

Safekeeping of 35 U.S.C. 156 Extensions



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Safekeeping of 35 U.S.C. 156 extensions

- High level basics
 - ◆ terminally disclaimed patents are eligible for extension
 - ◆ 35 U.S.C. 156 term additive to PTA under 35 U.S.C. 154(b)
- Application of basics to 35 U.S.C. 156
- Scenario #1
- Scenario #2
- Scenario #3
- Take Home Lessons



Terminally Disclaimed Patents Eligible for 35 U.S.C. 156

- A patent may be extended under 35 U.S.C. 156, even though it has been terminally disclaimed. MPEP 2751.
- 35 U.S.C. 154(b)(2)(B)) (May 29, 2000) provides that a patent cannot be adjusted beyond the date set by the disclaimer (see MPEP § 2730), but there is no similar provision in 35 U.S.C. 156. MPEP 2751



Terminally Disclaimed Patents Eligible for 35 U.S.C. 156

Which is correct TD language?

- (A) The patentee, Z, owner of 100 percent interest in the instant patent hereby disclaims, except as provided below, the terminal part of the statutory term of the instant patent which would extend beyond the expiration date of the **full statutory term** of patent No. Y,YYY,YYY (the “reference patent”), as the term of said reference patent is presently shortened by any terminal disclaimer. . . .*OR*
- (B) The patentee, Z, owner of 100 percent interest in the instant patent hereby disclaims, except as provided below, the terminal part of the statutory term of the instant patent which would extend beyond the expiration date of the **full statutory term as defined in 35 U.S.C. 154 to 156 and 173** of patent No. Y,YYY,YYY (the “reference patent”), as the term of said reference patent is presently shortened by any terminal disclaimer. . . .



Terminally Disclaimed Patents Eligible for 35 U.S.C. 156

(A) The patentee, Z, owner of 100 percent interest in the instant patent hereby disclaims, except as provided below, the terminal part of the statutory term of the instant patent which would extend beyond the expiration date of the **full statutory term** of patent No. Y,YYY,YYY (the “reference patent”), as the term of said reference patent is presently shortened by any terminal disclaimer. . .

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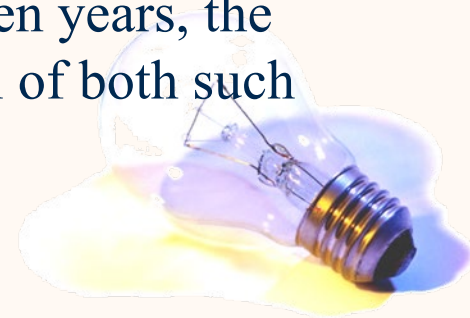
Application of Basics to 35 U.S.C. 156

- Patents may receive a patent term extension under 35 U.S.C. 156 beyond an expiration date set by a terminal disclaimer. See *Merck & Co., Inc. v. Hi-Tech Pharmacal, Co., Inc.*, 482 F.3d 1317, 82 USPQ2d 1203 (Fed. Cir. 2007).
- Any terminal disclaimer filed in a patent must be filed prior to the expiration date of the reference patent in order to be effective. *Boehringer Ingelheim Int'l GmbH v. Barr Lab. Inc.*, 592 F3d 1340, 93 USPQ2d 1417 (Fed. Cir. 2010).
- The extended term of a patent can be affected by a terminal disclaimer filed against a later issued earlier expiring patent. *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 110 USPQ2d 1551 (Fed. Cir. 2014).



35 U.S.C. 156 term additive to PTA under 35 U.S.C. 154(b)

- Effective May 29, 2000, 35 U.S.C. 154(b) was amended to provide the grant of additional term due to delays in processing patent applications at USPTO. This additional term is added to the 20 year term defined in 35 U.S.C. 154(a). MPEP 2730.
- Extension under 35 U.S.C. 156 is added to the original term. The original expiration date of a patent for which extension is sought is relevant when calculating the length of the extension and considering 156(c)(3) which states, “if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years.”



Application of Basics to 35 U.S.C. 156

- Term calculated under 35 U.S.C. 156(c)—and limited by 156(g)(6), if relevant—is added onto the original term of the patent, as defined under 35 U.S.C. 154(a) and (b). The language in 35 U.S.C. 156(a) specifically states, “[t]he term of a patent which . . . shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if”



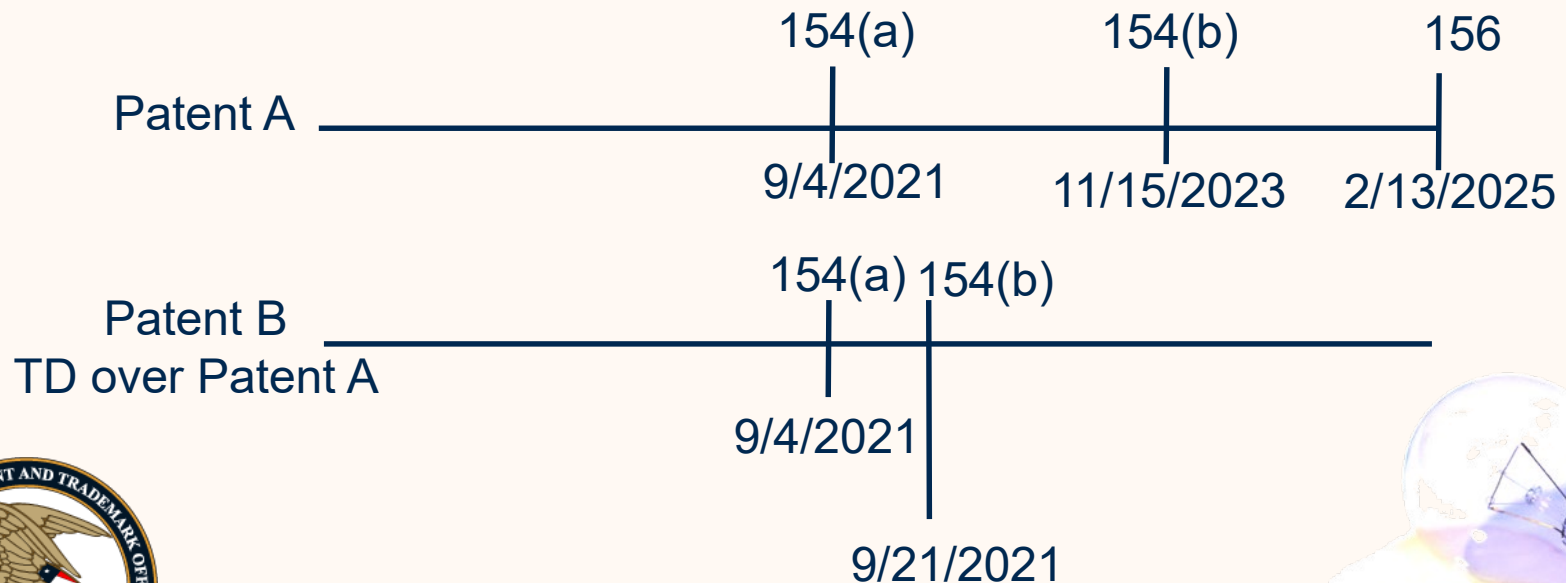
Scenario #1

- Patent A-claims API and composition of API, issued 1st
 - ◆ 154(a) term ends September 4, 2021
 - ◆ 154(b) term is 801 days
 - ◆ Original expiration date: November 15, 2023 (154(a) + 154(b) term)
 - ◆ Approval date is February 13, 2011
 - ◆ Calculated 156 term is 1,025 days, but this exceeds 14-year cap of 156(c)(3)
 - ◆ Entitled to extension of 456 days, extended expiry date February 13, 2025
- Patent B-claims specific composition of API, issued 2nd
 - ◆ 154(a) term ends September 4, 2021
 - ◆ 154(b) term is 17 days
 - ◆ Original expiration date: September 21, 2021 (154(a) + 154(b) term)
 - ◆ TD filed over patent A



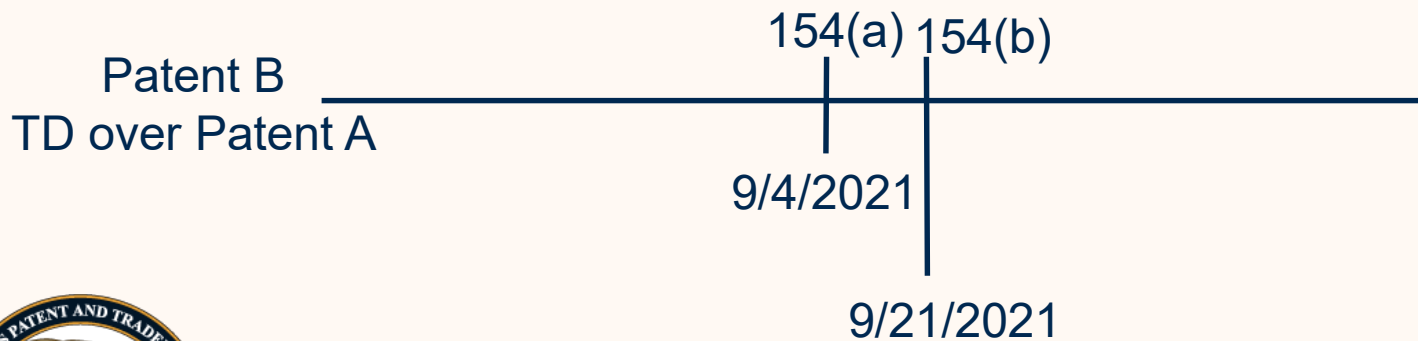
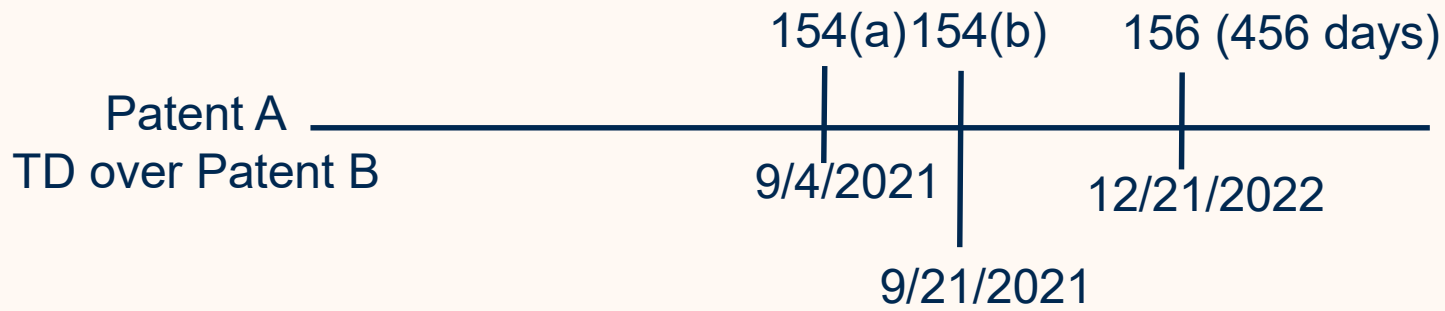
Scenario #1

- Patent B is terminally disclaimed over patent A. What would be the effect of a terminal disclaimer filed in patent A over patent B, to address ODP concern concerns regarding a later issuing, earlier expiring patent?



Scenario #1

- Terminal Disclaimer of Patent A over Patent B.



Scenario #1

- Patent B is terminally disclaimed over patent A. Could Patent A be reissued to address the ODP issue with patent B?
 - ◆ There must be a reissuable error.
 - ◆ Opening up patent to all bases of rejection
 - ◆ Original patent is surrendered upon grant of reissue (35 U.S.C. 252)
 - ◆ Reissue is for the unexpired part of the term of the original patent (35 U.S.C. 251)
 - ◆ Depends upon scope of claims in each patent, is there an argument for non-obviousness?



Scenario #2

- Patent X-claims API and composition of API
 - ◆ 154(a) term ends August 20, 2021
 - ◆ Original 154(b) term is 489 days
 - ◆ Original expiration date: December 22, 2022 (154(a) + 154(b) term)
 - ◆ Approval date is June 17, 2009, 14-year cap of 156(c)(3) is June 17, 2023
 - ◆ Calculated 156 term is 205 days: extended expiration date would be July 15, 2023, but this is beyond 14-year cap of 156(c)(3)
 - ◆ Requested extension of 177 days, extended expiry date June 17, 2023.
- Petition under 35 U.S.C. 154 and suit filed against USPTO regarding the 489 days of PTA granted to Patent X



Scenario #2

- Petition under 35 U.S.C. 154 and suit filed against USPTO regarding the 489 days of PTA granted to Patent X
 - ◆ In light of USPTO implementation of Federal Circuit opinion in *Wyeth v. Dudas*, patent is entitled to additional 642 days of PTA.
 - ◆ New expiration date is September 24, 2024, beyond the 14-year cap of 156(c)(3).
 - ◆ USPTO final determination as to the length of the term extension, 0 days.
 - ◆ Final Determination sets one month time period for reconsideration.
 - ◆ If no action taken by applicant, papers are placed in patent file with no further action taken.
- How to handle later issuing, earlier expiring patent Y that patent X might need to disclaim over?



Scenario #3

- Patent #1-claims API, method of using API and method of manufacturing API
 - ◆ 154(a) term ends December 21, 2020
 - ◆ 154(b) term is 49 days
 - ◆ Original expiration date of Patent #1: February 8, 2021 (154(a) + 154(b) term)
 - ◆ Approval date is July 1, 2011
 - ◆ Calculated 156 term is 1,354 days
 - ◆ Requested extension of 1,354 days; extended expiry date would be October 24, 2024
- Terminal Disclaimer filed over Patent #2 in Patent #1 during PTE processing



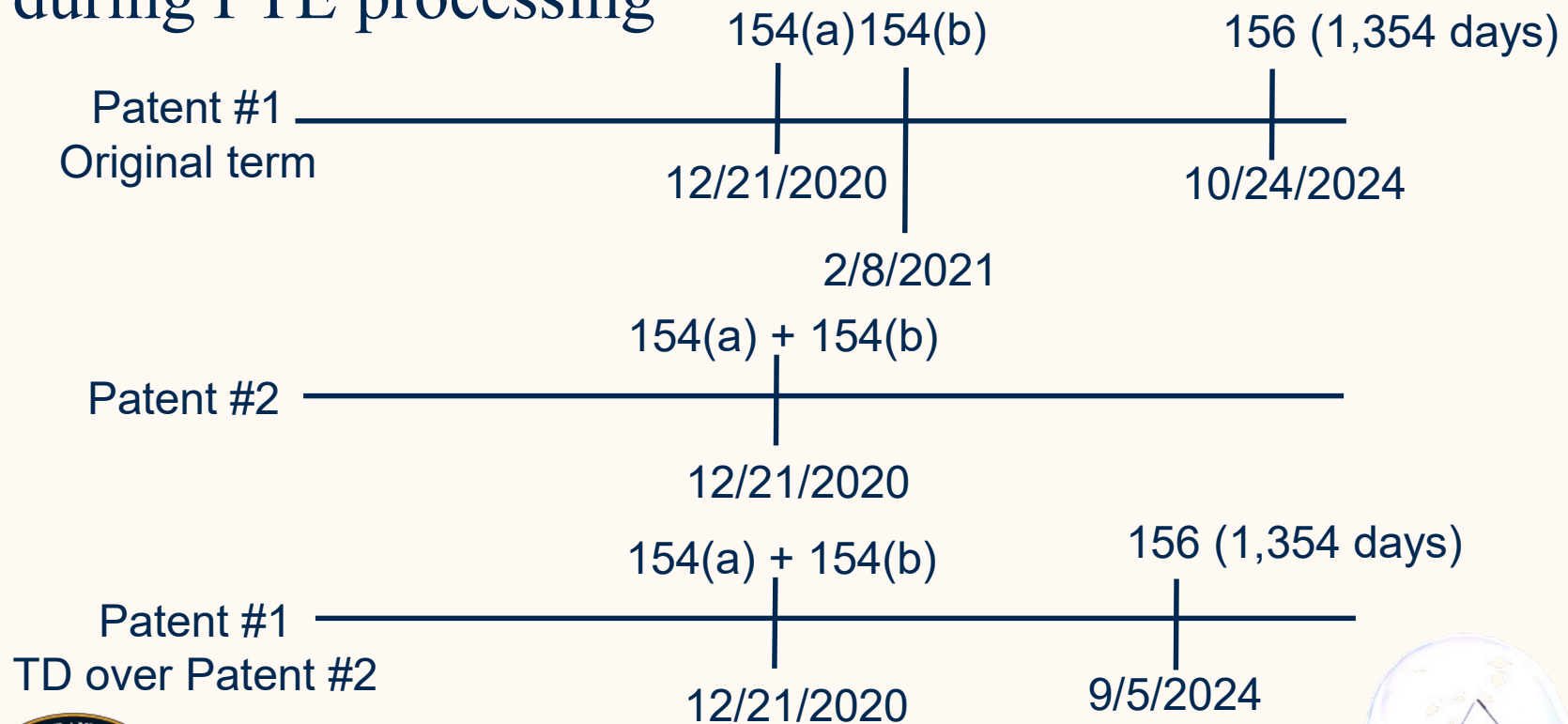
Scenario #3

- Terminal Disclaimer filed over Patent #2 in Patent #1 during PTE processing
 - ◆ Patent #2 154(a) term ends December 21, 2020
 - ◆ Patent #2 had 0 days of 154(b)
 - ◆ Original expiration date Patent #1: December 21, 2020 (154(a) + 154(b) term)
 - ◆ Approval date is July 1, 2011
 - ◆ Calculated 156 term is 1,354 days
 - ◆ Requested extension of 1,354 days; extended expiry date would be September 5, 2024



Scenario #3

- Terminal Disclaimer filed over Patent #2 in Patent #1 during PTE processing



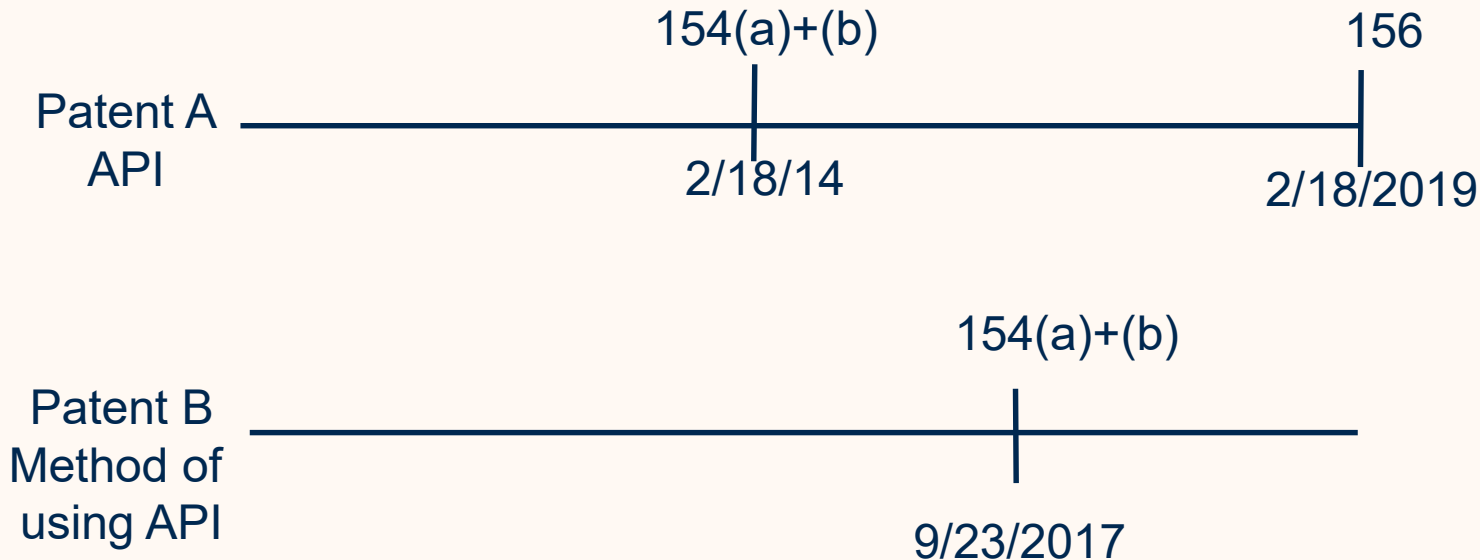
Take Home Lessons

- Even if 156 term calculated at date of approval is 0 days, file application anyway.
- If a terminal disclaimer is filed during PTE processing, submit updates to PTE application pursuant to duty of disclosure under 37 C.F.R. 1.765
- If 154(b) PTA changes after PTE application is filed, submit updates to PTE application pursuant to duty of disclosure under 37 C.F.R. 1.765



Bonus Scenario

- ◆ Patent A covers API. Patent B covers a method of using the API



- ◆ Here, the public would not be free to use the invention claimed in patent B until Patent A expires, how does this square with OTDP issues?



Thank You

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