STRATEGIES FOR
MAXIMIZING PATENT TERM

SAMUEL S. WOODLEY, PH.D.
Fish & Richardson

- Begins when patent issues
- Ends “20 years from filing”
  - 20 years from date when the application for patent was filed in the United States, or
  - 20 years from date when first non-provisional, priority application filed in the United States (for divisional, continuing and continuation-in-part applications)
  - Filing date of U.S. provisional application(s) and foreign priority applications under Paris Convention not considered when calculating 20 year expiration date
  - “Date when filed in the United States” is
    - Date when non-provisional application filed in the U.S. Patent and Trademark Office, or
    - Date PCT application designating United States was filed
Beyond the Standard 20 Years

Patent Term Adjustment (PTA)
- Governed by 35 U.S.C. § 154(b)
- Meant to compensate for USPTO delays examining and issuing patent
- Ensures that “no applicant diligently seeking to obtain a patent will receive a term of less than 17 years”

Patent Term Extension (PTE)
- Governed by 35 U.S.C. § 156
- Meant to compensate for delays in regulatory approval process for pharmaceutical and other products subject to pre-market approval

Total Patent Term = “Standard Term” + PTA + PTE
Patent Term Adjustment (PTA)

PTA = (Days of PTO Delay) – (Days of Applicant Delay)

- Can have days added to patent term, but can never have days subtracted (PTA ≥ 0)
- PTA = 0 if applicant delay equals or exceeds PTO delay

Eligibility:
- Available to applications filed on or after May 29, 2000
- For U.S. national phase applications, PCT filing date must be on or after May 29, 2000

Rules and Regulations Governing PTA:
- 37 C.F.R. §§ 1.702 – 1.705
- M.P.E.P. §§ 2730 - 2736
The ABC’s of Patent Term Adjustment

35 USC 154(b)(1)(A) – “A Delay”
   – PTO failure to timely issue Office Actions, or reply to Applicant’s responses to Office Actions

35 USC 154(b)(1)(B) – “B Delay”
   – PTO failure to issue patent within three years from application filing

35 USC 154(b)(1)(C) – “C Delay”
   – Delay resulting from
     • Appeal (BPAI or Federal Court)
     • Interferences
     • Secrecy Orders
“A Delay” - 35 USC 154(b)(1)(A)

PTO has:

- 14 months to issue 1st Office Action
  - A Restriction Requirement or OA on merits, not Notice to File Missing Parts
  - Measured from actual filing date for applications under 35 USC 111(a)
  - For applications under 35 USC 371 (PCT National Phase)
    - Measured from date on which PCT application “fulfilled the requirements of section 371” 35 USC 154(b)(1)(A)(i)(II)
    - PTO measures from completion of all § 371(c) requirement (can be later than date National Phase commences)

- 4 months to
  - reply to response or appeal by applicant
  - issue action after BPAI decision
  - issue patent after issue fee payment

Starts accumulating day after deadline
“B Delay” – 35 USC 154(b)(1)(B)

For delay due to PTO failure to issue patent within 3 years of “actual filing date of the application in the United States” 35 USC 154(b)(1)(B)
– Starts accumulating on day after application pending for 3 years

Events that stop the “3 year clock”
– Filing an RCE stops 3 year clock forever
  • Can get “B Delay” only for time before RCE filing date
– Interference (may recover time as “C Delay”)
– Secrecy Order (may recover time as “C Delay”)
– Notice of Appeal
  • May recover time as “C Delay” only for “successful” appeal
“Japan Tobacco” Issue

How to measure 3 year pendency (for “B Delay”)

- For applications under 35 USC 111(a)
  - Measured from actual filing date in USPTO
- For applications under 35 USC 371 (PCT National Phase)
  - Regulations say measure from when “national stage \textit{commenced} under 35 USC 371(b) or (f)” 37 CFR 1.702(b) (emphasis added)
  - PTO practice had been to measure from when national stage \textit{completed} under 35 USC 371(c)!!

F&R challenged for US 7,465,444 (Japan Tobacco)

- PTO granted petition, adjusted PTA
- PTO issues formal notice acknowledging “Japan Tobacco” error
  - “in process” of correcting the problem
  - Patentees must file request for correction within 2 months after patent grant
  - No provision for retroactive remedy
“C Delay” – 35 USC 154(b)(1)(C)

For delays due to

– Interferences
– Secrecy orders
– Appeals
  • Appeal must result in final decision by Board or Federal Court, reversing the rejection of at least one claim
Calculating PTA: Overlapping Delay Periods

The statute [35 USC 154(b)(2)(A)]:
- To the extent that period of “A Delay” and “B Delay” overlap, the period of adjustment shall not exceed the actual number of days the issuance of the patent was delayed
- Prevents double counting where there is overlap in “A” and “B” Delay
- PTO interpreted as entire period when application is pending
  • Granted patentees A Delay or B Delay, whichever was larger, but not both

Wyeth v. Kappos (591 F.3d 1364 (Fed. Cir., Jan. 2010)):
- Overruled PTO interpretation of statute
- Patentee is entitled to the addition of “A” and “B” Delay to extent they do not occur on the same calendar day(s)
**Wyeth v. Kappos**

- Increases PTA for many patents pending more than three years
  - “B” Delay does not begin to accrue until application is pending more than three years
  - Applicant also entitled to any “A” Delay occurring during first three years of prosecution

- **Jan. 20, 2010:** PTO and DOJ announce they will not appeal, making Fed. Cir. decision final

- **Jan. 26, 2010:** PTO publishes interim procedure for calculating PTO per *Wyeth*
  - Provides temporary grace period for selected patents
  - Only applicable to patents issued prior to Mar. 2, 2010 where request for recalculation is filed within 180 days of grant
    - *i.e.*, for patents granted from about Sept. 3, 2009 to Mar. 2, 2010
Applicant Delays

PTA reduced by “the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application” 35 USC 154(b)(2)(C)
Common Applicant Delays

- Filing response more than three months after PTO Office Action mailed
  - Every day after 3-month date counts (weekends, holidays, etc.)
  - E.g., filing response on Monday when three month due date is Saturday counts as 2 days of Applicant Delay

- Incomplete reply
  - E.g., non-responsive and non-compliant amendments

- Submitting supplemental reply

- Submitting IDS after response to Office Action, unless
  - Filed w/in 30 days of action in counterpart foreign application, and
  - All art first cited in the foreign action
Review and Correction of PTA

At Allowance
- PTO calculates PTA “to date” and indicates on Notice of Allowance
  - Only A and C Delay calculated at this stage
- Applicant must challenge any PTA errors by petition on or before payment of the Issue Fee (37 CFR 1.705(b))
  - Patent generally does not issue until PTO decides petition

At Issuance
- PTO calculates any other delay that has occurred after allowance (including any B Delay)
- Patentee must challenge any additional PTA awarded at issuance within 2 months of issue date (37 CFR 1.705(d))
Appeal of PTA Determination

- Applicant dissatisfied with final determination of PTA by Patent and Trademark Office
  - May appeal by civil action in D.D.C.
  - Appeal must be made within 180 days after the grant of the patent
  - No appeal or challenge of PTA by third parties

- PTO often has not concluded final review of PTA matters raised at issuance by the 180-day deadline
  - Applying 180-day deadline to B Delay matters would often cause civil action to be filed before receiving PTO’s final decision
Appeal After Patent Issues

The Statute:

- 35 USC 154(b)(4)(A): “applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia” (emphasis added)

- 35 USC 154(b)(3): “Director shall – (i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination with the written notice of allowance.” (emphasis added)

Novartis v. Kappos

- Civil action filed July 6, 2010
- Challenges PTA calculated for patents issued before Wyeth
  - All patents-in-suit issued more than 180 days before civil action filed
Novartis v. Kappos

Legal Theory Presented by Novartis

- Statute’s 180-day deadline for appeal applies only to PTA determination made in conjunction with notice of allowance
  - PTA calculation at issuance is not a determination “under paragraph (3) of statute
  - 180-day deadline inapplicable to B-Delay determinations
- Novartis lacked knowledge of PTO’s improper interpretation of statute
- Discovery of error could not have occurred prior to Wyeth
- Administrative Procedure Act (APA) bars civil action commenced more than six years after right of action accrues (patent issues)

Success would mean patents with Wyeth errors could be corrected even if not discovered until more than 180 days after patent issuance
Patent Term Extension (PTE)

Purpose is to remedy loss of patent term due to delays in regulatory processes for pharmaceuticals and other products subject to pre-market approval.

Governed by:
- Statute: 35 USC §156
- PTO Rules and Regulations
  - 37 CFR §§ 1.710 - 1.791
  - MPEP §§ 2750-2764
Eligibility for PTE

eligible patents must claim:

- A product subject to regulatory review *before* commercial marketing or use
  - Human drugs, antibiotic drugs and human biologics
  - Food additives and color additives
  - Medical devices
  - Animal drug products
  - Veterinary biological products
- Method of using product subject to regulatory review
- Method of manufacturing product subject to regulatory review
Eligibility for PTE (cont’d)

- Product must have been subject to regulatory review *before* commercial marketing or use
- Product must be specifically recited in the claim
  - Cannot rely on “comprising” language to argue product is inherently included.
    - *See*, for example, Vusion (US 4,911,932), March 19, 2009.
  - Patent claiming metabolite of approved prodrug is *not* eligible
    - The claimed ingredient must be present in drug-product when administered
    - *Hoeschst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997)
  - Unclear if patent only claiming product/use/manufacture by equivalents (but not literally) is eligible for PTE
Eligibility for PTE (cont’d)

- Only granted patents eligible for PTE
  - Can not file PTE application until patent issues
- Must file application for PTE before patent expires
  - Can file before regulatory approval if patent would expire before end of review period
- Must file application for PTE w/in 60 days after approval
- Only one PTE granted per product per patent
  - Patent must not have been previously granted PTE under § 156
  - If patent covers two distinct products, and both are subject to regulatory review, only one extension of the patent is possible
Regulatory Delay Period

- Length of regulatory review period calculated by FDA

- It is the sum of:
  - **Testing Phase** = Date IND became effective from date NDA filed
    -- and --
  - **Approval Phase** = Date NDA filed until date approved
Calculating PTE

USPTO calculates PTE based on regulatory review period
- Subtracts from regulatory review period:
  - Time applicant did not act with due diligence
  - Time before patent issued
- PTE = ($\frac{1}{2} \times$ Testing Phase) + Approval Phase
- Maximum PTE = 5 years
- Cannot result in total remaining patent term of more than 14 years
  - Measured from date of regulatory approval to date of expiration with PTE and any PTA

Extension period runs from expiration date of patent
- As shortened by any terminal disclaimer, or
- As extended by Patent Term Adjustment
One PTE per Product per Patent

Only one PTE granted per product per patent
- Patent must not have been previously granted PTE under § 156
- If patent covers two distinct products, and both are subject to regulatory review, only one extension of the patent is possible

If approved product covered by multiple patents, only one can be extended
- But, patentee can submit more than one application based on same regulatory period
- PTO will ask applicant to choose which patent to extended
- If applicant does not respond, first patent to expire is extended
First Commercial Marketing or Use

Product must have been subject to regulatory review before commercial marketing or use

- No PTE where patent claims combination of two previously approved drugs
  - No PTE for Vicoprofen (combination of ibuprofen and hydrocodone)
  - At least one of two active ingredients in combination must be new to marketplace as a drug product

- No PTE where patent claims new formulation of previously approved “product”
  - *Fisons PLC v. J. Quigg*, 876 F.2d 99 (Fed. Cir. 1989)
“Drug product” = active ingredient of new drug
  – “including any salt or ester of the active ingredient”
    [35 USC § 156(f)(2)]

PTE not possible where a “salt” or “ester” of active ingredient was previously approved

But, where “salt” of active ingredient had been previously approved, patent covering an “ester” of the active ingredient still eligible for extension
  – New product not a “salt” or “ester” of the previously approved product
  – *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990)
Scope of Protection During PTE

- Only “use approved for the product” is protected during PTE (35 USC § 156(b)(1))
- For patent covering method of manufacturing product, protection limited to method used in making the approved product
  - To infringe product-by-process claims, must manufacture product by process recited in claims. Must NDA holder manufacture product by same process?
  - Probably not
Scope of Protection Under PTE (cont’d)

Active “moiety” v. Active “ingredient”

– Active “moiety” approach for PTE enforcement does not require same active ingredient as the approved product

_Pfizer, Inc. v. Dr. Reddy’s Labs. Ltd., 359 F.3d 161_ (Fed. Cir. 2004)

– PTE for patent covering amlodipine besylate and amlodipine maleate (salts of amlodipine)
– Approved product was Norvasc® (amlodipine besylate)
– Dr. Reddy’s sought approval of amlodipine maleate
– PTE covered products with active moiety (amlodipine) and salts (besylate and maleate)

Inconsistent with _Glaxo Operations UK Ltd. v. Quigg_, 894 F.2d 392 (Fed. Cir. 1990)?
Active “Ingredient” v. Active “Moiety”

Photocure ASA v. Kappos, 603 F.3d 1372 (Fed. Cir. 2010)

- Previously marketed drug product was Levulan Kerastick® (aminolevulinic acid HCl or “ALA hydrochloride”) topical solution
- Photocure sought PTE for regulatory approval of Metvixia® (methyl aminolevulinate HCl or “MAL hydrochloride”)
  - Methyl ester of ALA hydrochloride
- PTO denied PTE application
  - Same active moiety (aminolevulinate or “ALA”) in both products
- Court reverses
  - “Active ingredient” in 35 USC 156 does not mean “active moiety”
  - Active ingredient was MAL hydrochloride, a new drug (different from ALA hydrochloride)
Active “Ingredient” v. Active “Moiety” (cont’d)

Must what is extended be the same as what is covered during the extension?

- PTE granted if no previous commercial marketing or use of the active *ingredient* (including its salts and esters) as a drug product
  - *Photocure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010)

  -- but --

- PTE enforced against all products containing the same active *moiety* as product subject to regulatory review
Strategies to Maximize Patent Term

Maximize PTA by minimizing applicant delay

– File responses on or before three-month deadline
  • Avoid using weekend/holiday carry-overs
  • Use of full 3 month period, without exceeding, *may* increase pendency time without penalizing for Applicant Delay

– Avoid incomplete/non-compliant replies
– Avoid supplemental amendments/responses
– File electronically
– File Information Disclosure Statements
  • Before receipt of first office action
  • With reply to non-final office action
    (IDS filed after response is treated as “supplemental reply”)
  • Within 30 days of foreign office action
    (with certification under 37 CFR 1.704(d))
Strategies for Maximizing Patent Term (cont’d)

Avoid Requesting Continued Examination (RCEs)

– Filing RCE permanently stops the 3 year clock for PTA
– Petition to have finality of office action withdrawn (if appropriate)
  • Final Office Action inappropriate if examiner makes a new rejection not necessitate by Applicant’s previous amendment
  • E.g., amendment only canceling dependent claims and amending independent claims to recite the canceled dependent claim limitations
Strategies for Maximizing Patent Term

**Prosecution by Appeal:**
- Consider filing a Notice of Appeal and Appeal Brief instead of RCE.
- If appeal goes to Board, C-Delay available if decision favorable to Applicant.
  - Only need to reverse one claim rejection.
- Examiner may reopen prosecution, issue new Office Action.
  - Can respond to new Office Action or reinstate appeal.
  - If Applicant responds, any C-delay accrued during appeal process is lost, but A- and B-Delay still available.
- Interview Examiner to strike deal.
- Examiner “throws in the towel” and allows.
Strategies for Maximizing PTA

Avoid Unnecessary Terminal Disclaimers

- Filing Terminal disclaimer may limit or eliminate PTA
- Consider filing strategies to minimize overlap that might create double patenting
  - \textit{E.g.}, filing to increase Restriction Requirements and responding without traverse
  - Double patenting rejection over divisional applications not appropriate (with some exceptions)

File \textbf{complete} National Phase applications

- 14-month clock for first Office Action does not start until application is “complete”
- Consider filing a continuation, rather than National Phase, of PCT
Patent Filing Strategies

File new applications as products developed and improved
- New formulations of existing drugs
- New combinations of existing drugs
- Stereoselectivity, single enantiomers
- New indications

Must be new and non-obvious over existing patent applications as prior art
- Unpublished US application not prior art if same inventors or same obligation to assign [35 USC 103(c)]
- Published applications may be prior art under §102(a) or §102(b)
Patent Filing Strategies (cont’d)

File first as provisional applications
- File as non-provisional one year later
- Patent term 20-years from first non-provisional filing
- Buys an extra year of patent term

Avoid filing Continuations-in-Part (CIPs)
- CIP patent term is 20-years from first non-provisional to which it claims priority
  - even if first non-provisional does not describe or enable the CIP’s invention
- Priority application may be “prior art” against CIP if priority does not describe and enable invention claimed in CIP
  - e.g., CIP claims obvious over published priority application or over unpublished priority application with different inventors (and different obligations to assign)
Questions?

Samuel S. Woodley, Ph.D.
Principal
Fish & Richardson
New York, NY
(212) 641-2363
woodley@fr.com