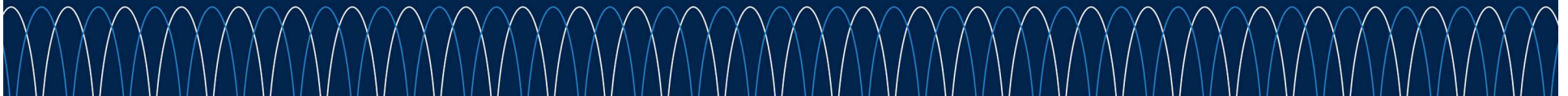




U.S. Patent Term

Why it Varies and How to Make the Most of it

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U.S. Patent Term – Why it Varies

- FR Switch to 20-year base term
- FR Terminal Disclaimers
- FR Patent Term Adjustment (PTA)



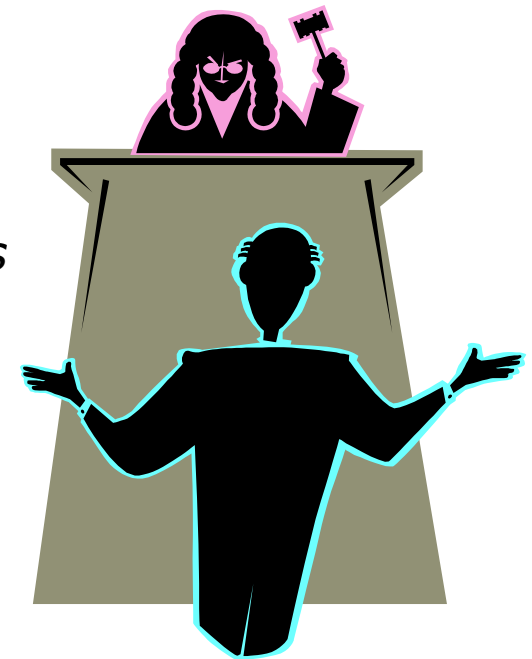


Switch to 20-Year Base Term

- ❖ U.S./PCT filing on or after **June 8, 1995**
 - term is 20 years from earliest U.S./PCT priority date
- ❖ Pending or unexpired on June 8, 1995
 - term is longer of:
 - 20 years from earliest U.S./PCT priority date, or
 - 17 years from issue date

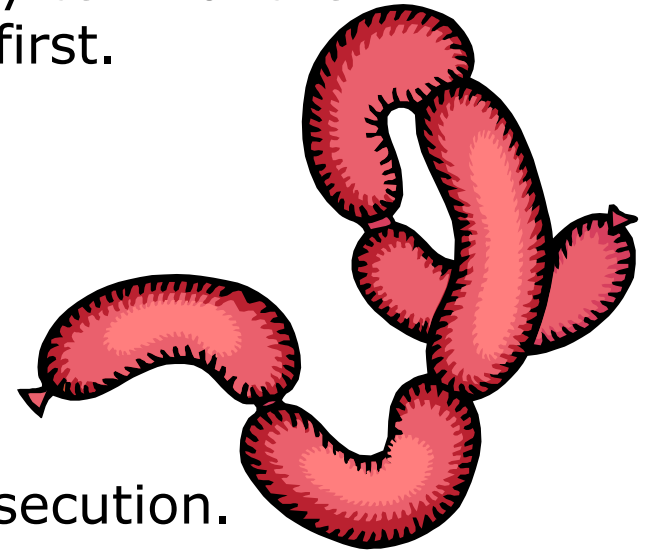
Obviousness-Type Double Patenting (OTDP)

- FR A “judicially created doctrine...[that] prevent[s] the extension of the term of a patent...by prohibiting the issuance of the claims in a second patent *not patentably distinct* from the claims of the first patent.” *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985)
- FR [It] is intended to prevent the patentee from obtaining a *time-wise extension of patent rights* for the same invention or an obvious modification thereof. *In re Lonardo*, 119 F.3d 960 (Fed. Cir. 1997)



Terminal Disclaimers

- ❖ Applicant's affirmative disclaimer of any term of the second patent beyond the term of the first.
- ❖ Acknowledgement that patents linked by a terminal disclaimer will only be enforceable while co-owned.
- ❖ Obviates an OTDP rejection during prosecution.





The Disclaimer

Pursuant to 37 CFR § 1.321(b) and to obviate a double patenting rejection, [ASSIGNEE] hereby waives and disclaims the terminal portion of the term of the entire patent to be granted upon the above identified application subsequent to the expiration date of U.S. Patent Nos. [x,xxx,xxx] and [y,yyy,yyy]. Further, any patent granted on the above identified application shall be enforceable only for and during such period that said patent is commonly owned with U.S. Patent Nos. [x,xxx,xxx] and [y,yyy,yyy].

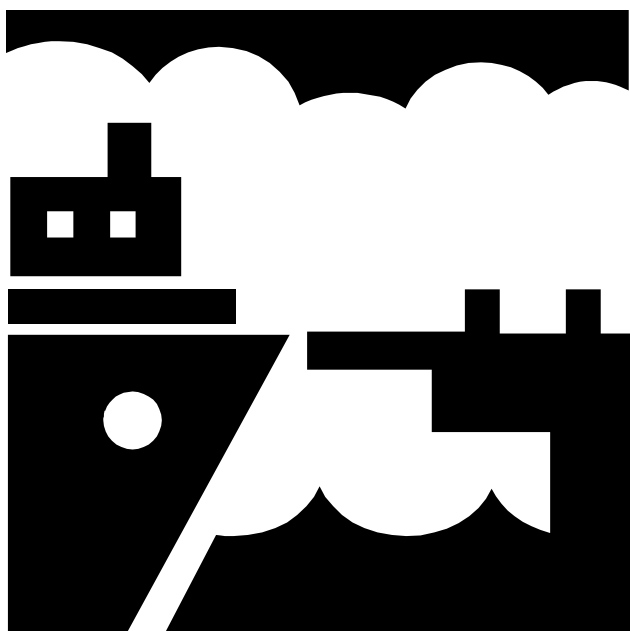
This patent is subject to a terminal disclaimer.



Post-Grant Terminal Disclaimers

- ❖ May be filed prior to any suggestion of ODTP.
- ❖ May be filed after validity has been challenged.
- ❖ May not be filed after earlier-issued patent has expired.
 - *Boehringer Ingelheim v. Barr*, No. 09-1032 (Fed. Cir. 2010)

Safe Harbor for Restricted Claims



A patent issuing on an application with respect to which a requirement for restriction ... has been made, or on an application filed **as a result of** such a requirement, shall not be used as a reference ... against **a divisional application** or against the original application or any patent issued on either of them.

35 U.S.C. § 121



Related Case Law – § 121 Safe Harbor

- ❖ *Amgen v. Hoffmann-LaRoche* (Fed. Cir. 2009)
 - Application deemed a CON is not protected even though substantively might be a DIV.
- ❖ *Symbol Technologies, Inc. v. Opticon, Inc.* (Fed. Cir. 1991)
 - CON protected because derived from DIV.
- ❖ *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.* (Fed. Cir. 2008)
 - CIP not protected.
- ❖ *Bristol-Myers Squibb v. Pharmachemie* (Fed. Cir. 2004)
 - DIV not protected because not filed as a result of a restriction.

Patent Term Adjustment (PTA)

- FR Accommodation for delayed prosecution
- FR For U.S./PCT applications filed on/after May 29, 2000
- FR Can only add to 20-year term
- FR $PTA = (PTO \text{ delay}) - (\text{Applicant delay})$

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 86 days.



PTA: Categories of PTO Delay

FR "A Delay"

– failure to respond promptly

FR "B Delay"

– failure to issue patent within 3 years

FR "C Delay"

– other reasons for adjustment

PTO "A Delay" – slow to respond

FR The PTO has:

- 14 months to issue 1st action (RR or OA; not NTFMP)
- 4 months to respond to our responses
- 4 months to issue action after an appeal brief
- 4 months to issue action after BPAI decision
- 4 months to issue patent after issue fee payment



"A Delay" starts
accumulating on the day
after a deadline date

35 U.S.C. § 154(b)(1)(A)

PTO "B Delay" – 3 years to issue

- ❖ PTO has 3 years from application filing to issue a patent
- ❖ "B Delay" starts accumulating on the day after the application has been pending for 3 years
- ❖ 3-Year Clock stopped by
 - Filing a Request for Continued Examination (RCE)
 - Declaration of interference
 - Secrecy order
 - Notice of Appeal

} Clock Paused

35 U.S.C. § 154(b)(1)(B)



Overlap of A Delay and B Delay

- ❖ Patentee is entitled to the addition of “A Delay” and “B Delay” to the extent that they do not overlap.
- ❖ A and B delays “overlap” only if they occur on the same day (which can only possibly occur after the application has been pending for at least 3 years).

Wyeth v. Kappos, No. 09-1120 (Fed. Cir. 2010)

PTO "C Delay" – miscellaneous delays

- ❖ Interferences
- ❖ Secrecy Orders
- ❖ Appeals
 - appeal must result in a final decision in favor of Applicant



35 U.S.C. § 154(b)(1)(C)



Common Applicant Delays

- ❖ Failure of applicant to “engage in reasonable efforts to conclude prosecution of the application”
- ❖ Filing a reply more than 3 months after action mailing date
- ❖ Submission of incomplete reply
- ❖ Submission of supplemental reply
 - IDS after response to Office Action (unless certified under § 1.97(e) and filed within 30 days of foreign action)



Less Common Applicant Delays

- ❖ Conversion of provisional to utility application
- ❖ Submission of preliminary paper within 1 month of office action, if a supplemental action is necessary as a result
- ❖ Suspension of action at Applicant's request
- ❖ Deferral of issuance at Applicant's request
- ❖ Failure to file petition to withdraw abandonment within 2 months of Notice of Abandonment
- ❖ Abandonment or late issue fee payment
- ❖ Pulling a case from issue after issue fee payment in order to cite additional art



Applicant Delays Post-Allowance

- ❖ Submission of papers after allowance, including but not limited to the following:
 - Formal Drawings (regardless of whether required by Examiner)
 - Amendments under 37 CFR § 1.312
 - Status Inquiries
 - Request for Refund
 - Late Priority Claims
 - Certified Copies of Priority Documents
 - Oaths/Declarations



Correcting PTA Calculations

At Allowance...

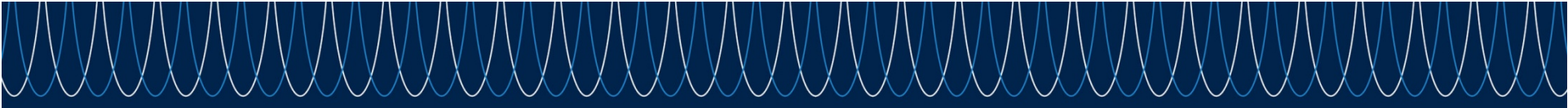
- Requests covering any pre-allowance PTA error must be filed **no later than** payment of issue fee.

At Issuance...

- Requests may only cover PTA errors that could not have been corrected at allowance.
- Requests must be filed within **2 months** of issue date.

Letters re PTA...

- Duty to notify PTO if too much PTA awarded.
- No deadline except “due course.”



U.S. Patent Term – How to Make the Most of It

- ❖ Avoid accumulating Applicant Delay whenever possible.
- ❖ Avoid stopping the 3-year clock (no RCEs).
- ❖ Avoid filing unnecessary terminal disclaimers.
- ❖ File complete national phase applications with Express Request for Examination.
- ❖ Be aware of circumstances that can result in accumulation of PTO Delay.

Avoiding Applicant Delay

- ❖ File all responses on or before the three month date (and don't use weekend or holiday carry-overs).
- ❖ Avoid supplemental responses (unless expressly requested by the Examiner).
- ❖ Avoid incomplete or non-compliant replies.
- ❖ Always file documents with the USPTO electronically or by express mail.
- ❖ Call with status inquiries.



Avoiding Applicant Delay

- ❖ Information Disclosure Statements should be filed:
 - before receipt of a first action
 - with or before a reply to a non-final action
 - Within 30 days of mailing date of foreign action (with certification under § 1.97(e))

- ❖ An IDS filed after a response to Office Action and without a certification under § 1.97(e) will be treated as a “supplemental reply”



Avoiding Applicant Delay

- ❖ File formal drawings early in prosecution (filing after allowance always triggers applicant delay).
- ❖ Avoid amendments after allowance (if amending after allowance, request a draft Examiner's amendment for review and approval).

Don't Stop the Clock



- ❖ Avoid filing RCEs (doing so permanently stops the 3-year clock).
- ❖ Consider after-final strategies that result in either a Notice of Allowance or the issuance of a non-final office action.
- ❖ Consider an appeal or a petition to have finality withdrawn (if appropriate).



Avoid Unnecessary Terminal Disclaimers

- ❖ Filing a terminal disclaimer can limit PTA (term cannot extend beyond that of the earlier patent).
- ❖ Also, maximize PTA while prosecuting all applications, because even if Patent A is not commercially important, it could nonetheless limit the term of Patent B if a terminal disclaimer must later be filed over Patent A (so the longer the term of Patent A, the better).

File Complete National Phase Applications



- ❖ Always include an Express Request for Examination.
- ❖ Results in the 14-month clock starting immediately with application filing (can result in greater accumulation of "A Delay").



Accumulating PTO “A Delay”

- ❖ Generally, Applicant’s actions do not affect PTO’s reply time.
- ❖ However, filing some petitions/requests may cause the PTO to exceed their time requirements (e.g., requests to correct PTA filed after allowance often delay patent issuance beyond 4 months).

Accumulating PTO "B Delay"

- ❖ Application pendency time is mostly within the control of the PTO.
- ❖ However, Applicant's use of the full 3 month response periods (even for NTFMP and RR, with extensions of time) may have an effect on pendency time for some applications (without triggering Applicant Delay).





Thank You

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