Patent Term Extension

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Patent term extension (PTE) is available under the 1984 Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act (The Act). The Act allows the extension of the term of a patent claiming a product that requires regulatory approval prior to being sold, or a method of using or manufacturing the product. Such products include human and veterinary pharmaceuticals, food additives, color additives and medical devices. PTE aims to restore a portion of the patent term that is lost while the patent holder is awaiting regulatory approval of the product.

The determination as to whether PTE should be granted is made by the U.S. Patent and Trademark Office (PTO), in consultation with the regulatory agency responsible for approval of the product.

Requirements for PTE Application Under 35 U.S.C. § 156

- Deadline for filing is **within 60 days** of the mailing date of a marketing approval of the product (37 C.F.R. § 1.720(f))
  - ◊ Approval of New Drug Application (NDA), Biologics License Application (BLA) or Premarketing Approval Application (PMA)
  - ◊ The approval date is counted as **day 1**
  - ◊ Saturdays, Sundays and Federal Holidays are counted
- Applicant is the owner of record or its agent (37 C.F.R. § 1.730(a))
- Must comply with the requirements provided in 37 C.F.R. § 1.740:
  - ◊ Complete identification of the approved product (37 C.F.R § 1.740(a)(1))
  - ◊ Complete identification of the Federal statute under which the regulatory review occurred
  - ◊ An identification of the date on which the commercial marketing approval was received
  - ◊ In case of a drug product, identification of each active ingredient and a statement that the product has not been previously approved
  - ◊ A statement that the PTE application is submitted within the 60-day period and an identification of the last day the application can be submitted
  - ◊ A complete identification of the patent for which extension is sought
  - ◊ A copy of the patent
  - ◊ A copy of any terminal disclaimer, certificate of correction, maintenance fee statement, or reexamination certificate
  - ◊ A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing for at least one claim how it reads on the product
    - » **Tip:** This showing can be conveniently provided as a claim chart
  - ◊ A statement of the relevant dates and information to enable the Secretary of Health and Human Services to determine the applicable regulatory review period
    - » An example of information for a human drug, antibiotic, or human biological product:
      - ■ The effective date of an Investigational New Drug application (IND) for human drugs
        - □ **Note:** Substantiate the date as necessary. Was there a clinical hold?
      - ■ The date of filing the NDA, BLA or PMA
      - ■ The date on which the NDA, BLA or PMA was approved
    - » Has to begin on a new page
  - ◊ A brief description of the significant activities and dates during the regulatory review period
    - » Has to begin on a new page
    - » **Tip:** Conveniently submitted as an attachment of a chronology of events
    - » **Note:** This is to show due diligence of the applicant during the regulatory review period. Can be challenged by a third party.
  - ◊ A statement that in the applicant's opinion, the patent is eligible for extension, including the length of the extension

and how it was determined
  - » Has to begin on a new page
  - » Requirements for eligibility:
    - The patent claims a product, a method of using the product, or a method of manufacturing
    - The patent has not expired
    - The term of the patent has never been extended
    - The application is submitted by the owner of record or its agent
    - The product has been subject to a regulatory review period before its commercial marketing or use
    - No other patent has been extended for the same regulatory review period (i.e., only one patent can be extended per approved product)
- ◊ A statement that applicant acknowledges the duty to disclose any information material to the determination of entitlement of the extension sought
- ◊ Payment of fees
  - » Currently, $1,120 for large, small and micro entities
- ◊ Information on the contact person
- ◊ Submitted as one original and two copies
  - » **Note:** Cannot be electronically filed
  - » **Tip:** Preferably hand-carried to the Office of Patent Legal Administration, Room MDW 7D55, Madison Building

Calculation of the Length of PTE

- PTE is the sum of the "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
- PTE cannot be more than 5 years
- PTE cannot extend the patent term over 14 years from the date of receipt of marketing approval
- The "testing period" starts on the IND effective date and ends on the date of NDA/BLA/PMA initial submission
- The "approval period" starts on the date of the NDA/BLA/PMA initial submission and ends on the date of approval of the NDA/BLA/PMA
  - ◊ **Note:** the FDA counts the NDA/BLA/PMA submission date in both the testing period and approval period

Interim Extension

- Available if the regulatory review period is reasonably expected to extend beyond the original expiration date of the patent
- Aims to maintain the patent term until regulatory approval is received
- Can be submitted during the period beginning 6 months before the patent term is due to expire and ending 15 days before the patent term is due to expire
- Available for not more than one year, but subsequent interim extensions can be filed
- Any interim extension terminates at the end of the 60-day period beginning the day on which the product receives a regulatory approval, unless the applicant submits a PTE application within this period

Best Practices and Other Tips

- A duty of disclosure exists during the PTE application process - remember to disclose information material to PTE determination (MPEP 2762)
  - ◊ In *in re Zetia* (Ezetimibe) Antitrust Litigation, defendants argued inequitable conduct because the patent owner withheld material information from the PTO during the PTE review period. 2019 WL 1397228, E. D. Va, Aug. 9, 2019
- Consider filing **more than one PTE application for different patents** based on a single regulatory review period
  - ◊ Postpones making the decision of which patent to extend, which may be helpful when there are:
    - » Differences in the projected patent terms of the different patents

- » Obviousness-type double patenting (ODP) considerations
  - Would a successful ODP challenge during litigation reduce a patent term adjustment (PTA) to which the patent may be entitled?
  - During the PTA extension period, the right to exclude with the patent reaches the **entire claim scope**
  - However, during the PTE extension period, the right to exclude with the patent only reaches, e.g., **the approved drug and approved indication**
  - The Federal Circuit held that obviousness-type double patenting did not invalidate an otherwise validly obtained patent term extension under 35 U.S.C. § 156. *Novartis AG v Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018)
  - The Federal Circuit held in *Novartis v. Breckenridge* that if a later patent expires earlier only because of the URAA's change in the patent term, the post-URAA patent is not an ODP reference against the pre-URAA patent. *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.,* 909 F.3d 1355 (Fed. Cir. 2018)
  - Having PTE granted on a patent is not a defense against an ODP challenge
    - Consider the following dicta from *Novartis v. Breckenridge* (D. Del. April 3, 2017): "The patent term extension provision of the Hatch-Waxman Act was intended to restore to a patent the time lost in seeking FDA approval for the drug claimed in the patent. I see no reason why such a patent term extension would protect a patent from a double patenting challenge."

◊ PTO will provide a period of time (usually one month) for the patent owner to elect the patent for which extension is desired

- Consider filing **more than one PTE application on the same patent** based on regulatory review periods of different products, if the products are covered by the same patent
  - ◊ Postpones making the decision of which product to extend, which may be helpful when there are:
    - » Differences in the markets of the different products
  - ◊ PTO will provide a period of time (usually one month) for the patent owner to elect the product for which extension is desired
- PTO has permitted an applicant under 37 C.F.R. § 1.103 to **suspend action** on a PTE application for up to 6 months upon showing good and sufficient cause
  - ◊ Useful when:
    - » An applicant wants the PTE extension to apply to a reissue patent that has not yet granted, rather than to the original patent
    - » There is an actual or impending litigation
- The filing of a **terminal disclaimer does not affect a PTE** to which a patent is entitled (*Merck v. Hi-Tech* (Fed. Cir. 2007))
- Make sure that at least one claim of the patent reads on the approved product
  - ◊ Angiotech sought to obtain PTE for U.S. Patent No. 5,811,447 (the '447 patent) based on FDA approval of Angiotech's drug-eluting stent. The claims of the '447 patent are directed to a method of biologically stenting a mammalian blood vessel that included administering a drug. The District Court agreed with the PTO's denial of Angiotech's PTE application because none of the claims recited any structure of a particular product and, therefore, did not specify that the drug was administered by a stent (*Angiotech v. Lee*, 191 F.Supp.3d 509 (E.D. Va. 2016))
- Special Considerations for Chemical Compounds
  - ◊ PTE determination turns on whether or not an "active ingredient" had previously been approved by the U.S. Food and Drug Administration
  - ◊ The Federal Circuit upheld PTE for a product containing the **enantiomer** levofloxacin, finding that it was different than a product containing its racemate ofloxacin (*Ortho-McNeil v. Lupin* (Fed. Cir. 2010))
  - ◊ However, the Federal Circuit has also upheld the denial of PTE for the **active methyl ester form** of a compound that had previously been approved for the same therapeutic use because it had the same "active moiety" as the previously approved product (*Photocure v. Kappos* (Fed. Cir. 2010))
- PTE could be available for **corresponding foreign patents** covering products approved in countries such as Australia, Canada, Chile, Europe, Israel, Japan, Malaysia, Singapore, South Korea, Taiwan, Vietnam, Russia and Ukraine, and also in Brunei, Costa Rica, Dominican Republic, El Salvador, Guatemala and Nicaragua
  - ◊ **Note:** The requirements and deadlines for foreign PTEs often vary from the U.S.
  - ◊ **Tip:** Once approval of a product in a foreign country is received, docket any deadlines to file PTE requests

- How do I know if a PTE request has been filed or granted?
  - ◊ Review the file history of the patent on the PTO's Patent Application Information Retrieval (PAIR) system (http://portal.uspto.gov/pair/PublicPair)
  - ◊ A list of extended patent terms is available at: http://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156
  - ◊ Check the issued patent for a certificate of correction indicating that a PTE has been granted