



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22314-1450
www.uspto.gov

Mr. Richard J. Berman
Arent Fox LLP
1717 K Street, NW
Washington, DC 20006

In re: Patent Term Extension
Application for
U.S. Patent No. 7,629,345

January 26, 2024

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 7,629,345, claims of which cover the human drug product known by the tradename VYZULTA® (latanoprostene bunod), and methods of using the same, is eligible for patent term extension under 35 U.S.C. 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR 1.136(a) are available.

Applicant also has applied for patent term extension of U.S. Patent Nos. 7,273,946 and 8,058,467 based on the regulatory review period of NDA 207795 for the human drug product known by the tradename VYZULTA® (latanoprostene bunod).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice or any extended time period under 37 CFR 1.136(a), and in accordance with 37 CFR 1.785(b), the applications for patent term extension in 7,629,345 and 8,058,467 will be denied. Accordingly, the application for patent term extension of the patent having the earliest date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No. 7,273,946. In the absence of such request for reconsideration and if U.S. Patent No. 7,629,345 is elected, the Director will issue a certificate of extension, under seal, for a period of five years in U.S. Patent No. 7,629,345.

The period of extension, if calculated using the Food and Drug Administration's determination of the length of the regulatory review period published in the Federal Register of March 1, 2023 (88 Fed. Reg. 12950), would be 1,862 days (5.1 years). Under 35 U.S.C. 156(c):

$$\begin{aligned}
 \text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2} (\text{TP} - \text{PGTP})^1 \\
 &= 3,879 - 992 - 0 - \frac{1}{2} (3,043 - 0) \\
 &= 1,862 \text{ days (5.1 years)}
 \end{aligned}$$

Since the regulatory review period began March 23, 2007, before the patent issued (December 8, 2009), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period under 35 U.S.C. 156(c). (From March 23, 2007, to and including December 8, 2009, is 992 days; this period is subtracted from the number of days occurring in the testing phase according to the Food and Drug Administration's determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. 156(c)(1) was made.

However, the five-year limitation of 35 U.S.C. 156(g)(6)(A) applies in the present situation, because it provides that the period of extension calculated under 35 U.S.C. 156(c) for the patent cannot exceed five years.² Here, the period of extension calculated above (1,862 days) would extend the term of U.S. Patent No. 7,629,345 from January 5, 2025 to February 10, 2030, which is beyond the five-year limit. By operation of 35 U.S.C. 156(g)(6)(A), the period of extension is thus limited to five years.

The 14-year limitation of 35 U.S.C. 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	7,629,345
Granted:	December 8, 2009
Original Expiration Date ³ :	January 5, 2025
Inventor:	Ennio ONGINI; Valerio CHIROLI; Francesca BENEDINI; and Piero Del SOLDATO
Owner of Record:	Nicox S.A.

¹ Consistent with 35 U.S.C. 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of $\frac{1}{2} (\text{TP} - \text{PGTP})$.

² 35 U.S.C. 156(g)(6)(A) applies to any patent issued after the 1984 enactment of 35 U.S.C. 156.

³ Subject to the provisions of 35 U.S.C. 41(b).

Title: Prostaglandin Derivatives

Product Trade Name: VYZULTA® (latanoprostene bunod)

Term Extended: five years

Expiration Date of Extension: January 5, 2030

Any correspondence from the patent term extension applicant with respect to this matter should be submitted via the USPTO patent electronic filing system using the appropriate document description.

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: VYZULTA® (latanoprostene
bunod)

Docket No.: FDA-2018-E-4427

Attention: Beverly Friedman