• Term extension 760 days
• Extended term expiration Feb. 14, 2014
SAMPLE PATENT TERM EXTENSION NOTICE

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,738,974, which claims the human drug product NEXIUM® (esomeprazole magnesium), methods of use thereof and a pharmaceutical composition comprising NEXIUM® (esomeprazole magnesium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 865 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 865 days.


\[
\text{Period of Extension} = \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\
= \frac{1}{2} (838) + 446 \\
= 865 \text{ days (2.4 years)}
\]

Since the regulatory review period began, after the patent issued (April 19, 1988), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.
Reconsideration of the Notice of Final Determination dated March 27, 2007 with respect to U.S. Patent RE 37,314 and the product Crestor is respectfully requested. In particular, Applicant requests correction of the calculation of the Period of Extension, which should have resulted in an extended term of 1305 days rather than 1304 days, giving an Expiration Date of Extension of January 8, 2016. It is respectfully submitted that this error arose from an erroneous rounding down (ignoring) of the one-half day in the 526½ days of the “½ (Testing Phase)” to 526 days when it was added to the 778 days of the “Approval Phase.” As detailed further below, under the regulations (specifically 37 CFR § 1.775(d)(1)(iii)), half days are to be “ignored for purposes of subtraction” of one-half of the Testing Phase from the total regulatory review period, i.e., 1,831 - 526 = 1305 days. To be consistent with the calculation detailed in the regulations (and past practice of the US Patent and Trademark Office), the one-half day should have been rounded up to 527 days when added to the days of the Approval Phase, i.e., 527 + 778 = 1305 days, in the manner the calculation was carried out by the US Patent and Trademark Office.
A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,738,974 for a period of 865 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for
THIRD PARTY HAS 180 DAYS AFTER PUBLICATION OF REGULATORY REVIEW PERIOD TO QUESTION DUE DILIGENCE OF PTE APPLICANT

Dear Director Dudas:

This is in regard to the patent term extension application for U.S. Patent No. 4,738,974 filed by AstraZeneca, LP, under 35 U.S.C. § 156. The patent claims Nexium (esomeprazole magnesium), new drug application (NDA) 21-153.

In the February 28, 2002, issue of the Federal Register (67 Fed. Reg. 9299), the Food and Drug Administration (FDA) published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before August 27, 2002, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired. FDA received one due diligence petition during the comment period. However, that petition has been withdrawn from consideration as confirmed by a telephone conversation, January 3, 2007, between Brian Pendleton, FDA, and Bruce D. Radin, Esq., Budd Larner, P.C. Therefore, FDA considers the regulatory review period determination to be final.
Aktionbolaget Hässle, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,738,974, filed an application for patent term extension under 35 U.S.C. § 156 on April 19, 2001. The original term of the patent is due to expire on April 19, 2005. The patent claims the active ingredient esomeprazole in the human drug product "NEXIUM®," and a method of use of said product. "NEXIUM®" (esomeprazole) was approved by the Food and Drug Administration for commercial marketing or use on February 20, 2001. An extension of 865 days is requested.

The initial review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by the Food and Drug Administration. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,738,974 is granted for a period of one year from the original expiration date of the patent, until April 19, 2006.
INFORMATION REQUIRED IN PTE APPLICATION
37 C.F.R. § 1.740

1. Identity of the Approved Product (37 C.F.R. § 1.740(a)(1))

Pursuant to 37 C.F.R. § 1.740, the chemical and generic name, physical structure or characteristics of the Approved Product, Nexium™ Delayed-Release Capsules, are as follows:

Nexium™ Delayed-Release Capsules contain, as the active ingredient, esomeprazole magnesium, which is the magnesium salt of the S-isomer of omeprazole and the chemical name of which is bis (5-methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole-1-yl) magnesium trihydrate.
INFORMATION REQUIRED IN PTE APPLICATION
37 C.F.R. § 1.740


The Approved Product is a drug product and the submission was approved under Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355(b)).

3. Identity of Date on Which Approved Product Received Permission for Commercial Marketing or Use (37 C.F.R. § 1.740(a)(3))

The Approved Product received permission for commercial marketing or use in a letter dated February 20, 2001, from Lilia Talarico, M.D., Director, Division of Gastrointestinal and Coagulation Drug Products, Office of Drug Evaluation III, and Mark J. Goldberger, M.D., M.P.H., Director, Division of Special Pathogen and Immunologic Drug Products, Office of Drug Evaluation IV, both of the Center for Drug Evaluation and Research, U.S. Food and Drug Administration.
INFORMATION REQUIRED IN PTE APPLICATION
37 C.F.R. § 1.740

4. Identity of Active Ingredient (37 C.F.R. § 1.740(a)(4))

Applicant avers that the active ingredient of the Approved Product is esomeprazole magnesium, which has not previously been approved for commercial marketing or use under the FDCA, 21 U.S.C. § 355(b). Please note that esomeprazole magnesium is a different active ingredient from omeprazole, which is marketed as Prilosec® (NDA 019810), for which a patent term extension has previously been granted.

5. Timely Filing of This Application (37 C.F.R. § 1.740(a)(5))

This application is filed, pursuant to 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), within the permitted sixty-day (60-day) period that began on February 20, 2001, the date the product received permission under 21 U.S.C. § 355(b), and that will expire on April 20, 2001.
6. **Identity of the Patent for Which an Extension Is Sought**
(37 C.F.R. § 1.740(a)(6))

Inventor: Arne E. Brändström  
Patent No.: 4,738,974  
Issued: April 19, 1988  
Expiration: April 19, 2005

7. **Copy of Patent Attached** (37 C.F.R. § 1.740(a)(7))

A copy of the patent for which an extension is being sought, including the entire specification (with claims) and drawings, is attached as Exhibit A.

8. **Disclaimers, Certificates of Correction, Receipts of Maintenance Fee Payment or Reexamination Certificate** (37 C.F.R. § 1.740(a)(8))

Documentation of maintenance fee payments for pay years 04, 08, and 12 is attached as Exhibit B. No disclaimer, certificate of correction or reexamination certificate has been issued with respect to the patent.
INFORMATION REQUIRED IN PTE APPLICATION
37 C.F.R. § 1.740

   (37 C.F.R. § 1.740(a)(9))

   U.S. Patent No. 4,738,974 claims the Approved Product, as shown in Exhibit C.

   Exhibit C presents a chart showing each applicable patent claim (claims 1-2, 4-6, 8-10, 12-14, 16-
   18 and 20) and the manner in which each such applicable patent claim reads on the Approved
   Product or method of using the Approved Product.

10. Statement of Relevant Dates and Information Pursuant to 35 U.S.C. § 156(g)
    (37 C.F.R. § 1.740(a)(10))

   Two NDAs, NDA 21-153 and NDA 21-154, were submitted and approved for Nexium™
   Delayed-Release Capsules. The relevant dates are as follows:
INFORMATION REQUIRED IN PTE APPLICATION
37 C.F.R. § 1.740

11. Brief Description of Significant Activities Undertaken by Marketing Applicant During Applicable Regulatory Review Period and Respective Dates (37 C.F.R. § 1.740(a)(11))

Attached as Exhibit D is a brief description of the significant activities undertaken by the marketing applicant, AstraZeneca LP, with respect to Nexium™ Delayed-Release Capsules during the regulatory review period for each of the two NDAs approved: (a) NDA 21-153, July 18, 1997, to February 20, 2001; and (b) NDA 21-154, November 21, 1997, to February 20, 2001.

12. Statement of Eligibility for Extension (37 C.F.R. § 1.740(a)(12))

Applicant believes that U.S. Patent No. 4,738,974 is eligible for extension under 35 U.S.C. § 156 because it satisfies all of the requirements for such extension as follows:
13. Statement as to Length of Extension Claimed and the Determination of Such Extension (37 C.F.R. § 1.740(a)(12))

In the opinion of the Applicant, U.S. Patent No. 4,738,974 is entitled to an extension of 865 days, pursuant to 35 U.S.C. § 156 and the implementing regulations, based upon the regulatory review period pertaining to NDA 21-153 for Nexium™ Delayed-Release Capsules.

Two NDAs, NDA 21-153 and NDA 21-154, have been approved for Nexium™ Delayed-Release Capsules. The regulatory review periods for NDAs 21-153 and 21-154 began on August 18, 1997, and December 21, 1997, respectively, but both were approved on February 20, 2001. Accordingly, the regulatory review period pertaining to NDA 21-153 is longer than the regulatory review period pertaining to NDA 21-154. All else being equal between the two NDAs, Applicant claims a length of extension of 865 days based upon the regulatory review period pertaining to NDA 21-153. Only as a subordinate claim for extension is the regulatory review period for NDA 21-154 set forth below.
14. **Statement of Acknowledgment of Duty to Disclose Material Information**  
(37 C.F.R. § 1.740(a)(13))

Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought in this application.
APPLICATION FOR PTE

• Application for PTE must be filed by the patent owner or its agent.

• Processing the application for PTE is joint responsibility of the US PTO and regulatory agency responsible for the premarket regulatory review.
  • No required time for response.
  • Keep track and make inquiries as appropriate.
PTE ELIGIBILITY

• Not precluded by terminal disclaimer
  • *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317 (Fed. Cir. 2007): “The terminal disclaimer is not ignored; the §156 patent term extension is calculated from the terminal disclaimer expiration date. The objectives of two separate policies are fulfilled.”

• The original term of the patent must not have expired at the time the application for patent term extension is filed.
  • Keep the foot on the accelerator during regulatory review period.

• The term of the patent must not have been previously extended under § 156.
PTE ELIGIBILITY (con’t)

• Only one patent may be extended for the same regulatory review period for any product.

• For drug products containing a combination of active ingredients, it must be the first approval for at least one active ingredient.
TERM EXTENSION: PROTECTION IN EXTENDED TERM

- Depends on type of patent claim.
  - Approved product - rights in the PTE limited to any use approved for the product that occurred before the expiration of the term of the patent.
  - Method of making approved product – rights in the PTE limited to the method of manufacturing as used to make the approved product.
  - Method of using approved product - rights in the PTE limited to any use claimed by the patent that has been approved for the product before the expiration of the term of the patent.
**PTE ELIGIBILITY: FILING REQUEST**

**WHY FILING EARLY CAN SAVE SO MUCH TROUBLE!**

- The Medicines Co. ("TMC") and their blood-thinning drug, Angiomax® (patent without extension expired March 23, 2010).

- TMC received FDA approval on Friday, Dec. 15, 2000 6:17 PM.

- TMC filed its extension request on Feb. 14, 2001, which complied with the 60-day deadline if the technical date of FDA approval was Monday, Dec. 18, but is one day late if the date of FDA approval was Dec. 15.
PTE ELIGIBILITY: FILING REQUEST
WHY FILING EARLY CAN SAVE SO MUCH TROUBLE!

• US PTO used the Dec. 15 date, and rejected the PTE request.

• In addition to suing the US PTO, TMC spent more than $13M on lobbying for relief.

  ○ “Congress intended for the applicant to have sixty days. The PTO interpreted the statute in a manner that deprives an applicant the sixty days that Congress intended for them to receive. For the forgoing reasons, summary judgment should be awarded to the Plaintiff.”
PTE ELIGIBILITY: FILING REQUEST
WHY FILING EARLY CAN SAVE SO MUCH TROUBLE!

- AIA amended 35 U.S.C. §156(d)(1) to include directions as to how days are to be counted (and extend the TMC patent no matter what happened further in the litigation).

- AIA SEC. 37, 125 STAT. 341: “For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term ‘business day’ means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.”
PTE ELIGIBILITY: FILING REQUEST
WHY FILING EARLY CAN SAVE SO MUCH TROUBLE!

- Retroactive:
  - “The amendment made by subsection (a) shall apply to any application for extension of a patent term under section 156 of title 35, United States Code, that is pending on, that is filed after, or as to which a decision regarding the application is subject to judicial review on, the date of the enactment of this Act.”
Thank You!

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