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[3510-16-P]

**DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**[Docket No.: PTO-P-2014-0068]**

**Grant of Interim Extension of the Term of U.S. Patent No. 5,593,823;**

**INTERCEPT® Blood System for Plasma**

**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 an order granting a second interim extension under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 5,593,823.

**FOR FURTHER INFORMATION CONTACT:** Mary C. Till by telephone at (571) 272-7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571) 273-7755; or by e-mail to [Mary.Till@uspto.gov](mailto:Mary.Till@uspto.gov).

**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 December 5, 2014, Cerus Corporation, the patent owner of record, timely filed an application under 35 U.S.C. § 156(d)(5) for a second interim extension of the term of U.S. Patent No. 5,593,823. The patent claims the medical device INTERCEPT® Blood System for Plasma. The application indicates that a Premarket Approval Application (PMA) was submitted to the Food and Drug Administration (FDA) in four modules. The PMA Shell number BM120078 was assigned on December 5, 2012. The first module was received by the FDA on March 1, 2013, the second module was received on June 3, 2013, by the FDA, the third module was received by the FDA on September 3, 2013, and the fourth module was received by the FDA on November 29, 2013. The medical device is currently undergoing regulatory review before the FDA for permission to market or use the product commercially.

Review of the 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 it is apparent that the regulatory review period will continue beyond the

extended expiration date of the patent, January 14, 2015, interim extension of the patent 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. 5,593,823 is granted for a period of one year from the extended expiration date of the patent.

Dated: December 23, 2014

Andrew Hirshfeld,  
Deputy Commissioner for Patent Examination Policy  
United States Patent and Trademark Office.

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