

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: September 6, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix**List of Topics Discussed in the Preliminary Decision Memorandum**

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. Discussion of the Methodology
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[FR Doc. 2024–22521 Filed 9–30–24; 8:45 am]

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DEPARTMENT OF COMMERCE**Patent and Trademark Office**

[Docket No. PTO–P–2024–0047]

Grant of Interim Extension of the Term of U.S. Patent No. 7,199,162—GRAFAPEX™ (Treosulfan)

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued a certificate for a one-year interim extension of the term of U.S. Patent No. 7,199,162.

FOR FURTHER INFORMATION CONTACT: Kathleen Kahler Fonda, Senior Legal Advisor (telephone (571) 272–7754; email kathleen.fonda@uspto.gov). Alternatively, mail may be addressed to Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450, and marked to the attention of Ms. Fonda.

SUPPLEMENTARY INFORMATION: Section 156 of title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On August 20, 2024, Medac Gesellschaft für Klinische Spezialpräparate mbH, the patent owner of record, timely filed an application

under 35 U.S.C. 156(d)(5) for a fourth interim extension of the term of U.S. Patent No. 7,199,162. The patent claims a method of using the human drug product GRAFAPEX™ (treosulfan). The application for patent term extension indicates that New Drug Application 214759 was submitted to the Food and Drug Administration on August 11, 2020, and its review in order for the patent owner to obtain permission to market and use the product commercially is ongoing.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the thrice-extended expiration date of the patent, October 12, 2024, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A fourth interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 7,199,162 is granted for a period of one year from the thrice-extended expiration date of the patent.

Charles Kim,

Deputy Commissioner for Patents, United States Patent and Trademark Office.

[FR Doc. 2024–22480 Filed 9–30–24; 8:45 am]

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DEPARTMENT OF COMMERCE**Patent and Trademark Office**

[Docket No.: PTO–P–2024–0051]

Extension and Termination of the After Final Consideration Pilot Program 2.0

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: On April 3, 2024, the United States Patent and Trademark Office (USPTO), when setting and adjusting patent fees for fiscal year 2025, proposed a new fee to recuperate costs affiliated with the submission of a request for consideration under the After Final Consideration Pilot Program 2.0 (AFCP 2.0). Commenters on the proposal expressed concerns about the AFCP 2.0 and the proposed fee. In view of these comments, the USPTO has decided to allow AFCP 2.0 to expire. While the program currently runs through September 30, 2024, to accommodate those who may be in the

process of preparing to use the program, the USPTO will provide a short extension of the expiration of the program. The USPTO is setting December 14, 2024, as the last day to submit a request for participation under the program.

DATES: The USPTO will not accept requests for consideration under the AFCP 2.0 filed after December 14, 2024.

FOR FURTHER INFORMATION CONTACT: Kery Fries, Senior Legal Advisor, at 571–272–7757; or Raul Tamayo, Senior Legal Advisor, at 571–272–7728, both with the Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents.

SUPPLEMENTARY INFORMATION: On May 19, 2013, the USPTO modified the After Final Consideration Pilot Program (AFCP) to create the AFCP 2.0. The three main differences between the AFCP and the AFCP 2.0 are: (1) an applicant must request to participate in AFCP 2.0; (2) a response to an after final rejection under AFCP 2.0 must include a non-broadening amendment to at least one independent claim; and (3) the examiner will schedule an interview with the applicant if the after-final response did not result in a determination by the examiner that all pending claims in the application were in condition for allowance.

The goal of the AFCP 2.0 was to improve pendency by reducing the number of Requests for Continued Examination (RCE) and encourage increased collaboration between the applicant and the examiner to effectively advance prosecution of the application. The AFCP 2.0 does not require any additional fees for an applicant to request consideration of an amendment after final rejection, but any necessary existing fee, *e.g.*, the fee for an extension of time, is required. Initially, the pilot program was scheduled to run for approximately one year and was set to end on September 30, 2014. The USPTO notified the public that the AFCP 2.0 may be extended (with or without modifications) depending on feedback from participants and based on a determination of the effectiveness of the pilot program. The USPTO repeatedly extended the pilot program, with the most recent extension set to end on September 30, 2024.

Since 2016, applicants have filed more than 60,000 AFCP 2.0 requests annually. Due to the high usage of the AFCP 2.0, costs to administer the program are significant. A large part of the AFCP 2.0's high usage is due to economic inefficiencies where participants receive program benefits without paying for the cost of the