



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent:

Patent No. : 5,716,981)
Inventors : William L. Hunter et al.)
Assignee : Angiogenesis Technologies, Inc.)
(Vancouver, CA))
Issued : February 10, 1998)
Title : ANTI-ANGIOGENIC COMPOSITIONS)
AND METHODS OF USE)

Atty. Dkt. No. 32286-201681
Customer Number 26694

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

APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Dear Commissioner:

This is an application for extension of patent term for US patent 5,716,981 (the '981 patent), pursuant to 35 U.S.C. § 156 and 37 C.F.R. § 1.740. The applicant is the owner of the '981 patent, Angiotech Pharmaceuticals, Inc. ("Angiotech") which is submitting this application by its duly authorized agent named below. Angiotech's corporate headquarters are located at 1618 Station Street, Vancouver, BC, Canada, V6A 1B6.

The information required under subsections (1) to (15) of 37 C.F.R. § 1.740(a) is set forth in detail below. The original and four copies of this application are being submitted as requested. If any further information is required, please advise the undersigned.

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- (1) Complete identification of the approved product by appropriate chemical and generic name, physical structure or characteristics

The approved product is Boston Scientific's Paclitaxel-Eluting Coronary Stent System for improving luminal diameter for the treatment of *de novo* lesions ≤ 28 mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter. The FDA Classification Name is stent, coronary, drug-eluting under the FDA product code "NIQ." The stent is marketed as the "Paclitaxel-Eluting Coronary Stent System " or alternatively under the trademarked name "TAXUSTM Express^{2TM}." The System includes a tubular stent coated with paclitaxel and the proprietary polymeric carrier, TransluteTM (Figure 1 (A) and (B)). The stent is delivered by an Express^{2TM} Monorail Catheter (Figure 2) or Over-the-Wire Catheter (Figure 3).

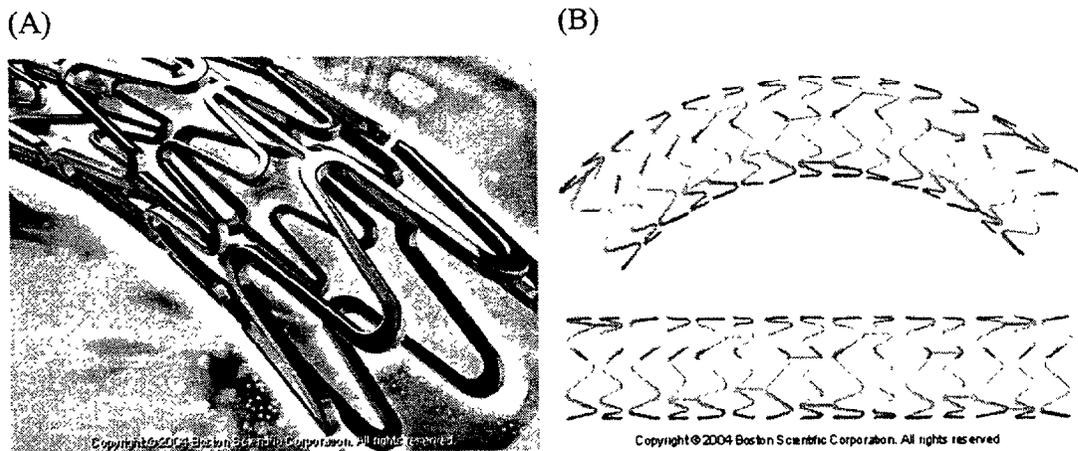


Figure 1. Paclitaxel-Eluting Coronary Stent: (A) close-up view, and (B) entire stent.¹

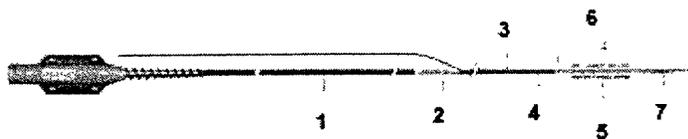


Figure 2. Express^{2TM} Monorail Catheter.^{1,2}

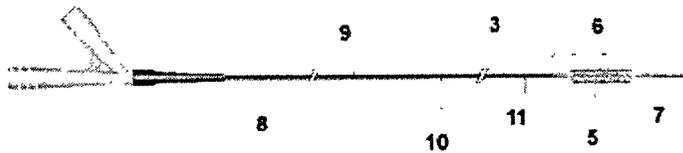


Figure 3. Express^{2TM} Over-the-Wire Catheter.^{1,2}

¹ See Appendix D. Photographs and data available at http://www.bostonscientific.com/med_specialty/deviceDetail.jhtml;jsessionid=1SPNLKZOYDIERLARAUSF EWAVAPCAIV0?task=tskBasicDevice.jhtml§ionId=4&relId=2,74,75,76&deviceId=11013&uniqueId=M PDB3622&clickType=HPpromo

² 1= 1.8/2.0F full length hypotube shaft; 2= tapered corewire; 3= Bioslider® hydrophilic coating; 4= PEBAX® distal shaft 2.7F; 5= DynaLEAP® balloon material; 6= Laser bonded technology; 7= Tapered Trak Tip™ 0.17" lesion entry profile; 8= Low profile (3.2F) proximal shaft; 9= Polyamide proximal shaft; 10= New variable stiffness Push Coil; 11= Transitionless distal shaft 2.7F.

- (2) A complete identification of the federal statute including the applicable provision of law under which the regulatory review occurred

The federal statute under which regulatory review took place for the TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System is Section 515 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360(e).

- (3) The date on which the product received permission for commercial marketing or use under the provision of law which the applicable regulatory review period occurred

The TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System was approved for marketing on March 4, 2004.

- (4) Not applicable

- (5) Statement that the present application is being submitted within the sixty day period permitted for submission and an identification of the date of the last day on which the application could be submitted

The present application for patent term extension is being submitted with the sixty day period permitted for submission pursuant to 37 C.F.R. §1.720(f). The last day for submission of the present application is May 3, 2004.

- (6) The complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue and the expiration date

The present application for extension is for U.S. Patent No. 5,716,981 (U.S. Patent

Application No. 08/478,203) issued February 10, 1998 and expiring February 10, 2015. The inventors are William L. Hunter; Lindsay S. Machan; and A. Larry Arsenault.

- (7) A copy of the entire patent for which extension is being sought, including the entire specification, claims and drawing

A copy of U.S. Patent No. 5,716,981 is attached as Appendix A.

- (8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent

There are no disclaimers, certificates of correction or reexamination certificates issued on U.S. Patent No. 5,716,981. A copy of the maintenance fee payment record retrieved from the USPTO PAIR database is provided as Appendix B.

- (9) Statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claims reads on the approved product

U.S. Patent No. 5,716,981 claims the Paclitaxel-Eluting Coronary Stent in the TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System approved on March 4, 2004. The Applicant asserts that at least claims 1, 6, 11, 12, 17, and 18 of the '981 patent read on the Paclitaxel-Eluting Coronary Stent and methods of using the Paclitaxel-Eluting Coronary Stent.

For example, claim 1 reads on the Paclitaxel-Eluting Coronary Stent as shown in Table 1. Claim 11 reads on the method of using the Paclitaxel-Eluting Coronary Stent as shown in

Table 2. The cited descriptions of the Paclitaxel-Eluting Coronary Stent are available at Boston Scientific's website.³

Table 1. Comparison of Claim 1 of U.S. Patent No. 5,716,981 element-by-element with the TAXUSTM Express^{2TM} Paclitaxel-Eluting Coronary Stent

Claim 1	Corresponding Feature of the TAXUS TM Express ^{2TM} Paclitaxel-Eluting Coronary Stent ¹
a stent for expanding the lumen of a body passageway, comprising	"The TAXUS Express ² Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of <i>de novo</i> lesions ≤ 8 mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter."
a generally tubular structure	The tubular structure is shown in Figs 1(A) & (B) in Section (1) above.
coated with a composition comprising paclitaxel, an analogue or derivative thereof, and	"The durable Translute Polymer protects the drug and maintains coating integrity during preparation, delivery, and stent expansion." "The polymer controls the release of paclitaxel, which may allow for consistent drug release and more uniform drug distribution."
a polymeric carrier.	"The TAXUS stent uses Translute TM Polymer, a proprietary polymer carrier technology, to control drug release."

³ description available at :
http://www.bostonscientific.com/common_templates/singleDetailList.jhtml?task=tskDeviceStatement.jhtml§ionId=4&relId=2,74,75,86,87&deviceId=11013

Table 2. Comparison of Claim 11 of U.S. Patent No. 5,716,981 element-by-element with the TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent

Claim 11	Corresponding Feature of the TAXUS™ Express ² ™ Paclitaxel-Eluting Coronary Stent ¹
a method for expanding the lumen of a body passageway, comprising	"The TAXUS Express ² Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of <i>de novo</i> lesions ≤ 28 mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter."
inserting a stent into the passageway, the stent having a generally tubular structure	The tubular structure is shown in Figs 1(A) & (B) in Section (1) above.
coated with a composition comprising paclitaxel, an analogue or derivative thereof, and	"The durable Translute Polymer protects the drug and maintains coating integrity during preparation, delivery, and stent expansion." "The polymer controls the release of paclitaxel, which may allow for consistent drug release and more uniform drug distribution."
a polymeric carrier,	"The TAXUS stent uses Translute™ Polymer, a proprietary polymer carrier technology, to control drug release."
such that said passageway is expanded.	"The durable Translute Polymer protects the drug and maintains coating integrity during preparation, delivery, and stent expansion."

(10) The relevant dates and information pursuant to 35 U.S.C. §156(g) to enable the Secretary of Health and Human Services to determine the applicable review period, as set forth in 37 C.F.R. § 1.740(a)(10)(v):

- A) The effective date of the investigational device exemption (IDE)
 Conditional approval of the IDE (No. G010274) for the TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System was provided on Oct. 25, 2001.
- B) The date on which the application for product approval under Section 515 of the

Federal Food Drug and Cosmetic Act was initially submitted and the number of the application.

- 1) A Pre-market Approval application (PMA) for the TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System was submitted on Feb. 25, 2003.
- 2) The PMA number is P030025.

C) The date on which the application was approved.

The TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System PMA was approved on March 4, 2004.

(11) Brief Description of the significant activities undertaken by the marketing applicant (Boston Scientific) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities

A chronological list of the events is provided as Appendix C.

- (12) Statement that in the opinion of the applicant the patent is eligible for extension and a statement as to the length of extension claimed, including how the extension was calculated

-Eligibility

The applicant respectfully asserts that U.S. Patent No. 5,716,981 is eligible for extension. The applicant has demonstrated that at least one claim of U.S. Patent No. 5,716,981 reads on the approved device (TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent) and that this application for extension is being timely filed.

The applicant is the owner of the '981 patent. The '981 patent is a division of U.S. Patent Application Ser. No. 08/417,160, filed Apr. 3, 1995, now abandoned, which is a continuation-in-part of U.S. Patent Application Ser. No. 08/094,536, filed Jul. 19, 1993, now abandoned. Hunter et. al. assigned their entire right, title and interest in U.S. Patent Application Ser. No. 08/094,536 together with all divisional applications, continuations and continuations-in-part to Angiogenesis Technologies, Inc. The assignments, recorded in the United States Patent and Trademark Office (USPTO) on October 17, 1994, are as follows: (i) assignment from William L. Hunter and Lindsay S. Machan to Angiogenesis Technologies Inc., executed July 7, 1994, recorded on Reel 7175, Frame 454-455; (2) assignment from A. Larry Arsenault to McMaster University, executed July 8, 1994, recorded on Reel 7186, Frames 141-142; and (3) assignment from McMaster University to Angiogenesis Technologies Inc., executed July 11, 1994, recorded on Reel 7186, Frames 136-137.

Hunter et. al. assigned their entire right, title and interest in continuation-in-part U.S. Patent Application No. 08/417,160 together with all divisional applications, continuations (including Ser. No. 08/478,203) and continuations-in-part to Angiogenesis Technologies, Inc.

The assignments, recorded in the United States Patent and Trademark Office (USPTO) on June 12, 1995, are as follows (i) assignment from William L. Hunter and Lindsay S. Machan to Angiogenesis Technologies Inc., executed May 3, 1995 and May 8, 1995, respectively, recorded on Reel 7503, Frame 0085; (2) assignment from A. Larry Arsenault to McMaster University, executed May 29, 1995, recorded on Reel 7519, Frame 0361; and (3) assignment from McMaster University to Angiogenesis Technologies Inc., executed May 29, 1995, recorded on Reel 7519, Frame 0358.

Angiogenesis Technologies, Inc. changed its name to Angiotech Pharmaceuticals, Inc. on September 6, 1996.

The marketing applicant is Boston Scientific Corp. ("Boston Scientific"). Boston Scientific is the co-exclusive licensee of Angiotech under the '981 patent with exclusive rights for purposes of obtaining marketing approval for Boston Scientific's Paclitaxel-Eluting Coronary Stent System.

-Calculation of extension period

The applicant respectfully submits that the date a clinical investigation on humans involving the device was begun according to 37 CFR § 1.777 (c)(1) was October 12, 2000, the initiation date of the clinical trial (TAXUS I) in Germany for the Paclitaxel-Eluting Coronary Stent System (see Appendix C). The calculation of the patent term extensions based on this date is presented in Table 3.⁴ Other pertinent dates used in the calculations are the filing date of first module of PMA, February 25, 2003; PMA approval date, March 4, 2004; patent issuance

⁴ This is the appropriate date because it is prior to the conditional approval of the IDE for the Paclitaxel-Eluting Coronary Stent System, October 25, 2001. If the testing period began on the IDE

date, February 10, 1998; and original patent expiration date, February 10, 2015.

The applicant respectfully submits that U.S. Patent No. 5,716,981 is eligible for a 807 day extension as calculated pursuant to 37 CFR §1.777 based on the first human clinical trial date.

approval date, the extended expiration date would be October 20, 2016.

Table 3.	
CALCULATION OF EXTENSION PERIOD	
Testing period under 37 CFR § 1.777 (c)(1)	
Start date	October 12, 2000
End date	February 24, 2003
Total Days*	866 days
Review period under 37 CFR § 1.777 (c)(2)	
Start date	February 25, 2003
End date	March 4, 2004
Total Days (including start date)	374 days
Sum of Testing and Review periods	1240 days
Subtraction under 37 CFR § 1.777 (d)(1)	
(i) on or before patent issued	0
(ii) without due diligence	0
one-half of the test period adjusted for (d)(1)(i) and (ii)	433 days
Maximum extension	807 days
Calculation under 37 CFR § 1.777 (d)(2)	April 27, 2017
Calculation under 37 CFR § 1.777 (d)(3)	March 4, 2018
Calculation under 37 CFR § 1.777 (d)(4)	April 27, 2017
eligible extension	807 days
Calculation under 37 CFR § 1.777 (d)(5)	February 10, 2020
extended expiration date	April 27, 2017

- (13) Statement that the applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information

which is material to the determination of entitlement to the extension

The applicant acknowledges a duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

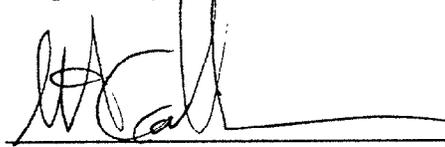
(14) The prescribed fee for receiving and acting upon the application for extension.

A check (No. P602912) in the amount of \$1060 for payment of the patent term extension application fee pursuant to 37 C.F.R. §1.20 (j)(1) is attached with this application.

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed.

Inquiries and correspondence should be directed to the undersigned.

Respectfully submitted,



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Date: May 3, 2004

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