



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-P-2025-0512]

Grant of Interim Extension of the Term of U.S. Patent No. 7,319,099; Bitopertin (GlyT1 inhibitor) Oral Tablets

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 under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 7,319,099 ('099 patent).

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-0909 or ali.salimi@uspto.gov; or Andrea S. Grossman, Legal Advisor, Office of Patent Legal Administration, at (571) 270-3314 or andrea.grossman@uspto.gov.

SUPPLEMENTARY INFORMATION:

35 U.S.C. 156 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. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period (RRP) is reasonably expected to extend beyond the expiration date of the patent.

On December 1, 2025, Hoffman-La Roche, Inc., the patent owner of record of the '099 patent, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of the '099 patent. The '099 patent claims the human drug product Bitopertin (GlyT1 inhibitor) oral tablets. The application indicates that the approval phase for the regulatory period, as described in 35 U.S.C. § 156(g)(1)(B)(ii), for NDA 220707 for the human drug product Bitopertin (GlyT1 inhibitor) oral tablets is ongoing before the Food and Drug Administration for permission to market and use the product commercially.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the '099 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 it appears reasonable to expect the approval phase of the RRP to continue beyond the expiration date of the patent, i.e., December 17, 2025, interim extension of the '099 patent's term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 7,319,099 is granted for a period of one year from the original expiration date of the patent.

Charles Kim

Deputy Commissioner for Patents,

United States Patent and Trademark Office

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