Veterinary Services
Safeguarding Animal Health

Animal and Plant Health Inspection Service

Veterinary Services

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Patent Term Extensions

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Notes:

Patent Term Restoration

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Overview

A patent owner can potentially get part of the term of a patent restored, i.e. get additional time beyond the patents original expiration date, if part of the patent life was 'lost' due to a federally-mandated regulatory-review process, such as licensure of a veterinary biologic (35 U.S.C. 156 and 9 CFR 124). The purpose of the patent system is to facilitate innovation and advancements, thereby serving the public good, by requiring public disclosure of emerging scientific and intellectual information that would otherwise remain proprietary. In exchange for a period of federally-protected intellectual property exclusivity, the patent owner must divulge information, in the "enablement" section of the patent, that is sufficiently specific and complete enough to enable a suitably-knowledgeable expert in the field to recreate the patented material. The federal government honors this purpose, in a *quid pro quo* fashion, by restoring time such that the original expiration date is extended to account for time spent in the regulatory-review process during the patents' original term. This is frequently referred to as "patent extension."

Introduction

A firm that has a patent from the United States Patent and Trademark Office (USPTO) for an unlicensed veterinary biologic product is not allowed to market or sell the product until the product is licensed. This effectively means that the firm has 'lost' a portion of the period of market exclusivity for that intellectual property. The USPTO has the discretionary authority to restore part of the patent term by granting an extension to the patent term if the patent holder has been subject to limitations in the exercise of their property rights due to a governmental requirement, such as licensure by the Policy, Evaluation, and Licensing (PEL) section of the Center for Veterinary Biologics (CVB). As such, patent holders are entitled to patent restoration for a period of time equal to that period during which the product was under regulatory review (9 CFR 124.20 through 124.23).

In order to exercise this right, the firm must submit their request for a patent term extension to the USPTO within 60 days after the product is first licensed. In response to this request, the USPTO contacts the CVB to initially inquire whether the CVB confirms or refutes that the patent qualifies for this consideration. If the CVB response confirms that the qualification applies, then, the USPTO makes a second inquiry to the CVB requesting that the CVB provide the number of days of the restoration, commonly referred to as the "extension," with associated calculations.

Since this extension might impact the rights of or be disputed by members of the public, the proposed extension length must be publically available for review and response, generally referred to as "comment," in a federal publication in the form of a Notice in the Federal Register (FRN). For example, manufacturer Z, who is planning to use the enablement section of rival manufacturer Y's patent for the production of their own product, has a legal right to know of and respond to proposed changes in the patent term. The CVB reviews the responses at the end of the comment period and responds to any comments that are substantive or otherwise require a response. If the CVB determines that the comment period has not yielded any issues delaying or barring the extension, then the CVB informs the USPTO of their disposition, and the USPTO exercises their discretionary authority to grant or to deny a patent restoration.

Procedure

The verbage for the letters in these exchanges is consistent and standardized, just requiring an exchange of the few product particulars. The three MLs created are for the applicability inquiry, length inquiry, and Federal Register Notice (FRN) including the CVB post-FRN response letter. The first two ML types are "Correspondence" and the third is "Federal Register Notice." The CVB person preparing the response letters will need to request creation of the third ML. [redacted]

1. Applicability Inquiry:
   a. After a firm requests a patent extension from the USPTO, the USPTO sends a letter to the Director's Office, Center for Veterinary Biologics (CVB) requesting assistance in confirming that the product was subject to a regulatory review by CVB prior to its licensure. A copy of the application for patent term extension is provided with the letter, and the USPTO provides the date of filing within their letter. The USPTO is asking the CVB to confirm or to refute that the CVB has subjected a product associated with the patented intellectual property to a period of mandatory regulatory-review culminating in federal licensure..The CVB creates a Mail Log (ML) for this inquiry and the response. [redacted] The CVB provides a formal response letter to confirm or refute that the product has been subject to mandatory federal review and whether the application was filed within 60 days of issuance of the license. In the letter, the CVB provides the licensure date and a determination whether the firm, based on the timing of their request to the USPTO, complied with the statutory requirement to submit a patent term extension to the USPTO within 60 days of CVB licensure of the product. [redacted]
      i. To determine the date of licensure, go to LSRTIS and select "Licensing". In thedrop-down menu, select "Product Licenses", which brings up "Product LicenseSearch". Enter the

establishment number and the product code, then select"Search". The screen will provide the "First Issue Date" for the license (see Appendix C).

2. Length (Number of Days) Inquiry:

   a. If the USPTO concludes that the subject patent appears eligible for an extension, then the USPTO submits a follow-up letter to the CVB requesting that the CVB determine the time length, in number of days, attributable to the regulatory review process. The CVB should respond not later than 30 days after receipt of the request from the USPTO (9 CFR 124.21). [redacted]

   b. The CVB response letter states the preliminary determination and the total number of days the product was under review and explains how it calculated this number of days (9 CFR 124.20). The CVB must issue this letter within 30 days of receipt of this USPTO inquiry and cc: the firms' legal counsel. The letter also states that the CVB will publish a Federal Register Notice regarding the determination (9 CFR 124.21). . [redacted]

      Patent term extension calculation

      i. The CVB calculates the review period as the sum of the following (9CFR 124.20): [redacted]

         (1) The number of days in the period beginning on the date the CVB first authorized the applicant to prepare an experimental biological product under the Virus-Serum-Toxin Act and ending on the date the applicant submitted the application for a license under the Virus-Serum-Toxin Act to the CVB; and
         (2) The number of days in the period beginning on the date the applicant submitted the application for a license under the Virus-Serum-Toxin Act to the CVB and ending on the date the CVB issued the license.

      ii. A license application is "initially submitted" on the date that the CVB determines the application contains sufficient information for the CVB to commence review of the application. In general, this is the date that the CVB received the APHIS Form 2003. A product license is issued on the date that the CVB puts in the CVB letter officially notifying the applicant that the CVB has issued the license, or permit. This same date appears on the license. The CVB, by issuing a license, approves the commercial marketing or use of the product subject to ongoing regulatory oversight. Only a subset of products will qualify for time prior to submission of the application for a license.

      To determine the date of licensure, go to LSRTIS and select "Licensing". In thedrop-down menu, select "Product Licenses", which brings up "Product LicenseSearch". Enter the establishment number and the product code, then select"Search". The screen will provide the "First Issue Date" for the license (seeAppendix C).

iii. To determine the date a product application was submitted to CVB, go to the MailLog and select "Search". In the drop-down menu, select "Advanced Search(PEL)", then "Doc Search". Enter "Form 2003" in the first box and, farther down,the establishment number and the product code. Then select "Search" (see Appendix D). The screen will provide the link to the APHIS Form 2003 and thedate it was signed (Box 13) and submitted to CVB. The calculation of days includes theend date, i.e. one day is added.

3. Public Notice in the Federal Register
   a. Publication of the Notice. The Center for Veterinary Biologics must publish a Federal Register notice, as required by 9CFR 124.21, that provides members of the public with all the following information [redacted]
      (1) The name of the applicant;
      (2) The trade name and true name of the product;
      (3) The number of the patent for which an extension of the term is sought;
      (4) The approved indications or uses for the product;
      (5) The regulatory review period determination, including a statement of the length of each phase of the review period and the dates used in calculating each phase.

   b. Comment period. The public has 180 days to contest and/or comment on the determination of the review period using one, or more, of the submission mechanisms described in the Notice and 9 CFR 124.23. The CVB may also modify its determination of the regulatory review period in response to new information from USPTO records or CVB/APHIS records.
      (1) The Notice provides that, up to 30 days a person may request a revision to the determination and up to 180 days after publication, any interested person can file a petition with the CVB as to whether the patent term extension applicant acted with due diligence during the regulatory review period (9CFR 124.22).
      (2) If no substantive responses (revisions or petitions)are received during the regulatory review period, then the CVB will consider its regulatory period determination to be final and will send a letter to the USPTO stating such (9 CFR 124.23)(See Section IV and [redacted]
      (3) If the CVB receives substantive public response(s) (due diligence petition filed, or requests for a hearing and/or revision) or identifies new relevant record (USPTO or CVB/APHIS) information contesting the determination, then:
         a. The CVB prepares a revised Federal Register Notice containing the new proposed patent extension determination. The CVB must notify the PTO of the revised determination and send copies of the notice to the USPTO, requesting party, applicant, and petitioner. (9CFR 124.22)
         b. This process is repeated, as necessary, until the CVB decides that no more revisions are required. The process includes opportunities for the applicant and CVB/APHIS to respond to petitions and changes in the determination.

4. CVB Post-FRN Response to USPTO
   The CVB Director sends a letter informing the USPTO and stating that CVB considers the regulatory review period determination to be final (see Appendix B, letter-6), per 9CFR 124.23. It is important to make note of when the 180 day period will end, then follow up with

Riverdale staff to confirm that no petitions have been filed, before responding to the USPTO. [redacted]

5. USPTO Disposition
   If the patent was not in force during all of the regulatory review period or due diligence was not observed, the USPTO will subtract days from the patent term extension as they deem appropriate. In time the USPTO, will send a letter back to the CVB Director indicating that the application process has been completed. The CVB Director does not inform the applicant/patent holder, as the USPTO informs the patent holder and other relevant parties of the final disposition of the request.

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