



3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2020-0046]

Grant of Interim Extension of the Term of U.S. Patent No. 7,057,053; Vernakalant Hydrochloride

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

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting a one-year interim extension of the term of U.S. Patent No. 7,057,053 ('053 patent).

FOR FURTHER INFORMATION CONTACT: Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, by telephone at 571-272-7728 or by email to raul.tamayo@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 is reasonably expected to extend beyond the expiration date of the patent.

On July 14, 2020, Correvio International Sàrl, the owner of record of the '053 patent, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of the '053 patent.

The '053 patent claims the product vernakalant hydrochloride. The application for interim patent term extension indicates that New Drug Application No. 22-034 for vernakalant hydrochloride

was submitted to the Food and Drug Administration (FDA) on December 19, 2006, and that the FDA's review thereof is ongoing.

Review of the interim patent term extension application indicates that, except for permission to market or use the product commercially, the '053 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it appears the approval phase of the regulatory review period will continue beyond the original expiration date of the patent, i.e., October 16, 2020, interim extension of the '053 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. 7,057,053 is granted for a period of one year from the original expiration date of the '053 patent.

Robert Bahr,

Deputy Commissioner for Patent Examination Policy,

United States Patent and Trademark Office.

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