



JUL 24 2000

Richard S. Parr
Merck & Co., Inc.
P.O. Box 2000
Rahway NJ 07065-0907Re: Patent Term Extension
Application for
U.S. Patent No. 5,292,756

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,292,756, which claims the human drug product AGGRASTAT® (tirofiban) and the method of use of AGGRASTAT® (tirofiban), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 433 days.

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 not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 433 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 11, 1999 (64 Fed. Reg. 25350). Under 35 U.S.C. § 156(c):

Period of Extension	$\frac{1}{2}$ (Testing Phase) + Approval Phase
	$\frac{1}{2}(2051 - 718) + 196$
	863 days

Since the regulatory review period began March 21, 1992, before the patent issued (March 8, 1994), 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 35 U.S.C. § 156(c). (From March 21, 1992 to March 8, 1994 is 718 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA 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.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 863 days, would extend the patent from March 8, 2011 (35 U.S.C. § 154) to May 14, 2012, which is beyond the 14-year limit (the approval date is May 14, 1998, thus the 14 year limit is May 14, 2012). The period of extension is thus limited to May 14, 2012, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, March 8, 2011, to and including May 14, 2012, or 433 days.

The limitations of 35 U.S.C. § 156(g)(6) do 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:

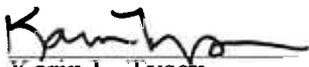
U.S. Patent No.	5,292,756
Granted	March 8, 1994
Original Expiration Date ¹	March 8, 2011
Applicant:	Duggan et. al.
Owner of Record	Merck & Co., Inc.
Title:	Novel Sulfonamide Fibrinogen Receptor Antagonists
Classification:	514/331
Product Trade Name:	AGGRASTAT® (tirofiban)
Term Extended	433 days
Expiration Date of Extension:	May 14, 2012

Any correspondence with respect to this matter should be addressed as follows

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: AGGRASTAT®
FDA Docket No.: 98E-0842

¹Subject to the provisions of 35 U.S.C. § 41(b).