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

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In the United States, patent term extension is available under the 1984 Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act (“The Act”).¹ 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.² The determination as to whether a patent term extension should be granted is made by the U.S. Patent and Trademark Office (“USPTO”), in consultation with the regulatory agency responsible for approval of the product. The term extension aims to restore a portion of the patent term that is lost while the patent holder is awaiting regulatory approval of the safety and efficacy of the product.

The patent term extension is based on the time the product is in clinical testing and regulatory review. A patent term may be extended for a period of time that is the sum of one-half of the time in the testing phase, plus all the time in the review phase.³ However, the extension period is reduced if any of this period occurred prior to the patent’s issuance or if the applicant is found not to have acted with due diligence during clinical testing and regulatory review. The patent term extension cannot exceed five years. The total patent term including the extension cannot exceed 14 years following regulatory approval.

An application for patent term extension must be filed with the USPTO within 60 days of the regulatory approval of the product.⁴ Only one patent term can be extended for the same regulatory review period for the product. At least one claim of the patent must cover the product or a method of manufacturing or using the product. The application for term extension must show that the patent has not expired and that the patent has not previously been extended based on a regulatory review. The application must also establish the product was subject to regulatory review and include details about the patent and the activities undertaken to secure regulatory approval. In addition, the application must state the length of the term extension claimed and explain how this extension was determined.⁵

An applicant requesting an extension of patent term based on delay due to regulatory review must file three copies of the request and a fee of \$1,120 with the USPTO. The application must be submitted by the patent owner or by an agent of the patent owner. Unlike most other USPTO correspondence, the application cannot be filed electronically.⁶ If the applicant for the extension is not the marketing applicant before the regulatory agency, then there must be an agency relationship between the patent owner and the marketing applicant during the regulatory review period. To show that such an applicant is authorized to rely upon the activities of the marketing applicant, it is advisable for the applicant to obtain a letter from the marketing applicant specifically authorizing such reliance.⁷

Although an application for patent term extension cannot be submitted before the product receives regulatory approval, an interim extension of patent term can be obtained if the regulatory review period is reasonably expected to extend

¹ See 35 U.S.C. §156 (2011).

² 37 C.F.R. §1.710 (2012).

³ 37 C.F.R. §§ 1.775-1.779. The calculation of the length of the extension period varies depending on the type of product for which an extension is sought.

⁴ 37 C.F.R. § 1.720(f).

⁵ 37 C.F.R. § 1.740 (2012) for a listing of the formal requirements for an application for extension of patent term.

⁶ Manual of Patent Examining Procedure § 502 (2012).

⁷ Manual of Patent Examining Procedure § 2752.

beyond the original expiration date of the patent.⁸ The aim of such an interim extension is to maintain the patent term until regulatory approval is achieved. An application for an interim extension of patent term may 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. The interim extension is for a period of not more than one year. However, the applicant may apply for up to four subsequent interim extensions. Any interim extension terminates at the end of the 60-day period beginning on the day on which the product involved receives regulatory approval unless the applicant submits an application for term extension within this period.⁹

If you have any questions or wish to discuss how the revised guidelines will impact your business, please contact an attorney in the [Biotechnology & Pharmaceutical group](#) at Brinks Gilson & Lione.

8 37 C.F.R. §§1.790-1.791.

9 37 C.F.R. §1.791.