



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22314-1450  
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August 7, 2023

Mr. John Burr  
1672 Railroad Street  
Corona, CA 92878

In re: Patent Term Extension Application  
for U.S. Patent No. 9,345,772

**WITHDRAWAL OF APPLICATION FOR PATENT TERM EXTENSION**

On November 4, 2022, the United States Patent and Trademark Office (USPTO) mailed a Requirement for Information (RFI) pursuant to 37 CFR 1.750 to Tap Pharmaceuticals, AG (Tap). Tap, the patent owner of record, had filed an application under 35 U.S.C. 156 for extension of the patent term of U.S. Patent No. 9,345,772 on June 24, 2022. Tap had sought extension based on the premarket review under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act of a human drug product known by the tradename ERMEZA<sup>®</sup> and having the active ingredient levothyroxine sodium.

The RFI requested that Tap provide information regarding three issues:

- I. The name of the approved product
- II. Tap's authorization to rely on the activities of marketing applicant Mylan Pharmaceuticals Inc. before the Food and Drug Administration (FDA)
- III. The submission and approval dates of the new drug application (NDA 215809) for the product ERMEZA<sup>®</sup> (levothyroxine sodium)

The RFI provided Tap with a two-month period to respond, with extensions of time of up to five months available under 37 CFR 1.136. Additionally, the RFI indicated that failure to respond would result in the application for patent term extension being withdrawn. The deadline to receive the response would have been June 4, 2023.

Since no response was received by the deadline of June 4, 2023, Tap's application for extension of the term of U.S. Patent No. 9,345,772, based on the FDA's review of ERMEZA<sup>®</sup> (levothyroxine sodium) is hereby **withdrawn**.

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

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

Inquiries related to this determination should be directed to the undersigned at 571-272-7754 or kathleen.fonda@uspto.gov.

*/Kathleen Kahler Fonda/*

Kathleen Kahler Fonda  
Senior Legal Advisor  
Office of Patent Legal Administration

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

re: ERMEZA<sup>®</sup> (levothyroxine  
sodium)

Attention: Beverly Friedman