



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2023-0033]

Grant of Interim Extension of the Term of U.S. Patent No. 7,517,522; recombinant ADAMTS13 (rADAMTS13), a recombinant A disintegrin and metalloprotease with thrombospondin type-1 motifs 13

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. 7,517,522 ('522 patent).

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-0909 or ali.salimi@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 June 15, 2023, The Regents of the University of Michigan, the owner of record of the '522 patent, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of the '522 patent. The '522 patent claims a method of using the product recombinant ADAMTS13 (rADAMTS13), a recombinant A disintegrin and metalloprotease with thrombospondin type-1 motifs 13. The application for interim patent term extension indicates

that a Biologics License Application No. 125795/0 was submitted to the Food and Drug Administration (FDA) on March 17, 2023, 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 '522 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 expiration date of the patent, i.e., June 30, 2023, interim extension of the '522 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. 7,517,522 is granted for a period of one year from the original expiration date of the '522 patent.

Robert Bahr,

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

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