

Maximizing the Value of Biotech Patents

Knowledgeable Patent Owners Can Take Advantage of Patent-term Extension Provisions

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Biototechnology and pharmaceutical patents often reach their maximum value toward the end of their term when the inventions described in the patents have matured from the laboratory through product development, clinical trials, and regulatory approval and are on the market earning revenue.

While it is obvious to most companies that their bottom lines would be well-served by keeping competitors out of the market for as long as possible, many are not aware of the opportunities to extend the term of their patents beyond the standard 20 years. This article provides an overview of several mechanisms for maximizing patent term, with an emphasis on the opportunities and pitfalls of the U.S. Patent Office's Patent Term Adjustment rules.

Since the 1984 enactment of the Drug Price Competition and Patent Term Extension Act, patent-term extensions have been available for patents directed to a product (or method of manufacturing or using a product) that was subject to a regulatory review period (such as FDA review) prior to commercial marketing. The relevant statute (35 U.S.C. § 156) places significant limits on this type of patent term extension.

For example, the regulatory approval must be the first regulatory approval for the product (e.g., the first approval of the active ingredient). Thus, patents directed to new formulations or extended-release versions of existing drugs usu-

ally are not eligible for this type of extension. Additionally, the statute only permits one patent extension per approved product. Thus, if there is a family of patents directed to the product, the patent owner must select a single patent for extension. Also, a given patent only can be extended one time, even if it covers several different products.

The length of extension available depends on the length of the regulatory review process and may be reduced if the patent owner did not act with due diligence during the regulatory approval process. The maximum extension available under this statute is five years, and the patent term may not be extended beyond fourteen years from the date of regulatory approval. This type of extension can prove extremely valuable, but its limited applicability makes it available to only a small number of patents.

URAA

The Uruguay Round Agreements Act of 1994 (URAA, effective June 8, 1995) created another mechanism for patent term extension, which also has limited applicability. The URAA was intended to harmonize certain U.S. patent laws with those of other countries, and brought the 20-year patent term to the U.S. patent system.

Recognizing the significant delays and loss of effective patent term that could arise from certain Patent Office proceedings, Congress provided for patent-term extensions in cases where the patent application was subject to a secrecy order, an interference proceeding, or an appeal (including an appeal in federal court) that resulted in the reversal of an adverse determination of patentability (i.e., a decision favorable to the patent applicant). The relevant statute (effective from June 8, 1995 to May 28, 2000) provided for one day of extension for each day the secrecy order, interference proceeding, or appeal was pending, up to a maximum of five years.

Although the URAA extension provisions addressed the loss of patent term due to specific proceedings that delay the issuance of a patent, the 20-year term provisions of the URAA drove home the adverse consequences of other delays in the patent examination process.

Prior to the URAA, U.S. patent term was measured from the patent's issue date. Thus, patent examination delays did not affect patent term and in some cases even benefited patent owners, for example, by providing more time to ready a product for market before the patent term started running. With the 20-year term, however, any delay in the patent examination process limits the effective patent term

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because the 20-year clock starts running with the patent's earliest effective U.S. filing date.

PTA Provisions

The Patent Term Adjustment (PTA) provisions (codified in 35 U.S.C. § 154, effective May 29, 2000) were enacted to limit the loss of patent term due to Patent Office delays. The PTA statute includes the URAA extension provisions outlined above, and also grants patent term extensions if the Patent Office fails to meet certain internal timelines during the examination process.

For example, if the Patent Office takes more than fourteen months to issue a first Office Action, more than four months to issue a subsequent Office Action, or more than four months to grant a patent after the Issue Fee is paid, PTA begins to accrue in the patent applicant's favor. Importantly, the statute also requires deductions from any extension period to account for times when the patent applicant "failed to engage in reasonable efforts to conclude prosecution."

Examples of common PTA pitfalls and strategies for avoiding them are outlined below. By becoming familiar with these rules and adopting strategies for avoiding PTA deductions, patent owners can enjoy the full benefits of the PTA provisions, thereby maximizing the life of their patents and, hence, maximizing patent value.

PTA PITFALL

Filing a Preliminary Amendment within one month of an Office Action/Notice of Allowance will result in PTA deduction if the Examiner has to issue a supplemental Action/Notice of Allowance.

PTA Strategy: File Preliminary Amendments as soon as possible after an application is filed. Consider calling the Examiner to make sure an Action is not about to issue, and see if the Action can wait.

PTA PITFALL

Filing a response more than three months after the relevant Notice or Action will result in PTA deduction, even if the response period is properly extended. PTA also is reduced if a deadline falls on a weekend or federal holiday, and the response is not filed until the next business day.

PTA Strategy: File responses at the three-month deadline whenever possible. If a response deadline falls on a weekend or holiday, file it on the preceding business day, even though the Patent Office rules permit filing on the next business day.

PTA PITFALL

Filing a supplemental response will result in PTA deduction.

PTA Strategy: Minimize the number of supplemental responses

filed. Consider calling the Examiner to determine whether the issue can be addressed in response to the next Action or resolved by an Examiner's Amendment. If an Examiner suggests an amendment to allow the application, ask him/her to issue an Examiner's Amendment.

PTA PITFALL

Filing an Information Disclosure Statement (IDS) after the first Office Action will result in PTA deduction, unless the IDS is filed with a response or the submitted information was cited by a foreign patent office less than 30 days previously.

PTA Strategy: File IDSs well before the first Office Action. If an Office Action is pending, wait to file the IDS with the response. Advise foreign patent attorneys of the 30-day deadline, to ensure that foreign-cited references can be submitted within that time frame.

PTA PITFALL

Filing an Amendment after a Notice of Allowance has issued will result in PTA deduction.

PTA Strategy: Ask the Examiner to make the correction by an Examiner's Amendment. If the correction is a minor one that is supported by the prosecution file history, consid-

er making the correction by a Certificate of Correction after the patent has issued.

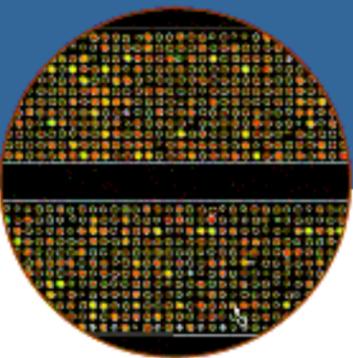
Patent owners who are aware of the different types of patent-term extension provisions can implement strategies to take advantage of these provisions and maximize the terms of their patents.

Such strategies are particularly important to biotechnology and pharmaceutical companies whose patents often continue to demonstrate significant value at the end of their terms.

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