Patent Term Adjustment (PTA) & Patent Term Extension (PTE)

Overview:
PTA
(AIPA 35 U.S.C. § 154(b))
PTE
(URAA § 532(a)(1))
PTA-PTE background

- Congress allowed modification of patent term when it changed the term of a patent:
  - from the date of patent grant + 17 years
  - to the filing date (or earliest filing date claimed under 35 U.S.C. §§ 120, 121, or 365(c)) + 20 years

- Congress first included provisions for PTE in the URAA in 1995 to address concerns with the loss of patent term due to USPTO delays (URAA PTE). Public Law 103-465.

- Congress then revised the provisions for patent term extension (now patent term adjustment) in the American Inventors Protection Act of 1999 (AIPA), expanding the bases for which an applicant could obtain patent term adjustment (AIPA PTA). Public Law 106-113.
PTA-PTE background

- The AIPA PTA provisions became effective on May 29, 2000, and apply to utility and plant applications filed on or after May 29, 2000.

- The URAA PTE provisions became effective on June 8, 1995, and apply to utility and plant applications filed on or after June 8, 1995, but before May 29, 2000.

- Neither AIPA PTA nor URAA PTE apply to applications for design patents or to any application filed before June 8, 1995 (the terms of these patents are measured from the grant date).
Bases for URAA PTE

• Provides patent term extension for:
  – Delays caused by an interference proceeding (35 U.S.C. § 135(a)),
  – Delays caused by imposition of a secrecy order (35 U.S.C. § 181), or
  – Delays caused by successful appellate review (requires a PTAB/court decision reversing an adverse patentability determination).
Bases for AIPA PTA

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

• Failure to take certain actions within specified time frames (14-4-4-4).
  – Failure to initially act on the application within fourteen months after filing/commencement date.
  – Failure to act on a reply or appeal brief within four months after date the reply or appeal brief is filed.
  – Failure to act on an application within four months after a PTAB or court decision if allowable claims remain in the application.
  – Failure to issue the patent within four months of the date the issue fee was paid and all outstanding requirements were satisfied.
AIPA PTA “B” delays

• USPTO failure to issue a patent within three years pendency measured from:

• The three-year period does not include time consumed by any of:
  – Continued examination under 35 U.S.C. § 132(b) (RCE),
  – Secrecy order, interference/derivation, or any appellate review, or
  – Applicant-requested delays.
AIPA PTA “C” delays

• Delays caused by an interference/derivation proceeding (35 U.S.C. § 135(a)).


• Delays caused by successful appellate review (requires a BPAI/court decision reversing an adverse patentability determination):
  – All rejections of at least one claim must be reversed.
  – In some instances, a remand shall be considered a decision reversing an adverse patentability determination.

• These delays are the bases for URRAA PTE.
Reduction of AIPA PTA

• Reduction of PTA for period during which applicant failed to engage in reasonable efforts to conclude processing or examination of an application (35 U.S.C. § 154(b)(2)(C)(i)).

• Failure to respond to a USPTO office action or notice within three months is a failure to engage in reasonable efforts to conclude processing or examination of an application (35 U.S.C. § 154(b)(2)(C)(ii)).

• The USPTO may also prescribe regulations to define what is a failure to engage in reasonable efforts to conclude processing or examination of an application (35 U.S.C. § 154(b)(2)(C)(iii)).
PTA – Overview of statute


§ 154(b)(1): Patent Term Guarantees

- Compensates patentees for certain delays while application is pending at the USPTO.
- Three categories of delay: “A” delay, “B” delay, and “C” delay

§ 154(b)(2): Limitations

- Reduces PTA total for certain events.
- Three categories of reduction: Overlap, disclaimed term, and “applicant delay” as determined by director

§ 154(b)(3): Procedures for PTA Determination

- PTA total provided when patent issues.
- Patentee provided an opportunity to seek reconsideration at the USPTO.

§ 154(b)(4): Appeal of PTA Determination

- Patentee can file civil action in EDVA within 180 days of USPTO decision.
35 U.S.C. § 154(b) Adjustment of Patent Term:

**“A” delay**
PTA increased for each day the USPTO misses deadline (e.g., 14 mos. to issue first office action)

**“B” delay**
PTA increased for each day application pends for more than three years, with exceptions (e.g., RCEs)

**“C” delay**
PTA increased for each day of certain events (e.g., successful appeals and interferences)

**Overlap**
PTA decreased for each calendar day with more than one type of USPTO delay (e.g., A & B delay) to avoid double-counting

**Disclaimed term**
PTA is cut off after disclaimed term (e.g., terminal disclaimer to earlier patent)

**“Applicant delay”**
PTA decreased for each day applicant fails to engage in reasonable efforts to conclude prosecution (as set forth in USPTO regulations)

Net PTA
Tracking PTA and PTE

• The Patent Application Locating and Monitoring (PALM) system tracks events/dates giving rise to PTE or PTA extensions/adjustments and reductions.

• PTE and PTA amounts are calculated by computer programs that use data from PALM to make the appropriate PTE or PTA determination.
  – Patent examiners and the Patent Examining Corps are not involved in the PTE/PTA determination process.

• Applicants can check the PALM data concerning these events via PAIR:
  – Applicants can contact the Technology Center Customer Service Center to correct PALM data that is in error.
Determining AIPA PTA

- 35 U.S.C. § 154(b)(3)(B)(i) provides that the USPTO shall make a PTA determination and transmit a notice of the PTA determination no later than the date of issuance of the patent.
  - The USPTO provides an advance PTA determination in the Issue notification letter that is mailed or given to applicant approximately three weeks before the patent issues.

- The PTA determination indicated on the front of the patent is the USPTO’s official determination and notification.
PTA summary (Public PAIR)

Bibliographic Data

Application Number: 11/988,862
Filing or 371 (c) Date: 01-15-2008
Application Type: Utility
Examiner Name: HEYER, DENNIS
Group Art Unit: 1628
Confirmation Number: 1575
Attorney Docket Number: EX06-011C-US
Class / Subclass: 544/356
First Named Inventor: William Batjagleh, San Francisco, CA (US)

Customer Number:
Status:
Status Date:
Location:
Earliest Publication No:
Earliest Publication Date:
Patent Number:
Issue Date of Patent:

Title of Invention: PHOSPHATIDYLINOSITOL 3-KINASE INHIBITORS AND METHODS OF THEIR USE

If you need help:
- Call the Patent Electronic Business Center at (866) 217-9197 (toll free) or e-mail EBC@uspto.gov for specific questions about Patent Application Information Retrieval (PAIR).
- Send general questions about USPTO programs to the USPTO Contact Center (UCC).
- If you experience technical difficulties or problems with this application, please report them via e-mail to Electronic Business Support or call 1 800-786-9199.
PTA summary (Public PAIR)
Notice of final PTA determination

United States Patent
Masinaci et al.

COMPOSITION FOR REPAIR OF DEFECTS IN OSSEOUS TISSUES

Inventors: Leila Masinaci, Norfolk, VA (US); Lloyd Wollinburger, Jr., Norfolk, VA (US)

Assignee: U.S. Nat. Health, Virginia Beach, VA (US)

Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 271 days.

App'l No.: 11/247,230
Filed: Oct. 12, 2005

Prior Publication Data

Patent No.: US 7,498,041 B2
Date of Patent: Mar. 3, 2009

Certificate of Correction

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:
The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 394 days.

Signed and Sealed this Seventh Day of August, 2012

[Signature]

Director of the United States Patent and Trademark Office
Reconsideration of PTA determination

• Procedures for determining adjustment:
  – 37 C.F.R. § 1.705 implements the provisions for PTA determinations and requests for reconsideration of USPTO patent term adjustment determinations.
  – Any request for reconsideration must be filed within two months from the date the patent was granted, but this two-month time period may be extended under 37 C.F.R. § 1.136(a).
Reinstatement of reduced PTA

• Procedures for determining adjustment:
  – 35 USC § 154(b)(3)(C) provides that applicants may also request reinstatement of period reduced due to failure to reply to any USPTO action within three months but limits the reinstatement to three month relief.

• Requires that the applicant, prior to issuance, make a showing that, in spite of all due care, the applicant was unable to respond within three months.
Reconsideration of PTA determination

• Procedures for determining adjustment:
  – Requests for reconsideration of USPTO’s PTA determinations and requests for reinstatement of reduced PTA are handled by the Office of Petitions.
    • Unusual situations and matters of first impression are referred to Office of Patent Legal Administration (OPLA) staff and/or other senior DC PEP managers who have PTA expertise.
  – Patent examiners and the Patent Examining Corps are not involved in these requests for reconsideration or reinstatement of PTA.
Judicial review of final PTA

- Judicial review of USPTO determination:
  - Applicant (patentee) has 180 days from the date of the director’s decision on the request for reconsideration of patent term adjustment to file a civil action.
  - The U.S. District Court for the Eastern District of Virginia has exclusive jurisdiction to address civil actions concerning patent term adjustment.
  - The decision of the U.S. District Court for the Eastern District of Virginia may be appealed to the U.S. Court of Appeals for the Federal Circuit.
Overview of PTA decisions from the Federal Circuit

• Decisions affecting the PTA calculation:
  – “A” Delay Pfizer, Actelion II
  – “B” Delay – Novartis, Mayo Foundation
  – Overlap – Wyeth
  – Disclaimed term – Daiichi
  – Applicant delay – Gilead, Supennus, Intra-Cellular
  – Continuation applications – Mohsenzadeh

• Decisions concerning PTA procedures and judicial review:
  – Wyeth Interim Procedure – Daiichi, Actelion I (rule 36)
  – Tolling (judicial review) – Novartis
AIPA PTA provisions

• Patent Term Adjustment (AIPA) provisions:
  – 35 U.S.C. § 154(b)
  – 37 C.F.R. §§ 1.702 - 1.705
  – MPEP 2730 - 2736
URAA PTE provisions

- Patent Term Extension (URAA) provisions:
  - Section 532(a)(1) of the URAA (Public Law. 103-465)
  - 37 C.F.R. § 1.701
  - MPEP 2720
PTA-PTE rule changes & notices

- 78 Fed. Reg. 62368 (Oct. 21, 2013) (final rule re PLT)
- 79 Fed. Reg. 34681 (June 18, 2014) (proposed rules re Novartis)
- 80 Fed. Reg. 1346 (Jan. 9, 2015) (final rule re Novartis and RCEs)
- 84 Fed. Reg. 20343 (May 9, 2019) (re implementation of Supernus)
Thank you!

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