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In Re: Patent Term Extension
Application for
U.S. Patent No. 10,968,453
Filed: June 9, 2023

November 29, 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. 10,968,453 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on June 9, 2023. The application (PTE application) was filed by Biogen MA Inc., the patent owner of record. Extension is sought of QALSODY® (tofersen) NDA-215887 which was approved for commercial use and sale by the Food and Drug Administration (FDA) on April 25, 2023—based upon the premarket review under §§ 505(i) and (b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), codified at 21 U.S.C. §§ 355 (i) and (b). An extension of 543 days is requested.

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

Evidence that Biogen MA Inc. is expressly authorized to rely upon the regulatory review activities by Biogen, Inc., the marketing applicant before the Food and Drug Administration to support the application for patent term extension of U.S. 10,968,453 (the '453 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 (3) on page 5 indicates that QALSODY® (tofersen) received approval for commercial marketing or use on April 25, 2023. According to the PTE application, however, the “Marking Applicant for QALSODY® (tofersen) is Biogen, Inc., Appendix D. Biogen MA Inc. is thus relying upon the premarket activities of Biogen, Inc. to support application for patent term extension. The Office now requires Biogen MA Inc. to provide evidence, as set forth above, of its eligibility to apply for extension of the term of the ’453 patent under 35 U.S.C. § 156. Namely, Biogen MA Inc. must demonstrate its agency relationship with the NDA holder (Biogen, Inc.) as it relates to the approved product and provide evidence of its express authorization to rely upon the regulatory activities by Biogen, Inc.

Applicant has **TWO MONTHS** from the date of this letter in order to file information satisfying this requirement. Extensions of time under 37 C.F.R. § 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 C.F.R. § 1.740(c).

Any correspondence from applicant with respect to this matter should be submitted via the USPTO’s Patent Center and should be addressed as follows:

Commissioner for Patents
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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,
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RE: QALSODY® (tofersen)

Attention: Beverly Friedman