



APR - 3 2007

Michael Gollin
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575 7th Street NW
Washington DC 20004

In re: Patent Term Extension
Application for
U.S. Patent No. 5,716,981

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,716,981, which claims the medical device TAXUS® EXPRESS²™ (Paclitaxel-Eluting Coronary Stent System), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 488 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 Director will issue a certificate of extension, under seal, for a period of 488 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 July 5, 2006 (71 Fed. Reg. 38170). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (456) + 260 \\ &= 488 \text{ days (1.3 years)} \end{aligned}$$

Since the regulatory review period began March 21, 2002, after the patent issued (February 10, 1998), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to 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.:	5,716,981
Granted:	February 10, 1998
Original Expiration Date ¹ :	February 10, 2015
Applicant:	William L. Hunter, et al.
Owner of Record:	Angiotech Pharmaceuticals, Inc.

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

Title: Anti-Angiogenic Compositions and Methods of Use

Product Trade Name: TAXUS® EXPRESS²™ (Paclitaxel-Eluting
Coronary Stent System)

Term Extended: 488 days

Expiration Date of Extension: June 12, 2016

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

By mail: Mail Stop Patent Ext. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7754

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7754.



Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane
Rockwall II Rm. 110
Rockville, MD 20857

Re: TAXUS® EXPRESS²™ (Paclitaxel-Eluting
Coronary Stent System)

FDA Docket No. 2004E-0396

Attention: Beverly Friedman