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Patent term extension (PTE) under 35 U.S.C. 156

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Patent term extension (PTE) background

- Part of the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)
- Codified as 35 U.S.C. 156
- Mitigates a patent owner's "loss" of patent term due to pre-market approval requirements of a regulating agency
- Administered by the USPTO in partnership with the relevant regulating agency

Relevant regulating agencies

- Food and Drug Administration (FDA)
  - for all eligible products, other than veterinary biologics and controlled substances
  - Drug Enforcement Agency (DEA)
    - for controlled substances
- Department of Agriculture (USDA)
  - for veterinary biologics

35 U.S.C. 156 eligibility requirements

- The patent must claim:
  - a product
  - a method of using a product, or
  - a method of manufacturing a product

35 U.S.C. 156(a)

35 U.S.C. 156 eligibility requirements (1/2)

- The patent term must not have expired before the PTE application is submitted. (§156(a)(1))
- The patent term must never have been extended under §156(e)(1). (§156(a)(2))
- The PTE application must be submitted by the patent owner of record or its agent. (§156(a)(3))

35 U.S.C. 156 Eligibility Requirements (2/2)

- The product must have been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use. (§156(a)(4))
- The permission to commercially market or use the product must be the first permission under the provision of law under which the regulatory review period occurred. (§156(a)(5))

Relevant regulatory review periods

- §505 of Federal Food Drug and Cosmetic Act (FFDCA) (new drugs) (§156(g)(1))
- §351 of the Public Health Services Act (human biological products) (§156(g)(1))
- §515 of the FFDCA (medical devices) (§156(g)(3))
  - §510(k) is not an RRP that gives rise to PTE
- §512 of the FFDCA (new animal drugs) (§156(g)(4))
- The Virus-Serum Toxin Act, 21 U.S.C. §§ 151-159 (veterinary biological products) (§156(g)(5))
- § 409 of the FFDCA (food additives and color additives) (§156(g)(2))

Timing of PTE application

- The PTE application must be submitted within 60 days of the product approval. (§156(d)(1))
- Date of approval = day 1

Meaning of "product"

- Drug products (§156(f))
  - human and animal drugs (§156(f)(2)(A))
  - human and veterinary biologicals (§156(f)(2)(B))
- Medical devices (§156(f)(1)(B))
- Food or color additives (§156(f)(1)(B))

Meaning of “drug product”

- The “active ingredient” of the drug or biological product
  - includes any salt or ester of the active ingredient
  - as a single entity or in combination with another active ingredient

(§156(f)(2))

“In combination”

- Where a product contains multiple active ingredients, if any one active ingredient has not been previously approved, it can form the basis for extension, provided the patent claims that ingredient.

Processing a PTE application

- Upon receipt of a PTE application, the USPTO performs its initial review:
  - Of the PTE application for compliance with 37 CFR 1.740(a)(1)-(15)
  - Of the patent claims for compliance with 35 U.S.C. 156(a)

After the USPTO's initial review

- The USPTO asks the regulating agency to confirm:
  - the product was subject to a qualifying regulatory review period (§156(a)(4))
  - the approval was "first" (§156(a)(5))
  - compliance with the 60-day deadline (§156(d)(1))

After regulating agency response

- If the agency response confirms eligibility, the USPTO then asks the agency to determine the length of the regulatory review period.
- If the agency response does not support eligibility, the USPTO issues a notice of ineligibility.

Agency determination of the regulatory review period (1/2)

- The agency reviews its records and responds to the USPTO with:
  - the testing start date
  - the date an application was submitted for approval
  - the date the application was approved

Agency determination of the regulatory review period (2/2)

- Using these dates, the agency's response to the USPTO also includes:
  - the length of the testing phase
  - the length of the approval phase
    - For a controlled substance, the length of the approval phrase also includes the time after the FDA grants approval through and including the date that the DEA issues an interim final rule
  - the total length of the review period

Agency publishes its determination of the regulatory review period

- The agency publishes its determination of the regulatory review period (RRP) in the Federal Register.
- The public or applicant is given 60 days to request redetermination of the RRP.
- The public is given 180 days to:
  - challenge any of the published dates
  - petition the agency to determine whether the PTE applicant acted with due diligence during the RRP

After the 180-day period

- Assuming no public comment, the agency informs the USPTO that its previous determination of the regulatory review period is final.
- The USPTO then determines the length of patent term extension.

USPTO's determination of the length of patent term extension (1/3)

- The USPTO first subjects the agency's determination of the regulatory review period (RRP) to the following subtractions:
  - any portion of the RRP that occurred before the date the patent issued (§156(c))
  - any portion of the RRP during which the agency determined a lack of due diligence (§156(c)(1))
  - half of the testing phase (§156(c)(2))

USPTO's determination of the length of patent term extension (2/3)

- The length of calculated extension will equal the agency's determination of the RRP minus the noted subtractions, unless:
  - the length of time from the product approval date to the end of the extended patent term exceeds 14 years (§156(c)(3)), or
  - the calculated extension exceeds 5 years (§156(g)(6)(A))

USPTO's determination of the length of patent term extension (3/3)

- The USPTO issues a Notice of Final Determination announcing the period of extension.
  - The PTE applicant is given a period to request reconsideration.
- Once the PTE applicant agrees with the USPTO or if there is no response from the PTE applicant, a certificate of extension is issued.

Interim extensions

- Two types:
  - if the patent will expire before product approval (156(d)(5))
  - if the product is approved and the patent will expire before processing of the PTE application is complete (156(e)(2))

35 U.S.C. 156(d)(5) interims

- Product must be in the “approval phase”.
- PTE applicant must file an application for interim extension during the period beginning 6 months and ending 15 days before the patent is due to expire.
- Interim period may not exceed 1 year and notice of the order granting interim extension is published in the Federal Register.

35 U.S.C. 156(e)(2) interims

- When an application under 156(d)(1) has been filed, but the patent will expire before the entire PTE process is complete, the PTE applicant may file an e(2) interim extension.
- Interim period may not exceed 1 year.
- No statutory time period for application submission.
  - 37 CFR § 1.760 indicates that any request should be filed at least 3 months before the patent expires.

Electronic filing

- PTE applications, interim PTE applications, and any related submissions should now be filed electronically.

PTE website

- www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156
- Provides of a list of applications for patent term extensions
- Provides a list of patents, which have been extended under 35 U.S.C. 156

Recent PTE issues - Biologics

- Whether a biologic is considered “first”
  - Similar proteins or vaccines
  - Improvements to bioavailability
- Patents directed to a platform technology
  - No written description for the protein/gene itself or disease
- Compliance with 37 CFR 1.740(a)(9)

Recent PTE issues - Agency and reliance on regulatory activities

- An agency relationship must exist between the patent owner and marketing application during the applicable regulatory review period.
  - Provide a letter of authorization from the marketing applicant to the patent owner who is seeking extension (MPEP 2752)
- Questions about whether a party is authorized to file a PTE will be dealt with on a case by case basis.

Thank you!

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