UNITED STATES PATENT AND TRADEMARK OFFICE

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November 28, 2023

David R. Marsh, Ph.D.
Arnold & Porter Kaye Scholer LLP
Attn: IP Docketing
601 Massachusetts Ave., NW
Washington, DC 20001-3743

In Re: Patent Term Extension
Application for
U.S. Patent No. 7,553,941
Filed: August 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. 7,553,941 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on August 24, 2023. The application was filed by Opko Biologics Ltd., the patent owner of record. Extension is sought based upon the premarket review under § 351(a) of the Public Health Service Act of NGENLA® (somatrogon-ghla), which was approved for commercial use and sale by the Food and Drug Administration (FDA) on June 27, 2023. An extension of 5 years is requested.

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

> Evidence that Opko Biologics Ltd. is expressly authorized to rely upon the regulatory review activities by Pfizer Ireland Pharmaceuticals (Pfizer), the marketing applicant before the Food and Drug Administration to support the application for patent term extension of U.S. Patent No. 7,553,941.

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 his 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 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

[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.

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 states "[u]nder the terms of the AMENDED AND RESTATED DEVELOPMENT AND COMMERCIALIZATION LICENSE AGREEMENT between Pfizer Inc. and OPKO Ireland Ltd. (effective May 12, 2020), Patent Term Extension Applicant OPKO Biologics Ltd., through OPKO Ireland Ltd., exclusively licensed U.S. Patent No. 7,553,941 to Pfizer Inc. for purposes of obtaining marketing authorization for NGENLA™ (Somatrogon-ghla). Accordingly, OPKO Biologics Ltd. is authorized to rely upon the activities of Pfizer Inc. for the purposes of this application for patent term extension of U.S. Patent No. 7,553,941." PTE Application at 5. However, an exclusive license is not an authorization to rely on the activities of the marketing applicant for a PTE application. Because Opko is relying on the premarket activities of Pfizer to support the application for patent term extension, the USPTO is requiring Opko to provide evidence, as set forth above, of its eligibility to apply for extension of the term of U.S. 7,553,941 under 35 U.S.C. § 156. In particular, Opko must demonstrate its agency relationship with the BLA holder (Pfizer) as it relates to the approved product and its receipt of express authorization to rely upon Pfizer's regulatory activities.

Applicant has **TWO MONTHS** from the date of this letter in order to file a response. 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 patent electronic filing 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 Andrea Grossman at (571) 270-3314.

/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: NGENLA® (somatrogon-ghla)
Docket No.: