

UNITED STATES  
PATENT AND TRADEMARK OFFICE



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

Overview:

PTA

(AIPA 35 U.S.C. § 154(b))

PTE

(URAA § 532(a)(1))

UNITED STATES  
PATENT AND TRADEMARK OFFICE

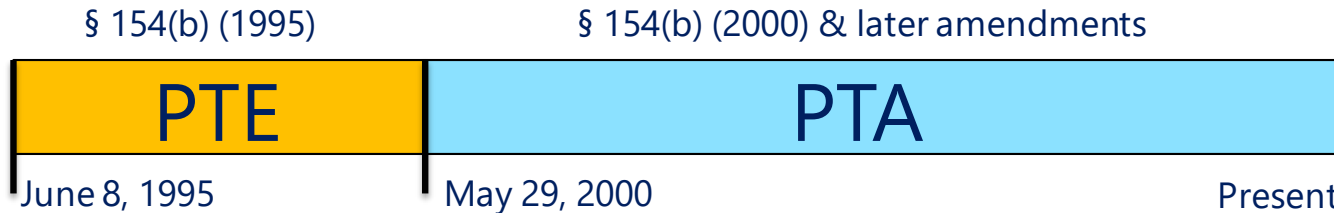


# PTA-PTE background

- 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 filing date in an application filed under 35 U.S.C. § 111(a).
  - The date of commencement of the national stage under 35 U.S.C. § 371 in an international application.
- 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 imposition of a secrecy order (35 U.S.C. § 181).
- 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 URAA 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

35 U.S.C. § 154(b) (2013):  
Adjustment of Patent Term –

§ 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

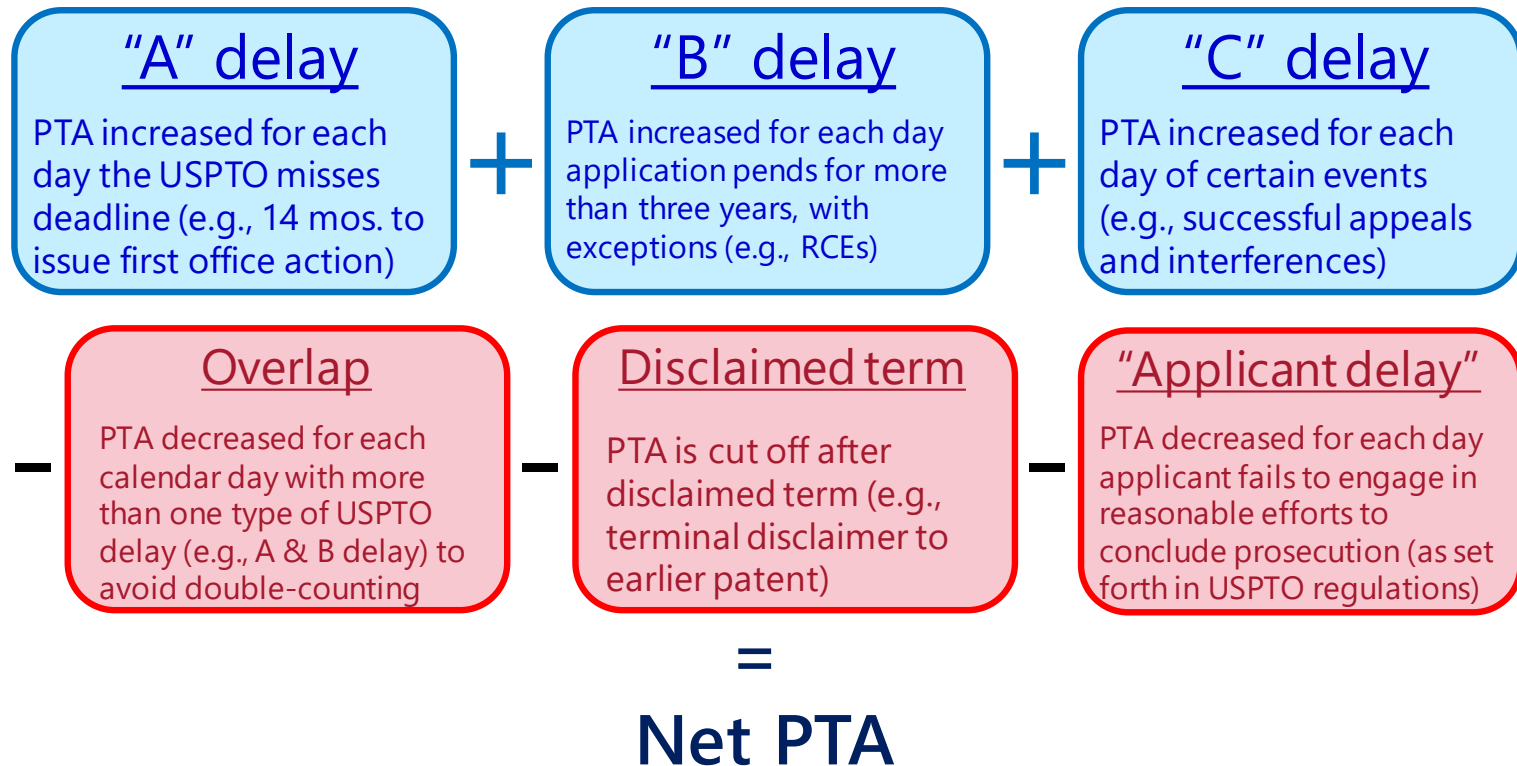
- PTA total provided when patent issues.
- Patentee provided an opportunity to seek reconsideration at the USPTO.

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

- Patentee can file civil action in EDVA within 180 days of USPTO decision.

# PTA – Big picture

35 U.S.C. § 154(b) Adjustment of Patent Term:



# 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.
  - See Revisions to Implement the Patent Term Adjustment Provisions of Leahy-Smith America Invents Act Technical Corrections Act, 79 Fed. Reg. 27555 (May 15, 2014).



# PTA summary (Public PAIR)

Patent Application Information Retrieval

[Order Certified Application As Filed](#) [Order Certified File Wrapper](#) [View Order List](#)

11/988,862      PHOSPHATIDYLINOSITOL 3-KINASE INHIBITORS AND METHODS OF THEIR USE      EX06-011C-US

Select New Case   Application Data   Transaction History   Image File Wrapper   **Patent Term Adjustments**   Continuity Data   Fees   Published Documents   Address & Attorney/Agent   Supplemental Content   Display References

### Bibliographic Data

Application Number:	11/988,862	Customer Number:	-
Filing or 371 (c) Date:	01-15-2008	Status:	Application Involved in Court Proceedings
Application Type:	Utility	Status Date:	03-10-2012
Examiner Name:	HEYER, DENNIS	Location:	ELECTRONIC
Group Art Unit:	1628	Location Date:	-
Confirmation Number:	1575	Earliest Publication No:	US 2010-0087440 A1
Attorney Docket Number:	EX06-011C-US	Earliest Publication Date:	04-08-2010
Class / Subclass:	544/356	Patent Number:	7,989,622
First Named Inventor:	William Bajjalieh , San Francisco, CA (US)	Issue Date of Patent:	08-02-2011

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](mailto: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)

Number	Date	Contents Description	PTO (Days)	APPL (Days)	Start
79.5	04-10-2011	PTA 36 Months	85		79.4
79.4	01-15-2008	Commencement Date			0
79	08-02-2011	Patent Issue Date Used in PTA Calculation			0
78	06-06-2011	Export to Final Data Capture			
77	06-03-2011	Finished Initial Data Capture			
76	06-03-2011	Dispatch to FDC			
75	05-17-2011	Mail-Petition Decision - Dismissed			
74	05-17-2011	Petition Decision - Dismissed			
73	05-02-2011	Application Is Considered Ready for Issue			
72	04-29-2011	Export to Initial Data Capture			
71	04-28-2011	Petition Entered			
70	04-28-2011	Issue Fee Payment Verified			
69	04-28-2011	Issue Fee Payment Received			
68	04-27-2011	Mail Notice of Allowance			
67	04-18-2011	Office Action Review			
66	04-18-2011	Office Action Review			
65	04-22-2011	Issue Revision Completed			
64	04-22-2011	Document Verification			
63	04-22-2011	Notice of Allowance Data Verification Complete			
62	04-22-2011	Case Docketed to Examiner in GAU			
61	04-18-2011	Office Action Review			

Number	Date	Contents Description	PTO (Days)	APPL (Days)	Start
79.5	04-10-2011	PTA 36 Months	85		79.4
79.4	01-15-2008	Commencement Date			0

11/988,862 PHOSPHATIDYLIINOSITOL 3-KINASE INHIBITORS AND METHODS OF THEIR USE EX06-011C-US 03-05-2012::18:46:38					
Patent Term Adjustments					
Patent Term Adjustment (PTA) for Application Number: 11/988,862					
Filing or 371(c) Date:	01-15-2008	Overlapping Days Between {A and B} or {A and C}:	0		
Issue Date of Patent:	08-02-2011	Non-Overlapping USPTO Delays:	429		
A Delays:	344	PTO Manual Adjustments:	0		
B Delays:	85	Applicant Delays:	61		
C Delays:	0	Total PTA Adjustments:	368		
Patent Term Adjustment History Explanation Of Calculations					
Number	Date	Contents Description	PTO (Days)	APPL (Days)	Start
79.5	04-10-2011	PTA 36 Months	85		79.4
79.4	01-15-2008	Commencement Date			0



# Notice of final PTA determination

(12) **United States Patent**  
**Masinaei et al.**

(10) **Patent No.:** US 7,498,041 B2  
(45) **Date of Patent:** Mar. 3, 2009

(54) **COMPOSITION FOR REPAIR OF DEFECTS  
IN OSSEOUS TISSUES**

(75) Inventors: **Leila Masinaei**, Norfolk, VA (US);  
**Lloyd Wolfinbarger, Jr.**, Norfolk, VA  
(US)

(73) Assignee: **LIFEPOINT 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.

(21) App. No.: **11/247,230**

(22) Filed: **Oct. 12, 2005**

(65) **Prior Publication Data**

US 2007/0082058 A1 Apr. 12, 2007

(51) **Int. Cl.**

5,674,292 A 10/1997 Tucker et al.

5,948,428 A

6,013,856 A

6,028,242 A

6,180,606 B1

6,372,257 B1

6,458,375 B1

6,461,630 B1

6,504,079 B2

6,576,249 B1

6,679,918 B1

6,933,326 B1

2004/0059364 A1 \*

\* cited by examiner

Primary Examiner  
(74) Attorney, Agent,  
T T D

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 7,498,041 B2  
APPLICATION NO. : 11/247230  
DATED : March 3, 2009  
INVENTOR(S) : Masinaei et al.

Page 1 of 1

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

*David J. Kappos*

David J. Kappos  
Director of the United States Patent and Trademark Office

# Reconsideration of PTA determination

- Procedures for determining adjustment:
  - 35 U.S.C. § 154(b)(3)(B)(ii) provides for one request for reconsideration of USPTO's patent term adjustment determination.
  - 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, Supernus, 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)
  - Final rule: *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 Fed. Reg. 56366 (Sep. 18, 2000)
  - Proposed rule: *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 Fed. Reg. 17215 (Mar. 31, 2000)
  - 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)
  - Final rule: *Changes to Implement 20-Year Patent Term and Provisional Applications*, 60 Fed. Reg. 20195 (Apr. 25, 1995).
  - Proposed rule: *Changes to Implement 20-Year Patent Term and Provisional Applications*, 59 Fed. Reg. 63951 (Dec. 12, 1994)
  - 37 C.F.R. § 1.701
  - MPEP 2720



# PTA-PTE rule changes & notices

- 1247 *Off. Gaz. Pat. Office* 111 (June 26, 2001) (re 37 C.F.R. § 1.704(c)(10))
- 68 *Fed. Reg.* 67818 (Dec. 4, 2003) (proposed PTA-PTE rules re Board remands)
- 69 *Fed. Reg.* 21704 (Apr. 22, 2004) (final PTA-PTE rules re Board remands)
- 69 *Fed. Reg.* 34283 (June 21, 2004) (explanation of 35 U.S.C. § 154(b)(2)(A))
- 75 *Fed. Reg.* 5043 (Feb. 1, 2010) (Interim *Wyeth* procedure)
- 75 *Fed. Reg.* 42079 (July 20, 2010) (treatment of miscellaneous PTA letters)
- 76 *Fed. Reg.* 18990 (Apr. 6, 2011) (proposed PTA rules re appellate review and IDS)
- 76 *Fed. Reg.* 74700 (Dec. 1, 2011) (final PTA rules re IDS)
- 76 *Fed. Reg.* 81432 (Dec. 28, 2011) (proposed PTA rules re appellate review)
- 77 *Fed. Reg.* 49354 (Aug. 16, 2012) (final PTA rules re appellate review)
- 78 *Fed. Reg.* 19416 (Apr. 1, 2013) (interim AIA Technical Corrections rule)
- 78 *Fed. Reg.* 62368 (Oct. 21, 2013) (final rule re PLT)
- 79 *Fed. Reg.* 27755 (May 15, 2014) (final AIA Technical Corrections rule)
- 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*)
- 84 *Fed. Reg.* 53090 (Oct. 4, 2019) (proposed rules re *Supernus*)



**Thank you!**

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