

Patent Term Adjustment

2012 IP Summer Seminar

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July 2012

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Overview

- ◆ What Are We Talking About?
- ◆ Compact Prosecution
- ◆ Patent Term Adjustment Statutory Scheme
- ◆ Particular Issues for National Phase Applications
- ◆ Open Issues
- ◆ Tips for Maximizing Patent Term Adjustment

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What Are We Talking About?

- ◆ Patent Term Adjustment (“PTA”) as established by the American Inventors Protection Act of 1999 and codified at 35 U.S.C. § 154(b)
- ◆ This should be distinguished from:
 - ◆ The old regime of PTA, which applied to patents issuing on applications filed on or after June 8, 1995, but before May 29, 2000; and
 - ◆ Patent Term Extension codified at 35 U.S.C. § 156 to compensate for delays associated with approval by the Food and Drug Administration (FDA)
- ◆ This presentation will not discuss the old PTA regime or Patent Term Extension

Why Was PTA Established?

- ◆ Prior to 1995, US patents were entitled to a patent term of 17 years from issue
- ◆ In 1995, the US changed to the patent term to 20 years from the earliest effective US non-provisional filing date to implement the TRIPS Agreement
- ◆ Under a 17-years-from-issue term, examination delays do not diminish the patent term
- ◆ Under a 20-years-from-earliest-effective-filing-date term, examination delays erode the effective patent term
 - ◆ If examination takes three years, the patent can only be enforced for 17 years
 - ◆ If examination takes five years, the patent can only be enforced for 15 years

Why is PTA Important?

- ◆ PTA lengthens a patent's term
- ◆ This can be extremely valuable for products that have long development and/or regulatory approval processes:
 - ◆ Pharmaceuticals
 - ◆ Medical devices
 - ◆ University-licensed technologies
- ◆ A "blockbuster drug" is a drug that generates at least \$1 billion in annual revenue
- ◆ Therefore, each additional day of patent term for a blockbuster drug equals at least \$2.7 million per day

Compact Prosecution

- ◆ What is "Compact Prosecution"?*
 - ◆ Conducting an initial search which is as complete as possible;
 - ◆ Citing pertinent art on the record in keeping with the scope of the claims as well as significant aspects of the disclosed invention;
 - ◆ Issuing a complete first Office action which clearly explains the Examiner's position on each essential issue; and
 - ◆ Identifying allowable subject matter in an effort to expedite prosecution.
- ◆ PTA law and rules generally reflect compact prosecution principles

* USPTO, "Best Practices in Compact Prosecution: Awareness Workshop,"
http://www.uspto.gov/patents/law/exam/compact_prosecution.pdf.

Patent Term Adjustment Statutory Scheme

- ◆ Three Types of Delays:
 - ◆ “A Delays”
 - ◆ “B Delays”
 - ◆ “C Delays”
- ◆ Limitations on Patent Term Adjustment
 - ◆ Double-Counting Prohibited
 - ◆ Adjusted Term May Not Extend Beyond Expiration Date Specified in Terminal Disclaimer
 - ◆ Reductions in PTA for Applicant Delays
- ◆ Procedures for Determining and Correcting Patent Term Adjustment

“A Delays”

- ◆ 35 USC § 154(b)(1)(A) provides adjustment of patent term for administrative delays (“the 14-4-4-4” Rule)
- ◆ Guarantee of prompt action requires USPTO to:
 - ◆ Issue an Office Action within 14 months after filing application
 - ◆ Respond to a reply or appeal within 4 months from the date that the reply or appeal was filed
 - ◆ Act on the application within 4 months after a decision from the Board of Patent Appeals and Interferences or Federal Court
 - ◆ Issue the patent within 4 months after payment of the issue fee

“B Delays”

- ◆ 35 USC § 154(b)(1)(B) provides guarantee of no more than 3-year application pendency (“the 3 Year Rule”):
 - ◆ The USPTO generally must issue a patent within 3 years from the filing date or from entry date into U.S. national stage
 - ◆ Exceptions include applicant delays
- ◆ “B Delay” excludes time consumed by:
 - ◆ Requests for Continued Examination
 - ◆ Appeals (both within the USPTO and Federal Courts)

“C Delays”

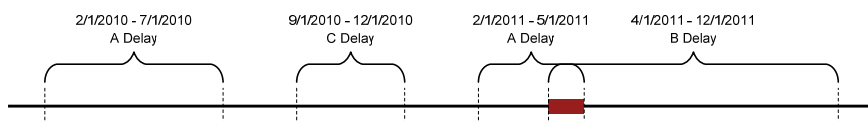
- ◆ 35 USC § 154(b)(1)(C) provides adjustment of patent term for:
 - ◆ Interferences
 - ◆ Secrecy orders
 - ◆ Successful appellate review

Overlapping Periods of PTA

- ◆ 35 USC § 154(b)(2)(A) states:

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

- ◆ Under *Wyeth v. Kappos*, delays only overlap if they occur on the same day
- ◆ $PTA = A \text{ Delay} + B \text{ Delay} + C \text{ Delay} - \text{Overlapping Delay} - \text{Applicant Delay}$



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PTA and Terminal Disclaimers

- ◆ PTA cannot be used to extend the term of a patent beyond the expiration date set in a terminal disclaimer
- ◆ Standard USPTO terminal disclaimer form states that disclaimed patent will not extend beyond the term of the prior patent
- ◆ Carefully consider whether a terminal disclaimer is required for all of the claims in an application:
 - ◆ Claims that were previously subject to a restriction requirement in a parent application are protected from double patenting rejections over the elected claims under 35 USC § 121
 - ◆ Are all pending claims properly subject to the double patenting rejection?
 - ◆ If not, consider whether to cancel the claims properly subject to the double patenting rejection

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Reductions in PTA for Applicant Delays

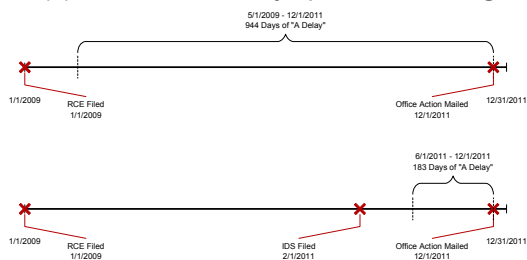
- ◆ PTA awards are reduced by failure of Applicants to engage in “reasonable efforts to conclude prosecution of the application”
- ◆ PTA is reduced for any failure to respond to an Office Action or other notice within three months (even if the period for responding without fees is shorter, e.g., Notices to File Missing Parts and Restriction Requirements)
- ◆ Other examples of Applicant delay are promulgated at 37 CFR § 1.705 and include:
 - ◆ Abandonment of an application
 - ◆ Submission of an incomplete reply
 - ◆ Submission of a supplemental reply (including, in some instances, an Information Disclosure Statement)
 - ◆ Submission of an amendment after a Notice of Allowance

Deadlines Falling on Weekends or Holidays

- ◆ Last year’s *ArQule v. Kappos* decision held that responses initially due on a weekend or holiday, but filed on the next business day do not incur reductions of PTA due to Applicant Delay
 - ◆ ArQule filed suit seeking one additional day of PTA
 - ◆ Three-month deadline fell on Veterans Day
 - ◆ ArQule filed a response on the next day
 - ◆ USPTO reduced PTA award by one day of Applicant Delay
 - ◆ Court holds that 35 USC § 21(b)’s weekend and holiday exception to USPTO deadlines also applies to the PTA provisions of 35 USC § 154
- ◆ The USPTO acquiesced to the decision, but still needs to procure a contract to revise the USPTO’s software

Interactions Between IDS and PTA

- ◆ An IDS filed after a response, but before next Office Action is considered to be a supplemental response unless a certification is submitted under 37 CFR § 1.705(d) stating that:
 - ◆ Each reference included in the IDS was first cited
 - ◆ In a communication from the USPTO or a foreign patent office
 - ◆ In a counterpart application and
 - ◆ This communication was not received by any individual designated in 37 CFR § 1.56(c) more than 30 days prior to the filing of the IDS



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Challenging PTA Calculations

- ◆ Notice containing initial PTA calculation is mailed with Notice of Allowance
- ◆ Detailed calculation is available in USPTO PAIR portal
- ◆ Any PTA errors detectable at that time must be challenged before or when paying the Issue Fee
- ◆ The Issue Notification and the issued Patent include the “final” PTA calculation that reflects the “B Delay”
- ◆ Petitions challenging the USPTO’s PTA must be filed within 2 months of issue
- ◆ Court actions challenging the USPTO’s PTA must be filed within 180 days of issue
- ◆ *Bristol-Myers Squibb v. Kappos* holds that 180-day deadline is tolled by timely-filed request for reconsideration before the USPTO, but the USPTO is currently challenging this holding

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PTA in National Phase Applications

- ◆ 35 USC § 154(b)(1)(B) provides a guarantee of no more than a three year application pendency from “**the actual filing date** of the application in the United States”
- ◆ 37 CFR § 1.702(b) clarifies that the three year period for § 154(b) begins on either:
 - ◆ The § 111(a) filing date OR
 - ◆ The date on which “the national stage commenced under 35 USC 371(b) or (f)”

When Does the National Stage Commence?

- ◆ § 371(b) states “Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the [Patent Cooperation Treaty (PCT)]”

When Does the National Stage Commence?

- ◆ There are two paths for commencing the national phase:
 - ◆ § 371(f) - Applicant commences the national phase upon express request and completion of the requirements of § 371(c) upon filing
 - ◆ § 371(b) – Applicant commences the national phase upon filing of application and expiration of the time limit under PCT Articles 22 or 39
- ◆ Commencement of the national phase at 30 months does not require the completion of the § 371(c) requirements (e.g. oath/declaration)

Why does this make a difference?

- ◆ The clock for an “A” delay for failure to issue a first Office Action or Notice of Allowance within 14 months is triggered by fulfillment of “the requirements of 35 U.S.C. § 371” (e.g., submission of a declaration)
- ◆ In contrast, the “B” delay accounts for significant delays in mailing a Notice of Missing Requirements

Open Issues

- ◆ When is an Office Action an Office Action?
- ◆ How is the “B Delay” Affected by RCE Filings?
- ◆ Proposed USPTO Rulemaking on Pre-Appeal Briefs

Oncolytics Biotech. Inc. v. Kappos

- ◆ Patentee was unable to respond because of inadequacies in Office Action
- ◆ After interview, USPTO issued new Office Action stating that previous Office Action is “vacated”
- ◆ USPTO’s PTA calculation treats the first Office Action as timely issued for purposes of four-month requirement
- ◆ USPTO asserts that the later *vacatur* of the first Office Action does not mean that the first Office Action was void *ab initio*
- ◆ Case stayed pending decision by USPTO on petition to invoke the Director’s supervisory authority
- ◆ Petition granted on May 24, 2012 awarding 122 days of PTA

Abbott Biotherapeutics Corp. v. Kappos

- ◆ USPTO rules state that the finding of an RCE terminates the accrual of B Delay for failure to issue a patent within three years
- ◆ Abbott challenges that:
 - ◆ while the USPTO can exclude time consumed by consideration of an RCE when determining whether it failed to issue a patent within three years (the “trigger”),
 - ◆ the USPTO cannot exclude the time consumed by the RCE when calculating the PTA resulting from the failure to issue a patent within three years (the “remedy”)
- ◆ Under Abbott’s argument, an RCE first filed more than three years after filing would not limit B Delay
- ◆ Alternatively, the period between allowance and issuance should not be considered excluded from B Delay as “time consumed by continued examination”
- ◆ Abbott’s reply brief on summary judgment is due July 18, 2012

Proposed USPTO Rulemaking on Pre-Appeal Brief Conference Pilot Program

- ◆ USPTO Pre-Appeal Brief Conference Pilot Program allows applicants to potentially avoid RCE or Notice of Appeal by filing short (<5 pages) arguments identifying clear factual or legal errors
- ◆ If successful, application is remanded to Examiner for new Office Action
- ◆ Request are filed with Notice of Appeal and under current rules pause the accrual of B Delay
- ◆ However, a remand to the Examiner is not sufficient to produce C Delay
- ◆ USPTO proposes to change its interpretation of the statute to allow accrual of B Delay until jurisdiction passes to Board of Patent Appeals and Interferences when full appeal brief is filed
- ◆ Notice of Proposed Rulemaking published on December 28, 2011

Tips for Maximizing PTA

- ◆ Avoid Responses beyond three (3) months
- ◆ Consider telephonic invention restrictions and elections of species
- ◆ Avoid terminal disclaimers
- ◆ Avoid requests for continued examination
- ◆ Engage counsel to review PTA calculations at allowance and issuance