Biotechnology Chemical Pharmaceutical Customer Partnership

Mary C. Till
Legal Advisor
Office of Patent Legal Administration

September 8, 2010

Best Practices for § 156 PTE

-Hatch-Waxman generally

-Products eligible

-Types of Review Periods

-Application Requirements

-Interim Extensions

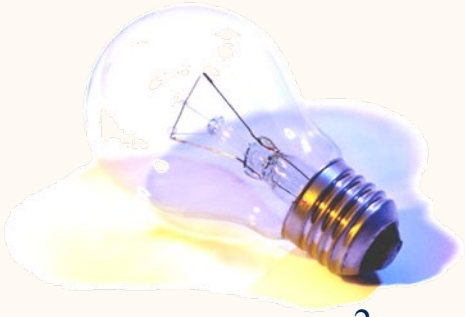
-Multiple Applications

-Combination Products

-Reissue during PTE processing time

-Recent case law decisions

-Frequently asked questions

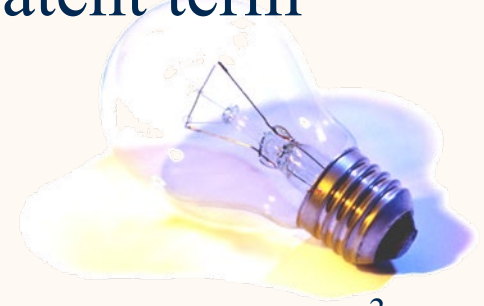


Best Practices for § 156 PTE

-Hatch-Waxman sought to balance interests of innovator pharmaceutical companies with those of the generic manufacturer industry.

-In addition to other provisions, Title I of Hatch-Waxman balances the reliance on innovator clinical data by the generic manufacturer with market exclusivity for the innovator company.

-Similarly, Title II of Hatch-Waxman balances the safe harbor provisions of § 271(e)(1) with the patent term extension provisions of § 156.



Best Practices for § 156 PTE

Eligible Products

-Drug Products (New drugs, antibiotic drugs, human biological products, new animal drugs, or veterinary biological products).

-Medical Devices

-Food Additives

-Color Additives

Best Practices for § 156 PTE

Relevant Regulatory Review Periods

-Section 505 of Federal Food Drug and Cosmetic Act (new drugs).

-Section 351 of the Public Health Services Act (human biological products).

-Section 515 of the Federal Food Drug and Cosmetic Act (medical devices).

-Section 512 of the Federal Food Drug and Cosmetic Act (new animal drugs).

-The Virus-Serum Toxin Act, 21 U.S.C. §§ 151-159 (veterinary biological product).

-Section the 409 of the Federal Food Drug and Cosmetic Act (food additives and color additives).

Best Practices for § 156 PTE

Section 156(d)(1) sets forth the application requirements:

(1) Identify the product and identify the statutory provision under which regulatory review occurred.

(2) Identify the patent and the claims of the patent that cover the product.

(3) Information to enable USPTO to determine eligibility and rights under the grant.

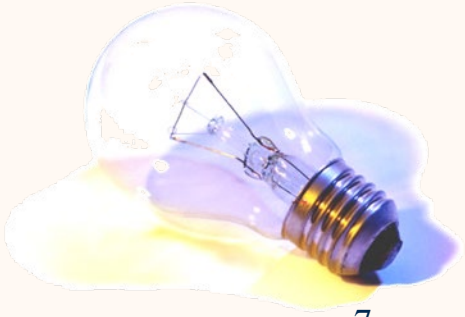
(4) Dates and activities during regulatory review.

(5) Any additional information.

Best Practices for § 156 PTE

Timely filed section 156(d)(1) application

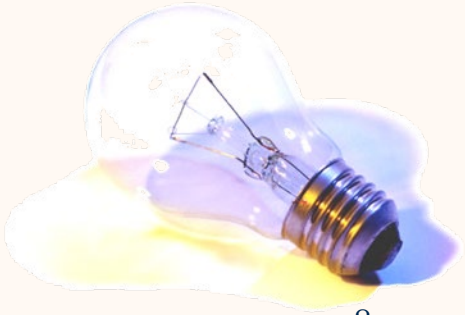
- § 156(d)(1) defines the period within which to file an application for term extension as, "within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use."



Best Practices for § 156 PTE

Interim Extension under 35 U.S.C. 156(d)(5)

-Section 156(d)(5)-product not approved, patent expiring while product is undergoing continued review by the regulating agency. Clinical work is done, agency is conducting approval review. Statutorily set time frame for application submission.

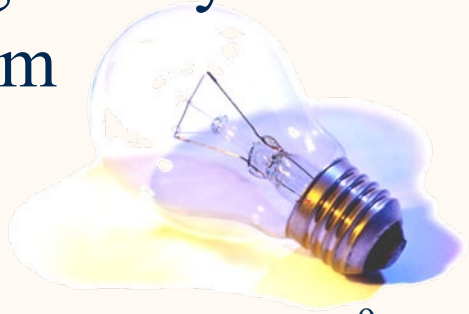


Best Practices for § 156 PTE

Timely filed section 156(d)(5) and subsequent section 156(d)(5) interim extensions

- § 156(d)(5)(A) defines the period within which to file an application for interim extension as, "beginning 6 months, and ending 15 days before such term is due to expire."

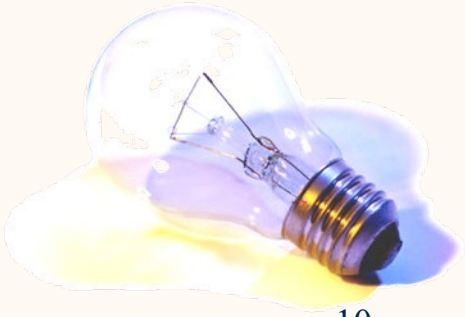
- § 156(d)(5)(C) defines the period within which to file a subsequent application for interim extension as, "the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension."



Best Practices for § 156 PTE

Interim Extension under 35 U.S.C. § 156(e)(2)

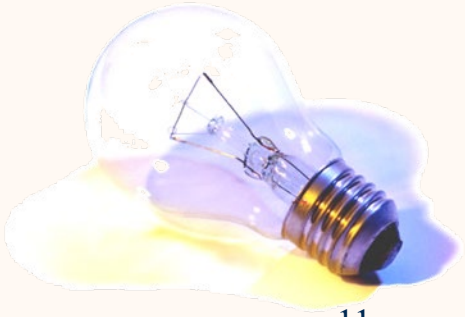
-Section 156(e)(2)-product approved, patent expiring before certificate of extension can be granted. No statutorily set time frame for application submission.



Best Practices for § 156 PTE

Timely filed section 156(e)(2) interim extension

-Section 156(e)(2) does not contain a statutory time period for application submission. 37 C.F.R. 1.760 indicates that any request for interim extension under 156(e)(2) should be filed at least 3 months before the patent expires.

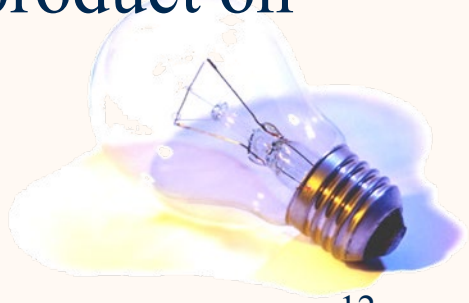


Best Practices for § 156 PTE

Two situations can give rise to multiple applications for PTE

-First, when multiple patents claim the approved product, or a method of using or manufacturing the approved product, patent owners may file multiple applications and choose the one to receive the extension at the end of the PTE process (see 37 C.F.R. § 1.785).

-Second, multiple approvals for the same product on the same day (35 U.S.C. § 156(c)(4)).



Best Practices for § 156 PTE

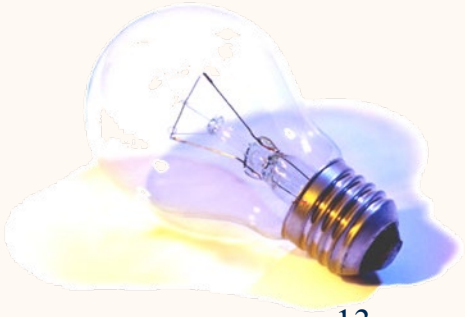
Combination Products

-Multiple active ingredients drug products

Arnold Partnership v. Dudas

Synergy?

-Drug/device combination products



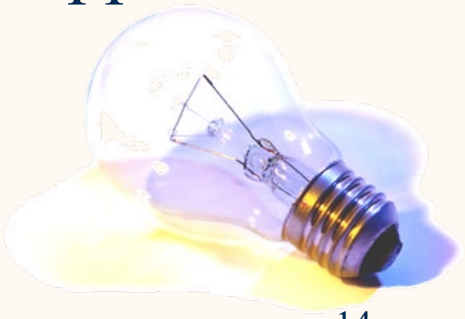
Best Practices for § 156 PTE

Seeking or Pending Reissue during PTE Processing

-Once a product receives approval, the patent owner has a 60 day window within which to submit an application for term extension (35 U.S.C. § 156(d)(1)).

-Sometimes a reissue of the patent for which extension has been sought is undergoing prosecution.

-Sometimes during the processing of the patent for which extension has been sought, a reissue application is filed for the patent.

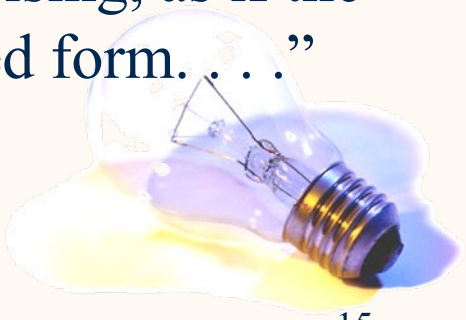


Best Practices for § 156 PTE

Effect of Reissue On PTE

-Section 251 states (in part), "on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent."

-Section 252 states (in part), "[t]he surrender of the original patent shall take effect upon the issue of the reissued patent, and every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form. . . ."



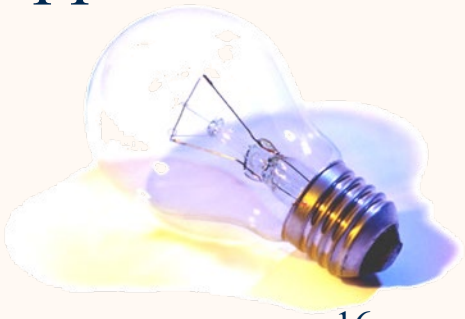
Best Practices for § 156 PTE

Wyeth v. Sebelius

(603 F.3d 1291 (Fed. Cir. 2010))

-When does the approval phase begin for a new animal drug application when the parts of the application are submitted on a rolling basis?

-The approval phase begins when the Administrative New Animal Drug Application is submitted to FDA referencing all the previously submitted and approved application components.



Best Practices for § 156 PTE

Ortho-McNeil v. Lupin

(603 F.3d 1377 (Fed. Cir. 2010))

-Is a patent claiming a specific enantiomer eligible for patent term extension when a racemate of the enantiomer was previously approved?

-Yes, a patent claiming the specific enantiomer may be extended under 35 U.S.C. § 156 even though the racemate of the enantiomer was previously approved and a patent claiming the racemate received extension.

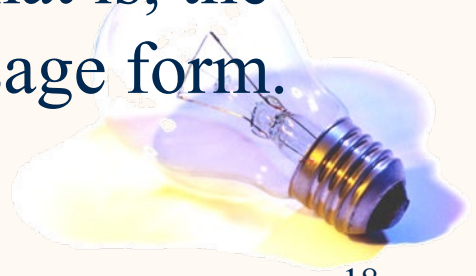
Best Practices for § 156 PTE

Photocure v. Kappos

(603 F.3d 1372 (Fed. Cir. 2010))

-Is a patent claiming an ester of a previously approved active ingredient eligible for patent term extension?

-Yes, the statutory language recites, "active ingredient including any salt or ester of the active ingredient," not active moiety. *Glaxo II* (894 F.2d 392 (Fed. Cir. 1990) is controlling in that the term "product" in § 156(a)(5)(A) means "active ingredient," that is, the substance physically present in the final dosage form.



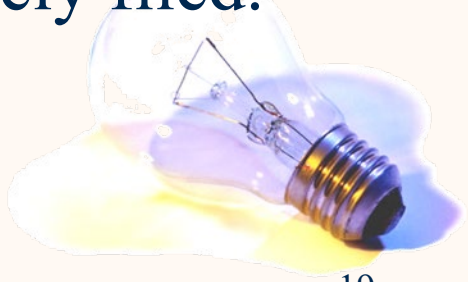
Best Practices for § 156 PTE

The Medicines Company v. Kappos

(94 USPQ2d 1748, E.D. Va. 2010)

-Does the term "date" as used in section 156(d)(1) ("beginning on the date. . . .") refer to a business day or calendar day?

-Medicines Company argues business day. Government argues calendar date. District court held that "date" in section 156(d)(1) means business day and ordered the USPTO to consider the PTE application timely filed. Case is still pending.



Best Practices for § 156 PTE

Frequent PTE Questions

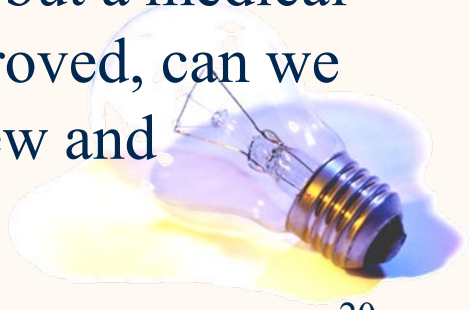
(1) Has U.S. Patent No. X,XXX,XXX been extended?

(2) The patent owner and the marketing applicant before the agency are not the same entity, do we need to submit anything extra with our application?

(3) Can a third party participate in the PTE process?

(4) The FDA's Orange Book lists lots of patents for product X, why is only one patent listed on the USPTO's list of extended patents?

(5) Our drug product has not received approval yet, but a medical device incorporating the drug product has been approved, can we extend one patent based on the medical device review and another patent based on the drug product review?



Best Practices for § 156 PTE

Answers to Frequent PTE Questions

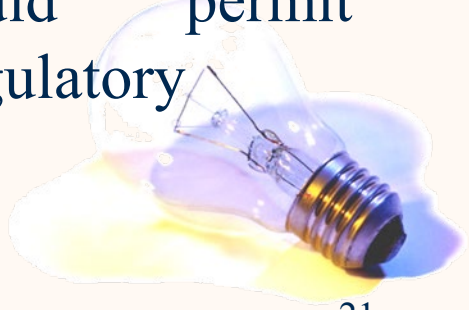
(1) Most PTE applications and grants are available for viewing in Public PAIR, check there first.

(2) An authorization letter from the marketing applicant that the patent owner can rely on his activities before the regulating agency should be submitted with the application.

(3) No.

(4) Because of 35 U.S.C. § 156(c)(4), only one patent may be extended per regulatory review period.

(5) Yes, language of §§ 156(a)(5)(A) and (c)(4) would permit this. Each was reviewed under a different regulatory provision.



Best Practices for § 156 PTE

Thank you!

Contact Information:

Mary C. Till

Legal Advisor, Office of Patent Legal Administration

USPTO

mary.till@uspto.gov

571-272-7755