Patent Term Extension

Overview

The United States Patent and Trademark Office (PTO) is responsible for extending patents issued to biologic manufacturers. Patent holders are entitled to patent extension for a period of time equal to that period during which the product was under regulatory review (9CFR 124.20 through 124.23). The firm must request a patent term extension within 60 days after the product is first licensed.

Procedure

1. If a firm requests a patent extension from the PTO, the PTO will send a letter to the CVB requesting assistance.

2. The reviewer will respond with a letter confirming that the product was under regulatory review. The date the biologic product was first licensed by the Center for Veterinary Biologics is provided, and the reviewer confirms whether the request for patent term extension complied with the 60-day filing requirement. [redacted]

3. If the PTO concludes that the subject patent appears eligible for an extension, the PTO will submit an additional letter to the CVB requesting a determination of the regulatory review period This submission includes a copy of the firm's application for an extension.

4. The CVB must determine, within 30 days of receipt of the application from the PTO, the total number of days the product was under review. The CVB then sends a letter to the PTO, with a cc: to the firm, stating the preliminary determination. [redacted]

> The review period (9CFR 124.20) is the sum of the following:
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> > (1) The number of days in the period beginning on the date authorization to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was initially submitted under the Virus-Serum-Toxin Act; and
> > (2) The number of days in the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.
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> A license application is "initially submitted" on the date it contains sufficient information to allow APHIS to commence review of the application. (Generally, but not always, this is the date the APHIS Form 2003 was received.) A product license is issued on the date of the APHIS letter informing the applicant of the issuance. The issuance of a license releases the product for commercial marketing or use.

5. The Center for Veterinary Biologics must publish a Federal Register notice, as required by 9CFR 124.21. The notice will include the following: (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.

6. The public has 180 days to contest the determination of the review period. If no comments are received by that time, the determination is considered to be final. (9 CFR 124.23)

7. If the determination is contested and a revision to the determination is made, a revised Federal Register notice must be prepared, and the PTO must be notified. (9CFR 124.22) This step is repeated, as necessary, until there are no more revisions.

[redacted]

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