Birch Stewart Kolasch Birch LLP

In re Cellect (Fed. Cir. 2023): analysis and insights into Patent Term Adjustment (PTA) under 35 USC § 154; Patent Term Extension (PTE) under 35 USC § 156; Obviousness-Type Double Patenting (OTDP); and Terminal Disclaimers (TD)

Whitney Remily

Birch
Stewart
Kolasch
Birch LLP

Patent Term

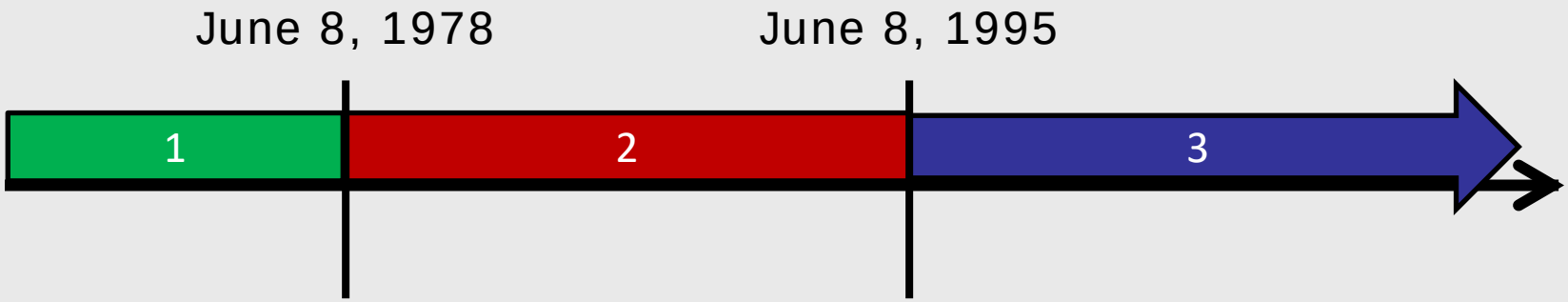
Changes to Patent Term over time…

- In 1861, the patent term was set to 17 years from grant

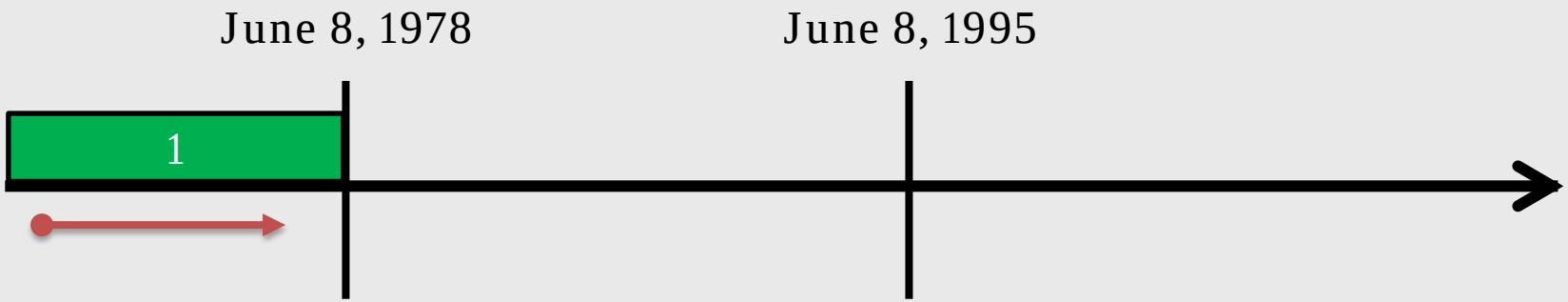
- In 1994, the U.S. signed the Uruguay Round Agreements Act
  - patent term measured from **the filing date** of the application and **not the grant date** of the patent

- In 1999, Congress amended 35 U.S.C. § 154 to provide for Patent Term Adjustment (PTA)
  - Applications filed **after May 28, 2000** became subject to the changes to 35 USC 154(b).

Patent Term (Utility & Plant)



Patent Term (Utility & Plant)

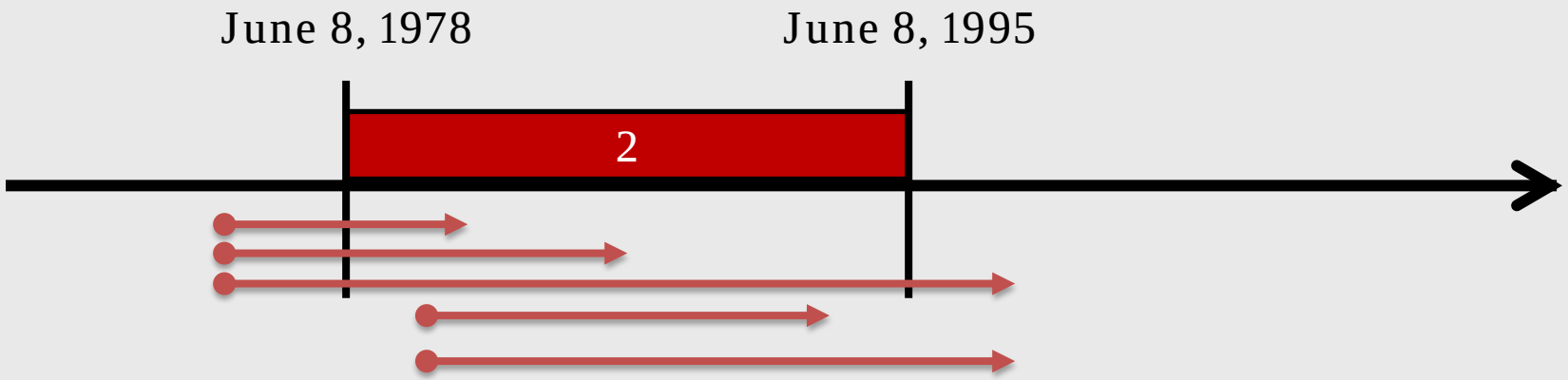


Zone 1

Issued and expired prior to June 8, 1978

17 Years from Issue Date

Patent Term (Utility & Plant)

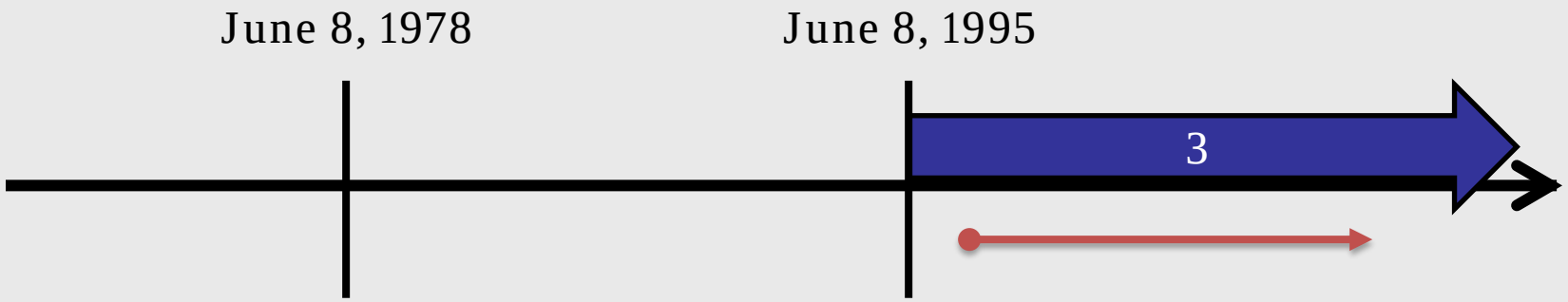


Zone 2

Filed prior to June 8, 1995 and Pending or Enforced on June 8, 1978

Longer of 17 Years from Issue Date & 20 Years from Earliest Filing Date (earliest parent US/PCT filing date, not foreign filing date)

Patent Term (Utility & Plant)

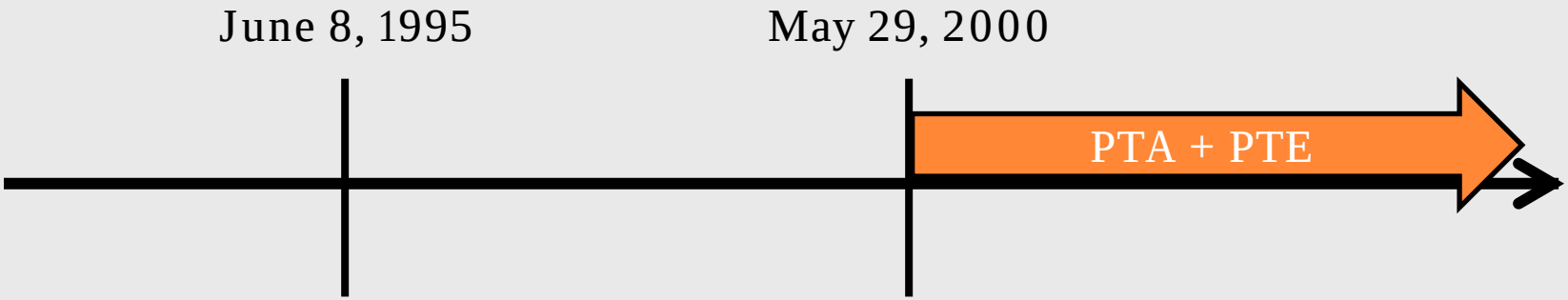


Zone 3

Filed on or after June 8, 1995

20 Years from Earliest Filing Date (earliest parent US/PCT filing date, not foreign filing date)

Patent Term Adjustment



PTA – 35 U.S.C. § 154

- **Filed on or after 5/29/2000**

PTE – 35 U.S.C. § 156

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Patent Term Adjustment (PTA)

Patent Term Adjustment

- **35 U.S.C. § 154(b)** applies to original utility and plant applications filed on or after May 29, 2000

Patent Term Adjustment

- **35 U.S.C. § 154(b)**
  - Three type of delays: "A" Delays, "B" Delays, and "C" delays

    (A) Guarantee of prompt patent and trademark office responses *(the "14-4-4-4 Rule")*

    (B) Guarantee of no more than 3-year application pendency *(the "3-Year Rule")*

    (C) Guarantee of adjustments for delays due to interferences, derivation proceedings, secrecy orders, and successful appeals

Patent Term Adjustment

For patent issued from application filed on or after 5/29/2000

- PTA = USPTO Delay – Applicant Delay
  = A Delay + B Delay + C Delay
  – Overlap (A/B and A/C)
  – Applicant Delay
- Patent Term = Original Term (20-yr rule)
  + PTA (always ≥ 0)
  (subject to Terminal Disclaimer)
  + PTE (II)

Patent Term Adjustment

- **“A” Delay occurs if USPTO does not**
  - Provide at least one notification within 14 months from filing date
    - Office Action
    - Restriction Requirement
    - Notice of Allowance
  - Respond within 4 months for other actions
    - Respond to a reply
    - Respond when an appeal is taken
    - Act on a decision by PTAB
    - Issue a patent after issue fee paid
  - The “14-4-4-4 Rule”

Patent Term Adjustment

- **“B” Delay occurs if USPTO does not**
  - Issue a patent within 3 years after the actual filing date
    - Not including
      - Any time consumed by interference, secrecy order, appellate review of PTAB or Federal court
      - Any delay at the request of the applicant
      - Any time consumed by continued examination (RCE*)
        - time from allowance to issuance would still count toward the PTO’s three-year allotment (*Novartis AG v. Lee*)

Patent Term Adjustment

- **“C” Delay occurs due to**
  - Interference
  - Secrecy order
  - Successful appellate review
    - Start from date jurisdiction passes to PTAB (Reply Brief received) until a final favorable decision (New 37 C.F.R. § 1.703(e))

Patent Term Adjustment Limitations

- Adjusted term cannot extend beyond expiration date specified in any filed (and approved) Terminal Disclaimer
- Reductions in PTA for Applicant delays

Patent Term Adjustment Limitations

- Double-counting prohibited
- Overlap occurs if
  - A/B and A/C Delays occur on the same calendar day(s)
- USPTO Delay

  = A Delay + B Delay + C Delay

  – Overlap (A/B and A/C)

Patent Term Adjustment—Applicant Delay

- **37 C.F.R. § 1.704**
  - time in excess of **3 months** to reply to any action or notice
  - suspension of action
  - deferral of issuance
  - abandonment or late payment of issue fees
  - failure to timely request withdrawal of a holding of abandonment
  - conversion of a provisional application
  - submission of a reply having an omission
  - submission of a supplemental reply or other paper (*e.g.*, IDS) not expressly requested by Examiner after a reply has been filed

Patent Term Adjustment —Applicant Delay

- **37 C.F.R. § 1.704 (cont.)**
  - submission of a preliminary amendment requiring the mailing of a supplemental office action
  - submission of an amendment after a decision by the PTAB…
  - submission of an amendment or **other paper** (other than RCE) after a notice of allowance has been mailed
  - failure to file Appeal Brief or RCE within 3 months after Notice of Appeal
  - submission of an RCE after Notice of Allowance
  - failure to provide an application in condition for examination within eight months from filing

Patent Term Adjustment

- **PTA = USPTO Delay – Applicant Delay**
  = A Delay + B Delay + C Delay
  – Overlap (A/B and A/C)
  – Applicant Delay
- Patent Term = Original Term (20-yr rule)
  + PTA (always ≥ 0)
  (subject to Terminal Disclaimer, Maintenance fees, *etc*.)

Patent Term Adjustment

- **USPTO PTA Determination**
  - USPTO only needs to provide PTA determination when patent grants
- **Request for Reconsideration of PTA**
  - Must be filed to USPTO no later than 2 months (extendable for up to 5 months) from the date the patent was granted
- **Appeal of Final Determination**
  - Must be filed to Federal District Court of E.D. Va within 180 days of the final decision on the Request for reconsideration

Patent Term Extension (PTE)

PTE Overview

- PTE available under the 1984 Drug Price Competition and Patent Restoration Act “Hatch-Waxman Act”

- PTE under 35 U.S.C. § 156 extends the term of a patent covering a pharmaceutical product due to delays in the FDA’s review process
  - 35 U.S.C. § 156 – Extension if a product “has been subject to a regulatory review period before its commercial marketing or use.”

- Products that require regulatory approval prior to marketing:
  - human and veterinary pharmaceuticals
  - food additives
  - color additive
  - medical device

PTE Overview

- Multiple patents may cover the product, but only **one** patent term can be extended per regulatory review period
- Maximum of 5 years PTE
- Patent term cannot be extended beyond 14 years after FDA approval
- Terminal Disclaimer does not negate the PTE

PTE Application process

- Determination made by the U.S. Patent and Trademark Office (USPTO), in consultation with the Food & Drug Administration (FDA).
- Within sixty days of regulatory approval, Applicant files application for PTE with the USPTO
- USPTO reviews PTE application for all formal requirements and whether the patent is eligible for extension
- The USPTO forwards the application to the FDA to confirm whether:

  (1) the product was subject to a regulatory review period prior to approval,

  (2) the FDA's approval was the first permitted commercial marketing or use of the product, and

  (3) the PTE application was filed within the required sixty-day period.

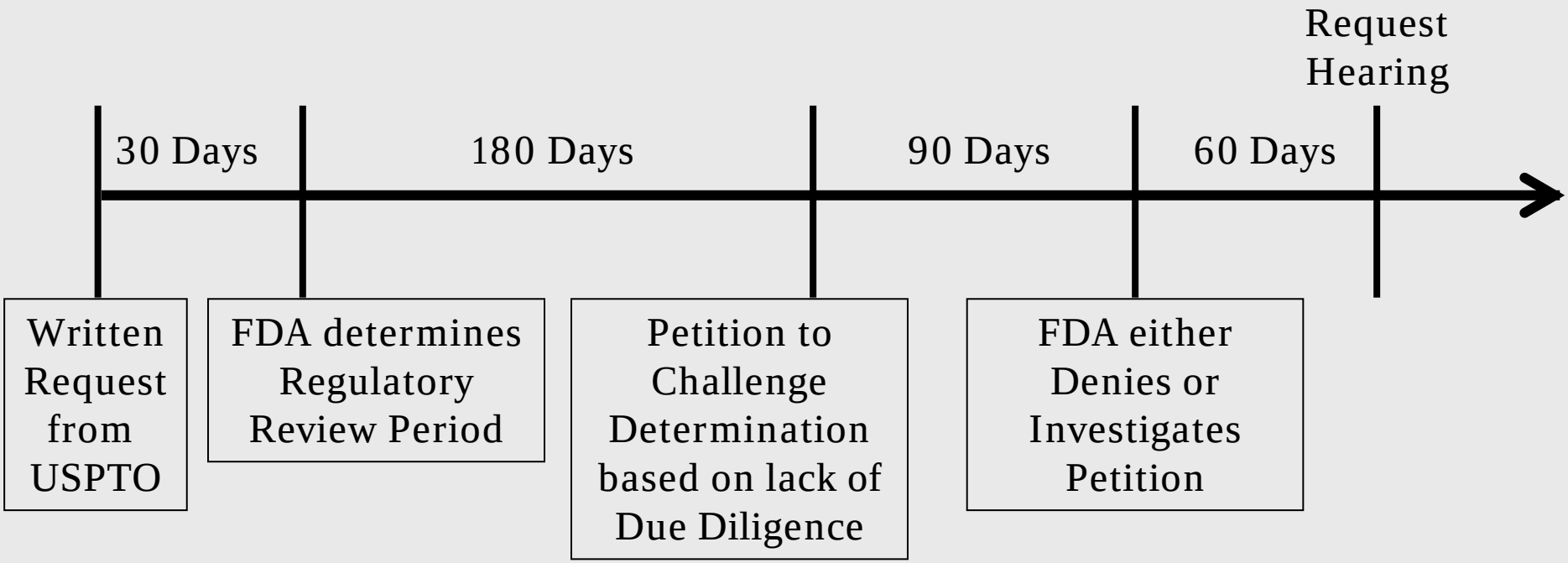
PTE Application process (con't)

- After receiving the FDA's eligibility determinations, the USPTO provides the FDA with notice and a copy of the application and requests a determination of the length of the regulatory review period of the product.
- The FDA calculates the regulatory review period, notifies the USPTO, and publishes the calculation in the Federal Register.
  - Other parties can intervene
  - Any person can request revision of the regulatory review period within 60 days from Federal Register publication
  - A third-party may file a due diligence petition within 180 days

PTE Application process (con't)

- After the 180-day notice ends, and the petitions/hearings are resolved, the FDA send its final regulatory review period determination to the USPTO
- The USPTO issues its final determination

Right To Challenge Regulatory Review Period

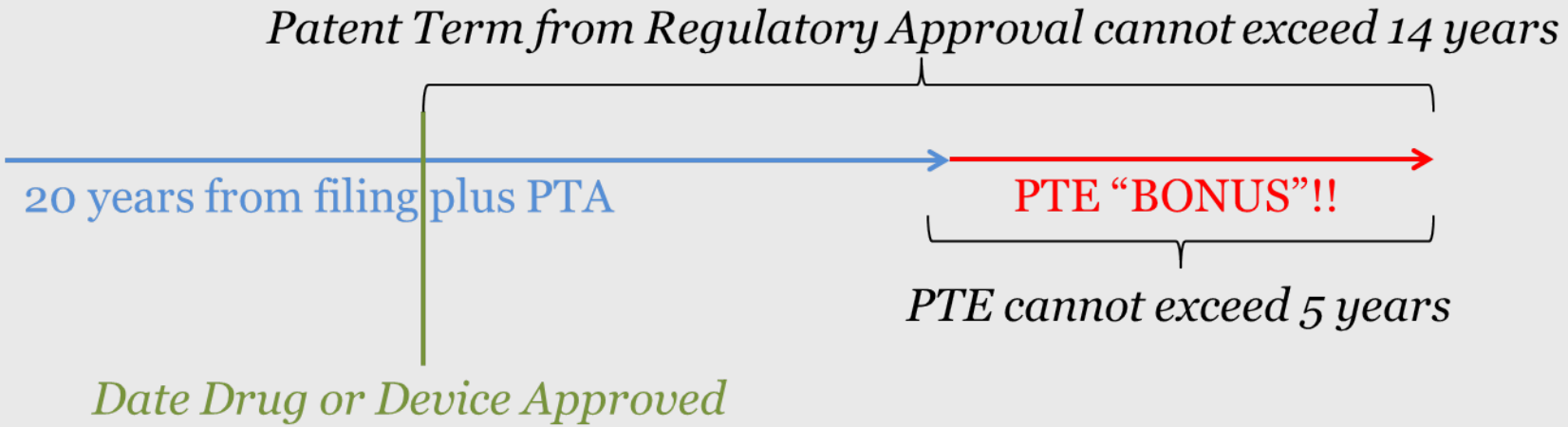


Right To Challenge USPTO PTE Determination

- The denial or amount of PTE can challenged by Applicant by filing against the USPTO under 5 USC 702 of the Administrative Procedure Action in the Eastern District of Virginia (*Photocure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010)).

- The granting or amount of PTE can be challenged in federal court litigation by a third party (*Ortho-McNeil Pharmaceutical, Inc. v. Lupin Pharms*., *Inc*., 603 F.3d 1377 (Fed. Cir. 2010)).

Length of PTE



- PTE may be available for up to 5 years (35 USC 156 (g)(6)(A)).
- Total patent term including PTE from date of Regulatory Approval CANNOT EXCEED 14 years (35 USC 156 (c)(3)).

Length of PTE

- The regulatory review period is based on the sum of “1/2 testing period” and the “approval period,” less:
  - The number of days which were on or before the patent issued
  - The number of days during which the applicant did not act with due diligence
  - One-half the number of days of the testing period after the patent issued

Regulatory Review Period

- Refer to 35 USC § 156(g), for (1) new drug, (2) a food additive or color additive, (3) medical device, (4) new animal drug, and (5) veterinary biological product
- For a drug:
  - **Testing Phase (IND to NDA)**: begins on the date a clinical investigation on humans is begun and ends on the data of an application for a New Drug Application is submitted
  - **Approval Phase (NDA and FDA approval)**: begins on the date an NDA is initially submitted and ends on the date the application is approved.

PTE Eligibility Requirements

- Must File Application Within 60 Days After Regulatory Approval
- Product Must Be Subject to Regulatory Review Before Commercial Marketing or Use
- Product Must Be Recited in The Claim
- Only Granted Patents Eligible for PTE

PTE Procedural Requirements

- PTE must be filed for before the patent expires
  - There are provisions under § 1.790 for the “Interim extension” of patent term under 35 U.S.C. 156(d)(5).

PTE Procedural Requirements

- Limitations
  - Only for first commercial marketing of the product
  - Only one PTE Can Be Applied to Each Patent; only one extension for a patent
  - Only One PTE Is Available for Each Approved Drug, Device, *etc*.; only one patent for a single regulatory period

Must be First Commercial Marketing of API

In case of an active pharmaceutical ingredient (API):

- Must be the first FDA approval for that “active ingredient”

- The Federal Circuit upheld PTE for a drug product of the **enantiomer** levofloxacin, finding that it was different than a drug product of its racemate ofloxacin (*Ortho-McNeil v. Lupin* (Fed. Cir. 2010))

- However, the Federal Circuit upheld the denial of PTE for the **active methyl ester form** of a compound that had previously been approved that had the same “active moiety” as the previously approved product (*Photocure v. Kappos* (Fed. Cir. 2010))

Combination Products

• For a drug product containing multiple active ingredients, if any one active ingredient has not been previously approved, it can form the basis of an extension of patent term provided the patent claims that ingredient.

See 35 U.S.C. 156(f)(2)(B).

Terminal Disclaimer does not negate PTE

- A patent was not proven invalid for OTDP, even though the patent's term had been terminally disclaimed during prosecution, and then extended via PTE past the reference patent's expiration date.
  - *Merck & Co. v. Hi-Tech Pharmacal,* 482 F.3d 1317 (Fed. Cir. 2007)

Terminal Disclaimer does not negate PTE

- Federal Circuit held that OTDP does not truncate validly obtained PTE, if the unextended patent would have been otherwise valid.
  - *Novartis AG v. Ezra Ventures*, 909 F.3d 1367 (Fed. Cir. 2018)

PTE Rights are Limited

35 U.S. C. § 156 (b) explains the rights derived from PTE during the period during which the term of the patent is extended with respect to the approved product—

(1)in the case of a patent which **claims a product**, be **limited to any use approved for the product**…

(2)in the case of a patent which **claims a method of using a product**, be **limited to any use claimed by the patent and approved for the product**…

(3)in the case of a patent which **claims a method of manufacturing a product**, be **limited to the method of manufacturing as used to make the approved product**…

How to check if a Patent has PTE granted

- Check file history on PAIR system
- Check Certificate of Correction
- UPSPTO website maintains a listing of extended patents

https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156

Patent Terms Extended Under 35 USC §156

NOTE: This list is for informational purposes only and is not intended to have legal effect. Furthermore, this list does not include patents which have been extended only under § 156(e)(2) or § 156(d)(5) (patents which have only received an interim extension). A copy of the certificate of extension should be included in the "correction" section of the patent's images. All patent images can be found in the Patent Full Text and Image Database.

For further information, contact Ali Salimi at (571) 272-0909 or ali.salimi@uspto.gov or Raul Tamayo at (571) 272-7728 or raul.tamayo@uspto.gov .

Please note that nearly all patent term extension applications are available on Public PAIR.

Additional information concerning patent expiration dates of human drug products can be obtained from the Food and Drug Administration, Center for Drug Evaluation and Research. The Patent and Exclusivity Addendum of the "Orange Book" the Approved Drug Products with Therapeutic Equivalents Evaluations includes an alphabetical listing of human drug products according to generic name with related patent information.

Patent No.	Tradename of Product (generic name, if applicable)	Original Expiration Date*	Period of Extension Granted
RE27757	CARDIOVERTER (Defilbrillator System)	10/26/1988	2 years
RE30577	BEPADIN/VASCOR(bepridil hydrochloride)	6/8/1993	2 years
RE30633	DEMADEX (torsemide)	4/19/1994	5 years
RE30811	ENICAID (encainide HCl)	12/20/1994	2 years
RE30910	DEURSIL (ursodeoxycholic acid)	1/7/1992	2 years
RE31244	PINDAC (Pinacidil)	11/8/1994	2 years
RE32969	ORCOLON (polyacrylamide)	9/10/2002	931 days

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Double Patenting

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Types of Double Patenting

- Statutory-Type Double Patenting
- Non-Statutory Obviousness-Type Double Patenting

Statutory-Type Double Patenting

35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain ***a patent*** therefor, subject to the conditions and requirements of this title.

Options:

- Amend or cancel claims so that they are not coextensive in scope
- Terminal Disclaimers not permitted

Responding to a Statutory-Type Double Patenting Rejection

Two-prong analysis:

- Compare application and patent claims to determine differences.
- Determine whether those differences render the claims patentably distinct.

- MPEP § 804: "A reliable test for double patenting under 35 U.S.C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). "

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Non-Statutory Obviousness-Type Double Patenting

- Non-Statutory
- Analysis
  - Scope/content of the potentially conflicting **claims** are compared
- In the OTDP analysis:
  - OTDP can be based on anticipation and/or obviousness arguments
  - Other prior art can be combined with a patent claim to support conclusion of OTDP

OTDP Analysis/Arguments

- Determine the scope and content of a **patent claim** from the earlier-filed patent/application relative to the **patent claim** in the later-filed patent/application;
- Determine the differences between the scope and content of each of the patent claims;
- Determine the level of ordinary skill in the pertinent art; and
- Evaluate any objective indicia of nonobviousness

OTDP Analysis/Arguments

- Proceed with Caution: your comments might characterize not only the present application, but also the reference (which may also be owned by your company/client)

Public Policy Considerations

- Prevent a patentee from expanding the scope of patent protection by filing multiple applications on the same invention, or obvious variations

- Patent system incentive to promote research and innovation by encouraging public disclosure
  - Public will be free to use not only the invention claimed in the patent, but also any obvious modifications

  In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985)

Public Policy Considerations

- Pre-GATT, the patent term was 17 years from issue date
- Post-GATT, the patent term is 20 years from the earliest claimed priority date
  - Patent term could still be different due to potential Patent Term Adjustment (PTA)

Public Policy Considerations

- Terminal Disclaimer intended to mitigate two main concerns:
  - Extension of the Patent Term
  - Multiple Lawsuits from multiple Patent Owners

Public Policy Considerations

- Public policy to prevent a patentee from expanding the scope of patent protection by filing multiple applications on the same invention, or obvious variations

- Patent system incentive to promote research and innovation by encouraging public disclosure
  - Public will be free to use not only the invention claimed in the patent, but also any obvious modifications

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Common Ownership

- The application and reference (application/patent) must have common ownership.
  - have at least one common inventor,
  - have a common applicant,
  - be commonly assigned/owned, or
  - are subject to a joint research agreement as set forth in 35 U.S.C. § 102(c) or in pre-AIA 35 U.S.C. § 103(c)(2) and (3).

At the time of invention (pre-AIA) or at the time of filing (AIA).

See MPEP 804; MPEP § 706.02(l)(2)

Common Ownership

- The patents must be “entirely or wholly owned by the same person(s) or organization(s)”.
  - No common ownership between (1) Novartis AG and (2) Novartis AG and Lohmann Therapie-Systeme AG(“LTS”)
    - *Novartis Pharm. Corp. v. Noven Pharm*., *Inc.*, Civ. No. 13-527-RGA, 2015 U.S. Dist. LEXIS 115246 (D. Del. Aug. 31, 2015)
  - No common ownership between (1) University of North Carolina (“UNC”), and the other application was assigned to (1) UNC and(2) E.I. du Pont de Nemours and Co.
    - *Ex Parte Brookhart*, No. 2005-2463, 2005 Pat. App. LEXIS 2485 (BPAI Sept. 19, 2005)

Terminal Disclaimers Filed During Prosecution

- Applies to whole patent, not individual claims. 35 U.S.C. § 253.

- A TD can be withdrawn via Petition during prosecution (37 CFR § 1.182; *see* MPEP § 1490), but must provide reasons.

Terminal Disclaimers – CANNOT WITHDRAW After Issuance

- Reissue application is not a basis to withdraw a previously filed Terminal Disclaimer (that was filed during prosecution of application).
  - *In re Yamazaki,* 702 F.3d 1327, 1332, 104 USPQ2d 2024, 2028 (Fed. Cir. 2012)
  - *In re Dinsmore,* 757 F.3d 1343 (Fed. Cir. 2014)

Terminal Disclaimers Are Difficult to Correct after issuance

- Petitions to withdraw TD due to errors will probably be denied
  - (i)transposition errors, (ii) errors in identifying the correct target application/patents number due to more than transposition errors, (iii) errors in filing a TD that is not commonly-owned, and (iv) errors due to miscommunication between practitioner and client
- *See* MPEP 1490, subsection VIII.B
  - File explanation of error; additional TD

Terminal Disclaimers – Can be filed after Issuance, but not retroactively

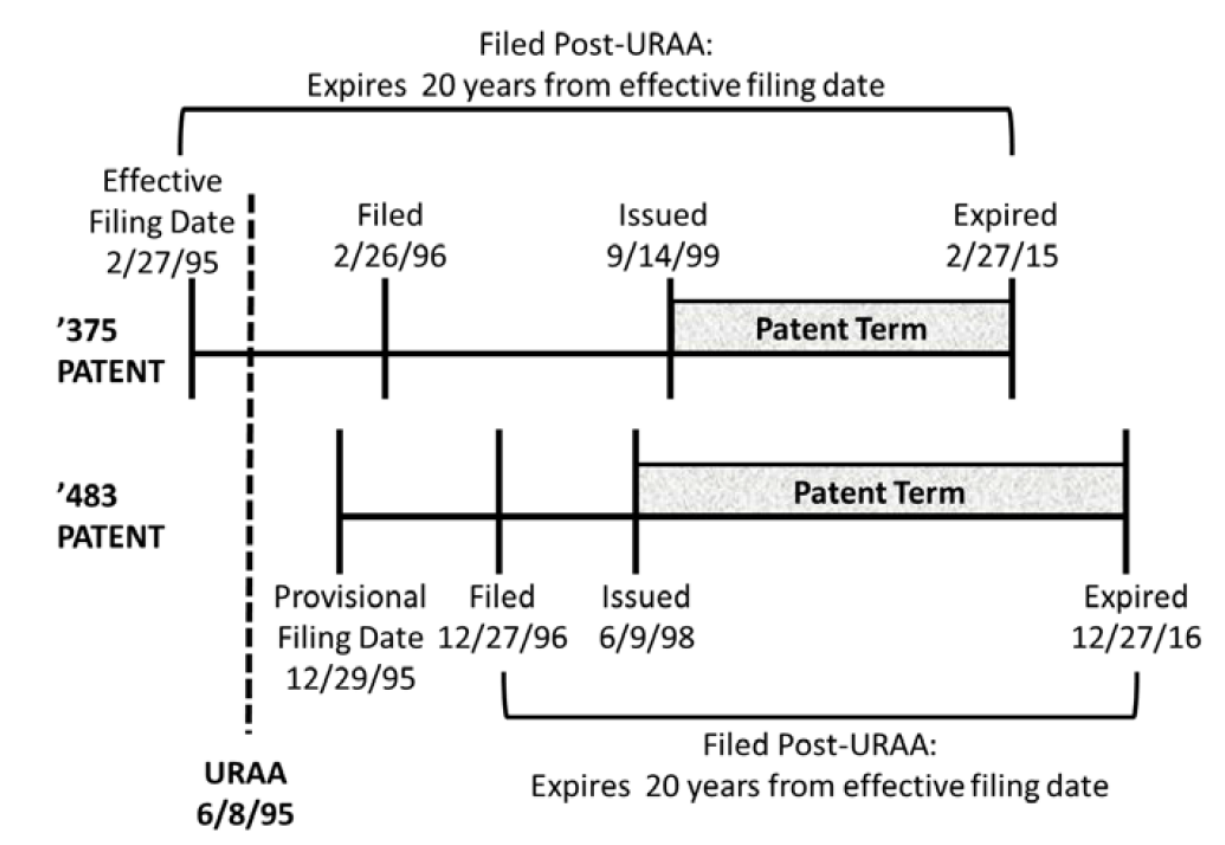
- TD can be filed post-issuance

- But cannot “retroactively” cure OTDP by filing TD after expiration of earlier patent
  - *Ingelheim International GmbH v. Barr Laboratories Inc*., 592 F.3d 1340, 93 U.S.P.Q.2d 1417 (Fed. Cir. 2010).

Gilead Sci., Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1210 (Fed. Cir. 2014)

- A later-issued but earlier-expiring patent could be applied as a reference to invalidate an earlier issued but later-expiring patent
- The OTDP analysis must focus on the **expiration dates** of the patents, not the issue dates
- A focus on issue date could lead to "gamesmanship during prosecution" (*e.g.,* arranging for applications with later filing dates to issue first)

Gilead Sci., Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1210 (Fed. Cir. 2014)



Gilead Sci., Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1210 (Fed. Cir. 2014)

- The ’375 patent could serve as a reference to the ’483 patent for OTDP

- Relying on expiration date (not the issuance date) better serves purposes of OTDP:
  - Reduce “gamesmanship during prosecution”
  - Significant difference in patent term based on only a few days difference in issue date
  - Preserves the ability to use TD

Effects of OTDP on PTE?

- A patent was not proven invalid for OTDP, even though the patent's term had been terminally disclaimed during prosecution, and then extended via PTE past the reference patent's expiration date.
  - *Merck & Co. v. Hi-Tech Pharmacal,* 482 F.3d 1317 (Fed. Cir. 2007)

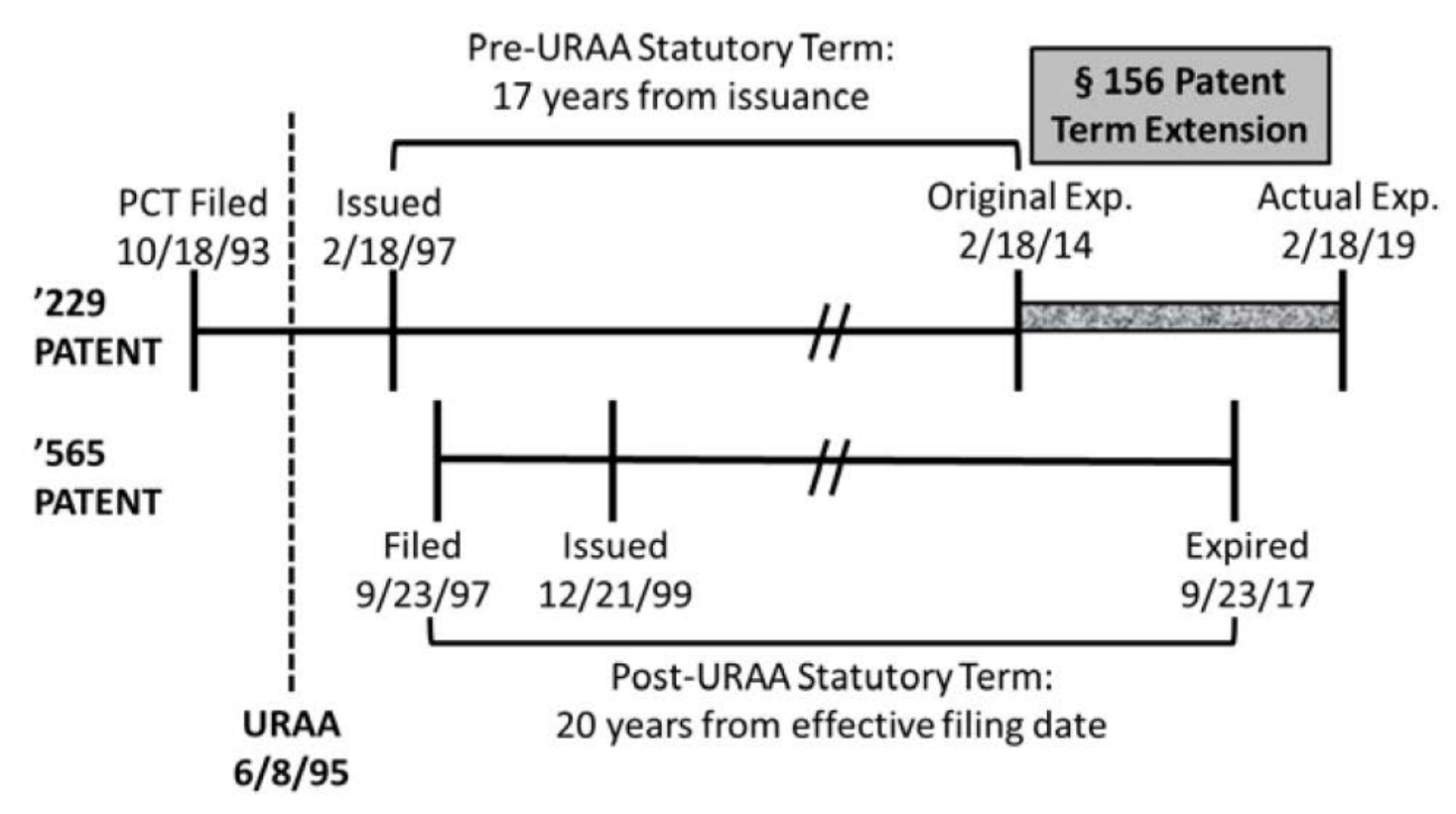
Effects of OTDP on PTE?

- Federal Circuit held that OTDP does not truncate validly obtained PTE, if the unextended patent would have been otherwise valid.
  - *Novartis AG v. Ezra Ventures*, 909 F.3d 1367 (Fed. Cir. 2018)

Novartis AG v. Ezra Ventures, 909 F.3d 1367 (Fed. Cir. 2018)

- Novartis had two patents:
  - The ’229 patent (compound)
  - The ’565 patent (methods of administering)
- Ezra argued the ’229 patent should be ruled invalid or terminally disclaimed
- Different laws apply to patent term:
  - The ’229 patent is pre-URAA patent (patent term is 17 years from issue date)
  - The ’565 patent is post-URAA patent (patent term is 20 years from earliest effective filing date)

Novartis AG v. Ezra Ventures, 909 F.3d 1367 (Fed. Cir. 2018)



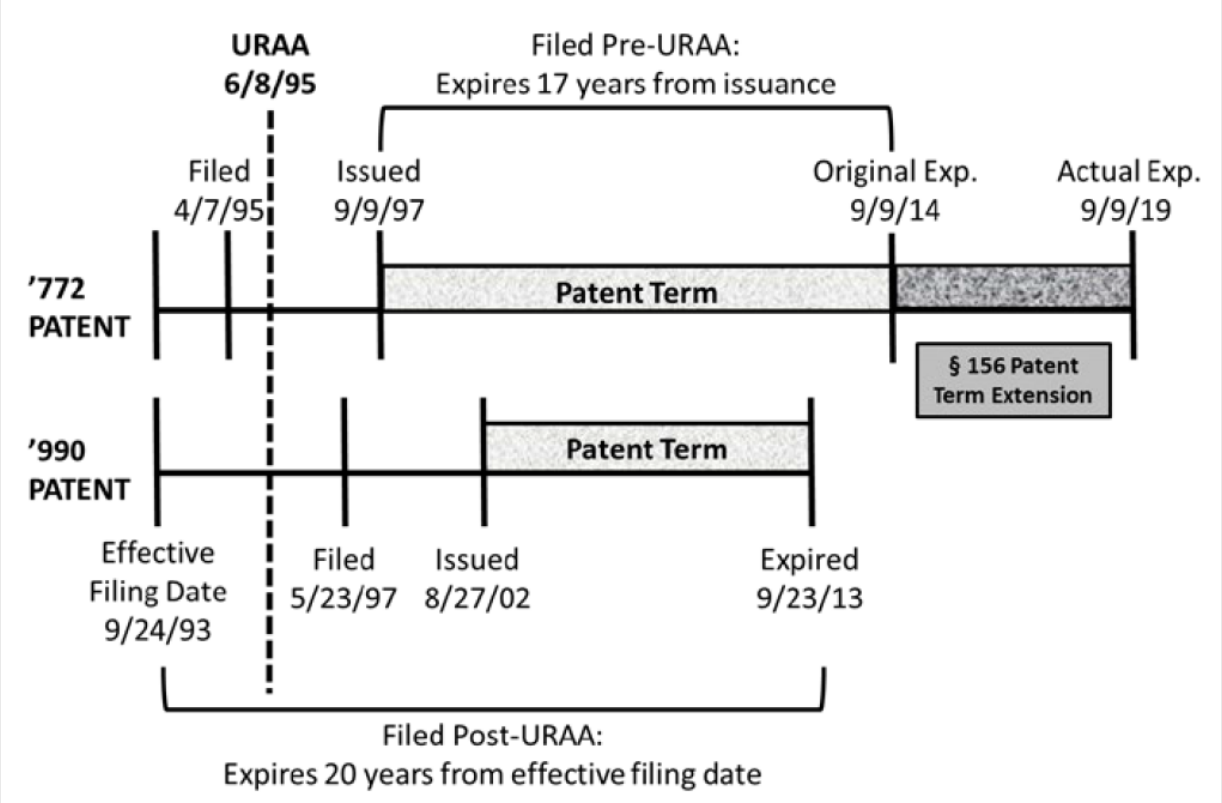
Novartis AG v. Ezra Ventures, 909 F.3d 1367 (Fed. Cir. 2018)

- The ’229 patent was not invalid for OTDP
- No potential gamesmanship issue
  - But for the PTE, the ’229 patent would have expired earlier
- “…agreeing with Ezra would mean that a judge-made doctrine would cut off a statutorily-authorized time extension. We decline to do so.”

Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical, 909 F.3d 1355 (Fed. Cir. 2018)

- Patent Owner concedes that the claimed inventions are obvious variants of each other
- Novartis' pre-GATT '772 patent expired on September 9, 2014, with PTE to September 9, 2019
- The reference patent: Novartis's GATT '990 patent was filed later, and issued after the '772 patent, but expired before the '772 pre-GATT patent

Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical, 909 F.3d 1355 (Fed. Cir. 2018)



***Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical*, 909 F.3d 1355 (Fed. Cir. 2018)**

- Federal Circuit said that *Gilead* and *AbbVie* were limited to where both patents are post-URAA patents. In contrast, the '772 patent is ***pre-URAA*** and the '990 patent is ***post-URAA***
- Both share the same effective filing date (no "gamesmanship"); "a change in patent term law should not truncate the term statutorily assigned to the pre-URAA '772 patent"
- A post-URAA patent that issues after and expires before a pre-URAA patent cannot qualify as an OTDP reference against the pre-URAA

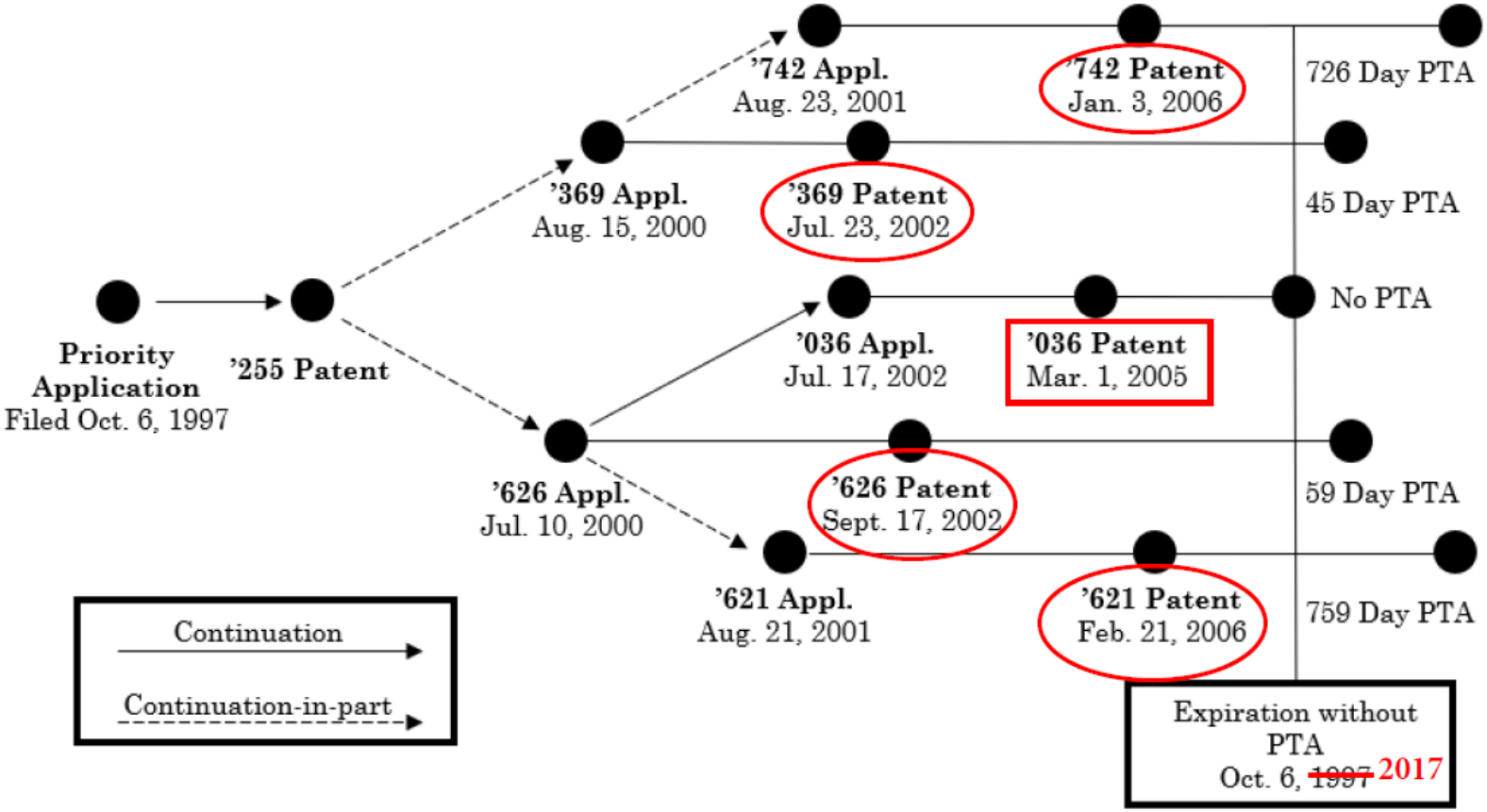
In re Cellect, LLC

Background

- Cellect, LLC (“Cellect”) sued Samsung Electronics, Co. (“Samsung”) for infringement of the challenged patents
- Samsung then requested *ex parte* reexamination
  - Asserted that patents were unpatentable for OTDP (which had not been raised by the Examiner during prosecution)
  - The PTAB (“the Board”) sustained the finding of unpatentability
- Cellect appeals from four *ex parte* reexamination decisions of the Board, affirming unpatentability of several claims for OTDP
- The Federal Circuit affirmed (Lourie, Dyk, Reyna).

Background

Patent	Claims	ODP Reference Patent
'742	22, **42**, 58, and 66	'369
'369	1, 17, 19, 21, 22, 27, **49**, 55, and 61	'036
'626	**1**, 5, 11, 33, 34, 58, and 64	'369
'621	25, 26, 27, 28, 29, and **33**	'626



Background

- Cellect does not dispute that:
  - The challenged and reference patents are commonly owned
  - The challenged patents expire after the reference patents
  - All challenged claims are patently indistinct over claims in the reference patents

Background

- Cellect did not file any TDs
- Examiner during prosecution did not raise OTDP rejections
- Patents at issue have now all expired, precluding any late filings of TDs
  - *By the time of the reexamination proceedings, the patents had expired. Nevertheless, the patentee was interested in pursuing damages for past infringement*.

USPTO position

- The Board argues that:
  - Where related patents filed at the same time claim overlapping subject matter, yet have different expiration dates due to PTA, then OTDP still applies to ensure that the Applicant does not receive an unjust timewise extension of patent term. *AbbVie*, 764 F.3d at 1373.
  - There is nothing to suggest the holding in *Novartis* should be extended to PTA in the context of OTDP

USPTO position

- The Board argues that:
  - 35 USC § 154 mentions TDs, but 35 USC § 156 does not mention TD
  - Even though 35 USC § 154 indicates PTA “shall” be granted if certain conditions are met, these are all limited by the presence of a TD in the same statute
    - The Board argues that this difference shows that Congress intended to treat 35 USC § 154 and 35 USC § 156 differently

USPTO position

- The Board argues that the following language is key:
  - 35 USC § 154 (b)(2)(B):

    Disclaimed term.—No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

Challenges on Appeal

1. Cellect argued that Board erred by considering OTDP based on expiration dates that included granted PTA

2. Cellect argued that Board failed to consider the underlying equitable concerns

3. Cellect argued that Board erred in finding a substantial new question ("SNQ") of patentability in the underlying *ex parte* reexaminations

Cellect—Challenge 1

- Cellect argues that PTA and PTE should be factored into an OTDP in the same way: based on their expiration dates before the addition of any granted PTA or PTE
  - Because PTA and PTE are both statutorily authorized extensions of term, the judicially-created OTDP cannot cut off PTA
  - Legislative intent illustrates that PTE and PTA were meant to be mandatory term adjustment/extension provisions that restore patent term lost to different administrative delays
  - The text of 35 USC § 154 and 35 USC § 156 were compared; both use the word “shall” be granted…

Fed. Cir. response

- Agreed with the USPTO that PTA and PTE should be treated differently from each other
  - Deal with different statutes and circumstances
  - 35 USC § 156 does not reference TDs
  - 35 USC § 156 provides for other requirements that must be met to obtain a PTE

Fed. Cir. response

- OTDP is a judicially-created doctrine based on 35 USC § 101, which states that an inventor may obtain “a patent” (a single patent) for an invention.
  - Prevents inventor from second, later-expiring patent for non-distinct claims

Cellect—Challenge 2

- Cellect argues that the equitable concerns underlying OTDP are not present, *e.g.,* improper timewise extension of patent term and potential harassment by multiple assignees do not exist in this case
- Cellect argues they have not purposely manipulated the system to delay issuance
- Cellect promises never to split patent among multiple owners; harassment by multiple litigants is not a concern

Fed. Cir. response

- The Fed. Circ. Agreed with the Board that Cellect received an unjustified timewise extension
  - gamesmanship is not the only issue
- There was also still a risk of separate ownership, *e.g.*, creditors dividing the patents after a bankruptcy proceeding, *etc.*
- Even in the absence of separate ownership, a TD would have been required
- Cellect's declaration/promise not to assign the patents was insufficient

Cellect—Challenge 3

- Cellect argued that Board erred in finding a substantial new question ("SNQ") of patentability in the underlying *ex parte* reexaminations

Fed. Cir. response

- Fed. Cir. agreed with the Board's determination that there was a substantial new question ("SNQ") of patentability in the *ex parte* reexaminations
- The Examiner's willingness to issue OTDP rejection in other applications but not in the challenged patents does not affirmatively indicate that he considered OTDP here
- A SNQ is not precluded by the fact that a patent or publication was previously cited/considered
- The file history does not explicitly show whether or not Examiner considered OTDP issue

Fed. Cir. response

- Fed. Cir. also agreed the Board correctly denied Cellect's request to invalidate only the granted adjustment period rather than the entire patent term
  - Invalidating only the adjustment would be tantamount to issuing a retroactive TD, which is improper
  - Cellect had opportunity to file TD during prosecution, even in the absence of an OTDP rejection, yet it declined to do so
  - Now the challenged patents have expired, and the opportunity has passed

Summary

- *In re Cellect,* the Federal Circuit invalidated several claims based on obviousness-type double-patenting (OTDP), where patents in the same family had different expiration dates due to Patent Term Adjustment (PTA) under 35 USC § 154.

Summary

- The Federal Circuit had previously held that when a patent has received Patent Term Extension (PTE) under 35 USC § 156, the expiration date used for the OTDP analysis is the patent's expiration date **before** the PTE has been added.

- Now, in *In re Cellect*, for the first time, the Federal Circuit determined that, if the patent's extended term is due to PTA, the expiration date **after** the PTA has been added should be used.

Takeaways and Strategies

- Based on the *Cellect* decision, patent claims can be found invalid under OTDP in the absence of a timely filed terminal disclaimer (TD), even where the Examiner during prosecution had not issued an OTDP rejection or required a TD for allowance of the patent application.

- Applicants may want to reconsider patent portfolios, and continuation patents, especially after a parent patent has been awarded PTA.

Takeaways and Strategies

- File a TD retroactively, assuming that the first patent has not yet expired
  - Can a Terminal Disclaimer be provisional or contingent? (*e.g.*, "disclaimer effective only if one or more claims is found unpatentable by PTAB…or a court…")
  - TD provide exceptions for situations were patent expires for failure to pay maintenance fees or is found to be invalid/unpatentable

- Sale/acquisition of related patents/applications together (ensure common ownership to avoid OTDP)

Takeaways and Strategies

- Make statements in prosecution history (maybe in an IDS) to show that OTDP issue was raised/considered, and was not applied by the Examiner

- Notify the USPTO during prosecution of applications that have related subject matter

  MPEP 2001.06(b):

  "the individuals covered by 37 CFR 1.56 ***cannot assume that the examiner of a particular application is necessarily aware of other applications which are "material to patentability" of the application in question, but must instead bring such other applications to the attention of the examiner***. See *Regeneron Pharm., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 560 (S.D.N.Y. 2015), and *Dayco Prod., Inc. v. Total Containment, Inc.,* 329 F.3d 1358, 1365-69, 66 USPQ2d 1801, 1806-08 (Fed. Cir. 2003)."

Takeaways and Strategies

- Present arguments showing that OTDP is not appropriate

- Do not file TD if the OTDP is based on patent/publication that is “102(b)” prior art
  - If the reference is a “102(b)” reference, present arguments, amend, or otherwise address the rejection

Takeaways and Strategies

- Issue the genus first, and establish species/genus are patentable over genus
  - Or maybe don’t let the genus issue?
  - Species will anticipate the genus

Takeaways and Strategies

- Supplemental examination (under 35 U.S.C. 257) to consider, reconsider, or correct information.

Takeaways and Strategies

- Provoke/Request a Restriction Requirement
  - Safe Harbor provisions
  - maintaining consonance

Takeaways and Strategies

- PTE considerations; consider how the TD interacts with the time limits for PTE
  - PTE may be available for up to 5 years (35 USC 156 (g)(6)(A)).
  - Total patent term including PTE from date of Regulatory Approval CANNOT EXCEED 14 years (35 USC 156 (c)(3)).

“Safe Harbor” under 35 U.S.C. § 121

- Must have had a prior Restriction Requirement
- Must be filed as a **divisional** application
  - Not a CON or a CIP
  - Cannot retroactively make a CIP into a DIV in reexamination; *In re Janssen Biotech, Inc*. (Fed. Cir. 2018)
  - Maintain clear demarcation in chain of divisionals
  - Consonance

“Safe Harbor” based on Restriction

- The safe harbor of § 121 applies even when the PTO issues a restriction requirement that leads to more than two separate applications.
  - *Ingelheim International GmbH v. Barr Laboratories Inc.*, 93 U.S.P.Q.2d 1417, 1425 (Fed. Cir. 2010).

- Reissue: If filed in original application, will carry over to the reissue application.

Birch Stewart Kolasch Birch LLP

Thank you!