UNITED STATES
PATENT AND
TRADEMARK OFFICE

Patent Term Extension under 35 U.S.C. § 156

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Patent Term Extension Under 35 U.S.C. §156

Patent Term Extension, under 35 U.S.C. § 156, as part of the Hatch-Waxman Act, restores to a patent owner, patent term which was effectively "lost" due to pre-market approval requirements before a regulating agency (the agencies involved are the Food and Drug Administration and the United States Department of Agriculture).

Statutory Requirements:

- The patent claims the product, or a method of using the product or a method of manufacturing the product. (35 U.S.C. § 156(a))
- The term of the patent has not expired before the application for PTE has been submitted (35 U.S.C. § 156(a)(1)).
- The term has never been extended under 156 before (35 U.S.C. § 156(a)(2)).

Statutory Requirements (cont'd):

- An application is submitted by the patent owner or its agent (35 U.S.C. § 156(a)(3)).
- The product claimed by the patent has been subject to regulatory review before its commercial marketing or use (35 U.S.C. § 156(a)(4)).

Statutory Requirements (cont'd):

- The permission for the commercial marketing or use of the product after the regulatory review period is the first permitted commercial marketing or use of the product under the provisions of law under which such regulatory review period occurred (35 U.S.C. §156(a)(5)).

Statutory Requirements (cont'd):

- An application for patent term extension must be submitted by the owner or record or its agent to the USPTO 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 (35 U.S.C. §156(d)(1)).

Scope of Patent Term Extension 35 U.S.C. § 156(b)

- The "rights derived" section of 156 specifically defines the scope of protection afforded during the extended period. The rights are dependent upon the type of patent for which extension was sought, i.e., a patent which claims the approved product (§ 156(b)(1)), or a patent which claims a method of using the approved product (§ 156(b)(2)) or a patent which claims a method of manufacturing the approved product (§ 156(b)(3)).

Limitations in 35 U.S.C. § 156(c)

The term of an eligible patent shall be extended by the time equal to the regulatory review period for the approved product:

- Includes only time after the date the patent is issued.
- Time where applicant failed to exercise due diligence as determined under §156(d)(2)(B) is subtracted.
- Only one-half of the time in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) is counted.
- Only one patent may be extended per regulatory review period.

Requirements of 35 U.S.C. 156(d)

- The owner of record or his agent must make the application (35 U.S.C. § (d)(1)).
- Within the sixty-day period beginning on the date the product received permission . . . for commercial marketing or use (35 U.S.C. § (d)(1)).
- Application contents (35 U.S.C. § (d)(1)(A)-(E)).

Duties under 35 U.S.C. § 156(e)

- The Director, upon determining eligibility and compliance with the statutory requirements, shall issue to the applicant for the extension of the term of the patent, a certificate of extension, under seal, for the period prescribed by subsection (c). The certificate of extension shall be recorded in the official file of the patent and shall be considered as part of the original patent.

Limitations on Amount of Term

- The total market exclusivity time of a drug cannot exceed 14 years, regardless of how much time was lost to clinical testing and regulatory review. See 35 U.S.C. § 156(c)(3).
- The total time of extension is limited to no more than 5 years. See 35 U.S.C. § 156(g)(6).

Combination Products

- Where a product contains 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).

Two Types of Interim Extensions

First, interim extensions are available if the patent will expire before product approval. However, product must be in the "approval phase."

- Application is filed under 35 U.S.C. § 156(d)(5). There is a time window for filing the application for interim extension where the product has not yet received regulatory approval, between six months and fifteen days before patent expiration.

Second, interim extensions are available if the patent will expire before processing of the application for PTE is complete.

- According to 35 U.S.C. § 156(e)(2), the Director shall extend the term of a patent for periods of up to one year, if the patent would expire before a certificate or extension can be issued or denied, if he determines that the patent is eligible for extension.

Patent Term Extension Under 35 U.S.C. §156

Somerset v. Dudas (Fed. Cir. 2007)

- Applicant sought to extend a patent based on the regulatory review of Emsam® (selegiline formulated in a transdermal patch).
- USPTO denied the application for patent term extension because the USPTO determined that the permission for commercial marketing or use of Emsam ® failed to comply with 35 U.S.C. § 156(a)(5)(A).
- Because the application for patent term extension was denied the USPTO had no authority to grant an interim extension pursuant to 35 U.S.C. § 156(e)(2).

USPTO Processing of Patent Term Extension Applications

- Review Application for compliance with 37 CFR 1.740(a)(1)-(15) and some formal matters (assignment, maintenance fee, trademark, etc.)
- Review claims for compliance with 35 U.S.C. 156(a), "the term of a patent which **claims** a product, a method of using a product or a method of manufacturing a product. . . ."

USPTO Processing of Patent Term Extension Applications (cont'd)

- After USPTO initial review, USPTO corresponds with the regulating agency and asks for the regulating agency's determination of eligibility.
- Once the regulating agency confirms eligibility, then USPTO requests that the regulating agency determine the regulatory review period and publish its findings in the Federal Register.
- Once the comment period and period for filing any due diligence petitions pursuant to the Federal Register notice is concluded, the regulating agency makes their final determination.
- Then the USPTO independently calculates the patent term extension and applies any of the statutory caps to the amount of term calculated and communicates their findings to the applicant.
- If applicant agrees with the USPTO's determination, the certificate of extension is granted.

Patent Term Extension Under 35 U.S.C. §156

Two statutory criteria hotly contested:

- Definition of "product"
- 60-day application filing period

Patent Term Extension Under 35 U.S.C. §156

"Product" means:

- A drug product
- Any medical device, food additive or color additive subject to regulation under the Federal Food, Drug and Cosmetic Act
- See 35 U.S.C. 156(f)(1)

Patent Term Extension Under 35 U.S.C. §156

Section 156(a)(5)(A) requires that the permission for the commercial marketing or use of the product . . . [be] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred

- Section 156(f)(1) defines product as drug product
- Section 156(f)(2) defines drug product as active ingredient of a new drug . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient

Photocure v. Dudas (E.D. Va.)

- Photocure filed PTE application for METVIXIA® (methyl aminolevulinate hydrochloride)
- USPTO denied the application for failing to be the first commercial marketing of the active ingredient
- USPTO reasons that ALA is active ingredient of both METVIXIA ® and the earlier-approved drug LEVULAN®

Photocure v. Dudas (E.D. Va.) (cont'd)

- Issue is: meaning of term "active ingredient"
- USPTO definition: active moiety, excluding salt or ester
- Stay tuned…summary judgment argued December 2008, awaiting decision.

60-Day Application Filing Window

- Section 156(d)(1) requires the owner of the patent to file an application, "within the sixty-day period beginning on the date the product received permission"

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Useful Information:

- Pursuant to 37 C.F.R. § 1.765 and §1.740(a)(13), the Applicant for extension has a duty of candor and good faith to the Director and the Secretary of Health and Human Services or the Secretary of Agriculture.
- More than one application for patent term extension can be filed per single regulatory review period. In accordance with 37 C.F.R. § 1.785, the USPTO would require that the applicant for patent term extension elect one patent to receive the extension.
- Patent Term Adjustment under 35 U.S.C. § 154(b) is added to the original expiration date prior to any extension under section 156.
- Terminally disclaimed patents are eligible (Merck & Co. v. Hi-Tech Pharmacal, Co., Inc., Fed. Cir. 2007) for extension under § 156.

Useful On-line Resources

- Public PAIR: http://portal.uspto.gov/external/portal/pair
  - Over 300 PTE applications associated with the patent files, some completed and some in process are available on Public PAIR.
- The USPTO updates the list of patent terms extended on an as needed basis. It can be found at: http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html
- Chapter 2700 of the Manual of Patent Examining Procedure provides some commentary on the finer points of PTE applications and processing: http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r5_2700.pdf

Thank you!

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