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In Re: Patent Term Extension
Application for
U.S. Patent No. 10,544,220
Filed: July 14, 2023

October 24, 2023

REQUIREMENT FOR INFORMATION PURSUANT TO 37 C.F.R. 1.750

An application for extension of the patent term of U.S. Patent No. 10,544,220 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on July 14, 2023. The application (PTE application) was filed by Genmab A/S, the patent owner of record. Extension is sought based upon the premarket review under Section 351(a) of the Public Health Service Act (PHSA) 42 U.S.C. § 262(a) and 21 C.F.R. §§ 314 and 601 of Biologics License Application (BLA) No. 761324 of EPKINLY® (epcoritamab-bysp) which was approved for commercial use and sale by the Food and Drug Administration (FDA) on May 19, 2023. An extension of 675 days is requested.

Pursuant to 37 C.F.R. 1.750, applicant is required to submit the following to the USPTO:

> Evidence that Genmab A/S is expressly authorized to rely upon the regulatory review activities by Genmab US, Inc., the marketing applicant before the Food and Drug Administration to support the application for patent term extension of U.S. 10,544,220 (the '220 patent).

The right to a PTE application pursuant to 35 U.S.C. § 156 is granted to patent owners to compensate for lost patent term while the patent owner, or its agent, sought premarket approval from a regulatory agency. *See*, Manual of Patent Examining Procedure, § 2750 and in particular § 2752.[1] Section 156(d)(1)(D) of Title 35 of the United States Code requires a description of the activities undertaken by the applicant (i.e., the patent owner or its agent) during the regulatory review period, and specifies in § 156(d)(2)(B)(i) that the lack of due diligence by the applicant during the regulatory review period may be taken into account. Given these statutory requirements, the Office has held that in order to be eligible for patent term extension, the patent owner or its agent must have undertaken the activities that led to the regulatory approval. If a patent owner has not been involved in the regulatory process, either directly or indirectly, that patent owner has not lost any effective patent life since it never invested time and resources

[1] Manual of Patent Examining Procedure (MPEP) § 2752: To show that an applicant is authorized to rely upon the activities of the marketing applicant before the Food and Drug Administration or the Department of Agriculture, it is advisable for the applicant for patent term extension to obtain a letter from the marketing applicant specifically authorizing such reliance. Also See, Amendment to Rules for Extension of Patent Term, 60 Fed. Reg. 25615 (May 12, 1995) explaining the applicant for term extension and the applicant who undertook the regulatory review activities as being the same entity or related through an agency relationship.

necessary to obtain approval for commercial marketing or use. *See*, Decision Denying Application (United States Patent and Trademark Office Deputy Assistant Comm'r for Patent Policy and Projects Apr. 3, 1995) (concerning patent term extension application for United States Patent No. 4,631,286); aff'd, *Hoechst-Roussel Pharms., Inc. v. Lehman*, No. 95-650-A (E.D. Va. Oct. 27, 1995); aff'd, 109 F.3d 756, 759, 42 U.S.P.Q.2d 1220, 1223 (Fed. Cir. 1997) (Newman, C.J., concurring) (affirming on other grounds, but Judge Newman concurring in the judgment on this basis). *See,* also Amendment to Rules for Extension of Patent Term, 60 Fed. Reg. 25615, 25616 (May 12, 1995).

The PTE application paragraph (C) on page 4 indicates that EPKINLY® (epcoritamab-bysp) received approval for commercial marketing or use on May 19, 2023. According to the PTE application, however, the "Marking Applicant for EPKINLY® (epcoritamab-bysp) is Genmab US, Inc., Exhibit 3. Genmab A/S is thus relying upon the premarket activities of Genmab US, Inc., PTE application paragraph A (page 4), to support application for patent term extension. The Office now requires Genmab A/S to provide evidence, as set forth above, of its eligibility to apply for extension of the term of the '220 patent under 35 U.S.C. § 156. Namely, Genmab A/S must demonstrate its agency relationship with the BLA holder (Genmab US, Inc.) as it relates to the approved product and provide evidence of its express authorization to rely upon the regulatory activities by Genmab US, Inc.

Applicant has **TWO MONTHS** from the date of this letter in order to file information satisfying this requirement. Extensions of time under 37 CFR 1.136 are available. Failure to respond will result in the application for patent term extension being processed as an informal application. Alternatively, applicant may have the holding of informality reviewed as set forth in 37 CFR 1.740(c).

Any correspondence from applicant with respect to this matter should be submitted via the USPTO's EFS Web system and should be addressed as follows:

Commissioner for Patents
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Telephone inquiries related to this notice should be directed to the undersigned at (571) 272-0909.

/Ali Salimi/

Ali Salimi
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patents

cc: FDA, CDER, Office of Regulatory Policy
10903 New Hampshire Avenue,
Bldg. 51 Room 6250
Silver Spring MD 20993-0002

Attention: Beverly Friedman

RE: EPKINLY® (epcoritamab-bysp)
Docket No.: