UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

ANGIOTECH PHARMACEUTICALS INC., **Plaintiff,**	
v.	**CIVIL ACTION NO. 1:15-cv-1673 TSE/TCB**
MICHELLE K. LEE, **Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and** **DREW HIRSHFELD,** **Commissioner for Patents,** **Defendants.**	

COMPLAINT

Plaintiff Angiotech Pharmaceuticals Inc. ("Angiotech") brings this civil action against Michelle K. Lee, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and Drew Hirshfeld, Commissioner for Patents ("Defendants") in their official capacities and alleges as follows:

1. This is an action for a declaratory judgment that Defendants' Final Determination Denying Patent Term Extension Application Under 35 U.S.C. § 156 for U.S. Patent No. 5,811,447 ("Final Decision") is contrary to law.

2. A copy of U.S. Patent No. 5,811,447 ("the '447 Patent") is attached as Exhibit A.

3. A copy of Defendants' initial Denial of Patent Term Extension Application Under 35 U.S.C. § 156 for U.S. Patent No. 5,811,447 ("Initial Decision"), dated October 16, 2015, with its exhibits incorporated by reference herein, is attached as Exhibit B.

4. A copy of Angiotech's Request for Reconsideration of the Initial Decision, incorporated by reference herein, is attached as Exhibit C.

5. A copy of the Final Decision, dated December 11, 2015, is attached as Exhibit D.

6. A copy of the Food and Drug Administration's Summary of Safety and Effectiveness Data for the ZILVER PTX Drug-Eluting Peripheral Stent is attached as Exhibit E.

7. A copy of the Food and Drug Administration's News Release announcing the approval of the ZILVER PTX Drug-Eluting Peripheral Stent is attached as Exhibit F.

8. A copy of the Food and Drug Administration's Executive Summary for the first-of-its-kind ZILVER PTX Drug-Eluting Peripheral Stent is attached as Exhibit G.

9. A copy of the Food and Drug Administration's Guidance for Industry: Coronary Drug-Eluting Stents – Nonclinical and Clinical Studies is attached as Exhibit H.

JURISDICTION AND VENUE

10. This action arises under 35 U.S.C. § 156 and the Administrative Procedure Act, 5 U.S.C. § 701, *et seq.*

11. This Court has jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 1361, and 2201 and 5 U.S.C. §§ 701-06.

12. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) and 35 U.S.C. § 1(b).

THE PARTIES

13. Plaintiff Angiotech Pharmaceuticals, Inc. is a Canadian corporation located in Vancouver, British Columbia. Angiotech is an exclusive licensee of U.S. Patent No. 5,811,447 with standing to bring this action.

14. Defendant Michelle K. Lee is named in her official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("PTO"). In this capacity, Defendant Lee is responsible for performing all duties required by law with respect to the granting and issuing of patents and is designated as the official with responsibility for decisions granting patent term extension under 35 U.S.C. § 156.

15. Defendant Drew Hirshfeld is named in his official capacity as Commissioner for Patents. The Commissioner for Patents is the chief operating officer responsible for the management and direction of all aspects of the activities of the PTO that affect the administration of patent operations. The Initial Decision and Final Decision denying Plaintiff's application for patent term extension were issued in the name of the Commissioner for Patents.

THE STATUTORY SCHEME

16. Under the Patent Act, 35 U.S.C. § 100, *et seq.* (the "Patent Act"), a United States patent expires after a certain term, generally 20 years from the date on which the patent application was filed. *See* 35 U.S.C. § 154(a)(2).

17. For patents claiming certain drug and medical devices, some or all of the patent term may be consumed by the rigorous and often lengthy Food and Drug Administration ("FDA") approval process for new products ("approved products") using that patent. The regulatory approval process often requires years to complete, greatly diminishing the commercial rights provided by the patent.

18. Recognizing this problem and the prejudice to patent owners caused by the administrative delay, Congress enacted Title II of The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch–Waxman Act" or "Act").

19. Under the Act, the term of a patent covering an approved product may be extended up to five years, and the length of the extension depends on how long the product was under review.

20. The FDA-approval process is divided into a testing phase followed by an approval phase. The approval phase begins on the date the application was initially submitted and ends on the date the FDA application was approved. Subject to specified caps and adjustments, the lengths of these phases determine the length of patent term extension.

21. The patent holder or its agent must submit an application for patent term extension to the PTO within the sixty-day period beginning on the date the product received FDA approval for commercial marketing or use.

22. If a patent relates to an approved product, responsibility for reviewing a patent term extension application is shared by the Director of the PTO and the Secretary of Health and Human Services, who has delegated her authority to the FDA.

23. The PTO is responsible for determining whether a patent is eligible for patent term extension under Section 156(a) of the Patent Act. The FDA, in turn, is responsible for determining the length of the applicable regulatory review period, meaning that it must determine the date the application was initially submitted to the FDA and the date the application was approved. A 1987 Memorandum of Understanding between the PTO and the FDA sets forth the procedure for their joint review of applications.

24. The Hatch-Waxman Act amended both the Food, Drug, and Cosmetic Act ("FDCA") and the Patent Act. The Hatch-Waxman Act is codified at 21 U.S.C. § 355 and 35 U.S.C. § 156, respectively. Together, Section 355 of the FDCA and Section 156 of the Patent

Act were intended to protect the intellectual property rights of manufacturers like Angiotech whose products are subject to the lengthy FDA approval process.

25. In relevant part, Section 355 of the FDCA provides that "[t]he applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which *claims a method of using* such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) (emphasis added).

26. Section 156 of the Patent Act provides that "[t]he term of a patent which *claims a product, a method of using a product, or a method of manufacturing a product* shall be extended in accordance with this section from the original expiration date of the patent" if "the product has been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156(a) (emphasis added).

27. Thus, Section 355 of the FDCA and Section 156 of the Patent Act provide a remedy to patent owners: an extended patent term to offset the loss of effective patent life during the period of regulatory review of a new approved product. By following this statutory scheme and granting patent term extension, the PTO fulfills Congress' intent to protect the intellectual property rights of drug manufacturers who seek FDA approval.

THE '447 PATENT RECITES A METHOD FOR BIOLOGICAL STENTING THROUGH ADMINISTRATION OF A DRUG

28. On September 22, 1998, the PTO issued the '447 Patent. The '447 Patent claims a method of using the ZILVER® PTX Drug Eluting Peripheral Stent (the "ZILVER PTX"). Claim 12 of the '447 Patent recites "[a] method for biologically stenting a mammalian blood vessel, which method comprises administering to the blood vessel of a mammal a cytoskeletal

inhibitor in an amount and for a period of time effective to inhibit the contraction or migration of the vascular smooth muscle cells."

29. The method recited in Claim 12 requires: (a) "administering to the blood vessel of a mammal a cytoskeletal inhibitor"; (b) "in an amount"; (c) "and for a period of time"; (d) "effective to inhibit the contraction or migration of the vascular smooth muscle cells." The '447 Patent's written description encompasses the local administration of drugs to the blood vessel wall. *See, e.g.*, col. 2, lines 19-22, 56-59; col. 36, lines 43-45, 52-54; col. 54, lines 41-46. The '447 Patent describes a sustained release of the drug by releasing "a therapeutic agent ... for a time period from about 3 to 21 days" or longer. *See* col. 9, lines 66 – col. 10, line 3; col. 3, lines 59-62.

30. The '447 Patent's written description also contemplates that the invention claimed in Claim 12 encompasses the local and sustained administration of the cytoskeletal inhibitor in conjunction with a physical angioplasty procedure that can include the placement of a physical stent. *See, e.g.*, col. 30, lines 39-43; col. 36, lines 43-45; col. 69, lines 22-24.

31. Claim 12 necessarily includes the method of "biological stenting" whereby a physical stent coated with a drug "administer[s] to the blood vessel of a mammal a cytoskeletal inhibitor in an amount and for a period of time effective to inhibit the contraction or migration of the vascular smooth muscle cells."

32. Accordingly, Claim 12 necessarily includes the drug component of ZILVER PTX.

IN APPROVING THE ZILVER PTX, THE FDA EXAMINED ITS METHOD FOR BIOLOGICAL STENTING THROUGH ADMINISTRATION OF A DRUG

33. In April 2009, Pre-Market Approval ("PMA") application No. P100022 was filed with the FDA for the ZILVER PTX.

34. The ZILVER PTX is an implantable blood-contacting device used for improving luminal diameter for the treatment of de novo or restenotic symptomatic lesions in vascular disease of arteries. The ZILVER PTX provides, among other things, continued biological stenting through locally directed, sustained release of its paclitaxel coating to maintain the dilation of the blood vessel wall achieved through angioplasty.

35. The ZILVER PTX – as evidenced by its full name "ZILVER® PTX Drug Eluting Peripheral Stent" – has both biological and physical stenting characteristics. Indeed, during regulatory approval, the ZILVER PTX was compared to its counterpart, the ZILVER Vascular Stent (the "ZILVER Stent"), which is not coated with paclitaxel and provides only physical stenting. Because of its biological stenting characteristics, the ZILVER PTX is significantly more effective in maintaining primary patency and reducing restenosis than the ZILVER Stent.

36. The biological stenting characteristics are a function of the product's drug ingredient, paclitaxel. Because the product has both a drug component (the paclitaxel coating) and a device component (the physical stent), it is a combination product within the meaning of 21 U.S.C. § 353(g). *See* Exhibit H, FDA, Guidance for Industry: Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies; Draft Guidance 2 (March 2008). A combination product that contains a drug component and a device component must be reviewed and approved within FDA based on its primary mode of action. Where the product's primary mode of action is that of a device, "the agency center charged with premarket review of devices shall have primary jurisdiction." 21 U.S.C. § 353(g). It is FDA's position that, "Coronary DESs (drug-eluting stents), where the device component provides the primary mode of action, are regulated as Class III devices that require the submission and approval of a premarket approval (PMA)" [under Section 515 of the FDCA]. *See* Exhibit H at 3.

37. Thus, although the ZILVER PTX is a combination product containing a drug component, it is regulated as a Class III device under the FDCA and was approved in a PMA. The "Device Description" for the product makes this clear – confirming that the FDA understood the ZILVER PTX to be a combination product and examined the biological characteristics of the ZILVER PTX. *See* Exhibit E, Part V ("Device Description") ("Drug Component Description"); Exhibit F (describing the ZILVER PTX as a "stent [ ] coated on its outer surface with the drug paclitaxel, a drug that helps prevent recurrent narrowing of arteries (restenosis)."); Exhibit G, Part 2 ("Device Description") ("Zilver PTX stents are coated with paclitaxel API (active pharmaceutical ingredient) using a proprietary process. No excipients, polymers, carriers, binding agents, other materials, or other device modifications are involved. Paclitaxel is the same API used in some currently approved coronary drug-eluting stents. The chemical description of paclitaxel is provided in Figure 3.").

38. On November 14, 2012, the FDA approved the PMA, thereby granting permission to commercially market or use the ZILVER PTX.

39. The '447 Patent claims a method of using the ZILVER PTX because the ZILVER PTX is a method of biological stenting comprising administering a therapeutic agent to maintain the dilation of the blood vessel wall.

ANGIOTECH'S APPLICATION FOR PATENT TERM EXTENSION

40. On December 7, 2012, Angiotech filed a patent term extension application under 35 U.S.C. § 156(d)(1) to extend the term of the '447 Patent based on FDA regulatory review of the ZILVER PTX. Angiotech supplemented its application on February 28, 2013.

41. On March 13, 2015, the PTO requested assistance from the FDA in determining the eligibility of the '447 Patent for patent term extension based on the regulatory review period of the ZILVER PTX.

42. On March 23, 2015, the PTO sent Angiotech a Requirement for Information seeking information about (a) how the '447 Patent claims a method of using the medical device subject to regulatory review under the FDCA, 21 U.S.C. § 360e, and (b) whether the amount of paclitaxel present in the ZILVER PTX is administered "in an amount and for a period of time effective to inhibit the contraction or migration of vascular muscle cells" to achieve the recited "method of biological stenting."

43. In response to the PTO's requested assistance, on May 11, 2015, the FDA confirmed in writing to the PTO that the ZILVER PTX had been subject to regulatory review under 21 U.S.C. § 360e and that approval of PMA No. P100022 represented the first permitted commercial marketing or use of the product subject to regulatory review. Thus, the FDA's May 11, 2015 written communication to the PTO explained that the approval of the ZILVER PTX formed the basis for patent term extension under 35 U.S.C. § 156(a).

44. In response to the PTO's Requirement for Information, on June 19, 2015, Angiotech filed a response explaining that at least Claim 12 of the '447 Patent claims a method of using the approved product. Because the PTO had not yet reached a decision and the '447 patent was set to expire on September 22, 2015, on June 19, 2015, Angiotech also filed a request for interim patent term extension under 35 U.S.C. § 156(e)(2).

45. On September 17, 2015, the PTO granted an interim patent term extension for three months from the original expiration date of the '447 Patent, or until December 22, 2015.

46. On October 16, 2015, the PTO issued its Initial Decision denying Angiotech's patent term extension application. On November 16, 2015, Angiotech submitted a Request for Reconsideration of the PTO's Initial Decision, a request for a second interim extension, and a request that the '447 Patent's term be extended. On December 11, 2015, the PTO issued its Final Decision denying Angiotech's request for reconsideration, interim extension, and patent term extension.

THE PTO'S ARBITRARY AND CAPRICIOUS DECISION

47. In essence, the PTO determined that the ZILVER PTX was a device, that the '447 Patent instead concerned a method of using a drug, and thus that the delay caused by the FDA approval process of the ZILVER PTX did not warrant extension of the '447 Patent term.

48. The PTO determined that, because the ZILVER PTX is regulated as a device and was approved in a PMA under Section 515 of the FDCA, the '447 Patent did not claim the approved product since the patent did not claim the device component of the approved product. In relevant part, the PTO's Initial Decision provides:

> In this case, the ZILVER® PTX Drug Eluting Peripheral Stent was reviewed and approved under section 515 of the FFDCA and, as such, is a medical device. Clearly Applicant agrees that the approved product is a medical device since the PTE application described the approved product, the ZILVER® PTX Drug Eluting Peripheral Stent, as "a flexible, slotted tube made of nitinol, i.e., nickel titanium, and *coated with paclitaxel*."
>
> For the '447 patent to claim a method of using the approved product, the method must claim using the ZILVER® PTX Drug Eluting Peripheral Stent. In other words, the claimed method must recite one or more structural elements of the ZILVER® PTX Drug Eluting Peripheral Stent, which is described by applicant as, "a flexible, slotted tube made of nitinol, i.e., nickel titanium, and *coated with paclitaxel*."

Exhibit B at 3-4 (emphasis added). This determination misconstrues the identity of the "approved product" that is entitled to patent term extension under Section 156 of the Patent Act.

49. In the case of a product approved in a PMA under Section 515 of the FDCA, the approved product is the product defined in the PMA. The approved product identified in the PMA for ZILVER PTX is a product that contains a physical stent component and a drug component identified as paclitaxel. While the PTO did acknowledge that the paclitaxel coating is a component part of the approved ZILVER PTX product, the PTO deemed the approved product not to be the product approved in the PMA but rather the component of the product with the device mode of action.

50. The PTO's application of Section 156 of the Patent Act is contrary to its plain meaning. The stent component of ZILVER PTX is not itself the approved product and was not the approved product. The approved product is the product that the PMA describes as being approved in the PMA. The FDA's description of the product in the PMA is administratively determinative and the PTO has no authority to redefine the product approved by the FDA in the PMA.

51. With its analysis, the PTO disregarded (i) the FDA's determination that the ZILVER PTX is a combination product that combines drug and device components (*i.e.*, biological stenting and physical stenting), (ii) the plain language of the Hatch-Waxman Act as well as FDA's interpretation of the relevant language found at both Section 355 of the FDCA and Section 156 of the Patent Act, and (iii) the plain language of the '447 Patent which claims a method of biological stenting using the ZILVER PTX.

The PTO Ignored The FDA's Evaluation Of The ZILVER PTX As A Combination Product

52. Under Section 156 of the Patent Act, the term of a patent may be extended "if the product has been subject to a regulatory review period before its commercial marketing or use." 35 USC § 156(a)(4). The PTO acknowledges that the ZILVER PTX has been subject to a

regulatory review period. However, in denying patent term extension, the PTO narrowly and unlawfully interpreted "the product" reviewed and approved by the FDA to include only the ZILVER Stent. This is not what the FDA reviewed and approved. Instead, "the product" reviewed and approved by the FDA was the ZILVER PTX, a new product that differs from the physical ZILVER Stent because of the drug-eluting paclitaxel drug coating.

53. Importantly, the uncoated ZILVER Stent had been approved by the FDA in June 2006. The FDA needed to conduct separate review and approval for the ZILVER PTX because it is different – it includes a drug component. If there had been no difference between the ZILVER Stent and the ZILVER PTX or if the FDA had considered the paclitaxel coating to be immaterial, the FDA would not have conducted an entirely separate review and approval of the ZILVER PTX. The FDA recognized that there is a difference with the ZILVER PTX – the drug coating and its effect on blood vessels. This is not only a structural feature and a function of the ZILVER PTX, but the very structure and function that necessitated approval separately and apart from the uncoated ZILVER Stent.

54. The FDA recognizes that a combination product, like the ZILVER PTX, includes both a device component (the physical stent) and a drug component (the paclitaxel coating). When approving the PMA for ZILVER PTX, the FDA evaluated the importance, characteristics and performance of the paclitaxel coating. In its "Jurisdictional Update: Drug-Eluting Cardiovascular Stents," the FDA explains "cardiovascular stents [are] coated with a drug component intended to maintain vessel patency by minimizing the occurrence of restenosis following stent implantation." *See* Exhibit D at Exhibit 1. The FDA further explains "the uncoated stent functions to physically maintain vessel lumen patency, while the drug component has played a secondary role in preventing restenosis, augmenting the safety and/or effectiveness

of the uncoated stent." *Id.* This is precisely the biological stenting provided by the ZILVER PTX and claimed in the '447 patent. Thus, while the FDA assigns administrative responsibility for premarket review and approval based on its determination about "the primary mode of action for the combination product," the FDA recognizes a combination product's drug component as being part of the approved product.

55. The FDA recognized the ZILVER PTX as a combination product. In denying patent term extension, however, the PTO wrongly asserted that because the ZILVER PTX was reviewed by the FDA as a device, it incorrectly viewed the ZILVER PTX exclusively as a device, and ignored the biological component and the recognized function of the paclitaxel coating. According to the PTO's reasoning, where a product is administratively classified by the FDA as primarily a device, a patent term extension can only be obtained for a patent claiming the device aspect of the system; yet, the FDA did not ignore the drug component of a combination product like the ZILVER PTX and instead recognized and evaluated the drug component's role in "minimizing the occurrence of restenosis following stent implantation" and "augmenting the safety and/or effectiveness of the uncoated stent."

56. By failing to acknowledge that the FDA evaluated and approved ZILVER PTX as a product consisting in part of a drug component, the PTO's decision was arbitrary and capricious and contrary to law.

The PTO Has Misconstrued The Hatch-Waxman Act By Largely Excluding Combination Products And Patents That Claim Them From The Act's Protections

57. Consistent with their interplay as part of the same statutory scheme, Section 355 of the FDCA and Section 156 of the Patent Act contain very similar language. Referring to the application, Section 355 of the FDCA addresses "any patent which ... *claims a method of using a drug.*" 21 U.S.C. § 355(b)(1) (emphasis added). Referring to the right to patent term extension

following the application, Section 156 of the Patent Act addresses "a patent which *claims ... a method of using a product.*" 35 U.S.C. § 156(a) (emphasis added).

58. Here, the ZILVER PTX provides a method of using a drug for purposes of Section 355 of the FDCA. Likewise, the '447 Patent claimed a method for using the ZILVER PTX for purposes of Section 156 of the Patent Act. Thus, the '447 Patent is entitled to patent term extension. In denying patent term extension, however, the PTO stated that "the claimed method must recite one or more structural elements" of the approved product. The PTO's assertion is at odds with the plain language of Section 156 of the Patent Act. All that is required is that the patent claim a method of using the product, and the '447 patent does claim a method of using the ZILVER PTX.

59. The PTO is interpreting the similar language found in Section 355 of the FDCA and Section 156 of the Patent Act differently than the FDA. Consistent with the "any patent which ... *claims a method of using a drug*" language in Section 355 of the FDCA, the FDA approves combination products based on evaluation of a product's device and drug components. By contrast, when applying the similar "a patent which *claims ... a method of using a product*" language in Section 156 of the Patent Act, the PTO instead determined that a patent term extension is not warranted if the product was primarily reviewed as a device and the patent primarily concerns a drug.

60. In other words, the PTO has wrongly determined to limit patent term extension to only the following situations: where the product is primarily a device and the patent primarily concerns that device; or where the product is primarily a drug and the patent primarily concerns that drug. Thus, unlike the FDA, the PTO wants to put products and patents in discrete buckets as either about a device or about a drug, and ignore the secondary function of an approved

combination product. However, the Hatch-Waxman Act provides the same protections regardless of whether a product or patent concern a device, a drug, or a combination of both.

61. The PTO's interpretation of Section 355 of the FDCA and Section 156 of the Patent Act should be afforded little, if any, deference. As a matter of law, the FDA and the PTO are required to interpret the similar language of Section 355 of the FDCA and Section 156 of the Patent Act in a similar manner. *See, e.g., Northcross v. Bd. of Ed. of Memphis City Sch.*, 412 U.S. 427, 428 (1973) (per curiam) ("The similarity of language in § 718 and § 204(b) is, of course, a strong indication that the two statutes should be interpreted pari passu."); *In re Crescent City Estates, LLC*, 588 F.3d 822, 829 (4th Cir. 2009) ("[S]imilar language is a strong indication that they are to be interpreted alike."); 2B George Sutherland, *Statutes and Statutory Construction* § 53.03, at 233 (5th ed. 1992) ("[B]y transposing the clear intent expressed in one or several statutes to a similar statute of doubtful meaning, the court . . . is able to give effect to the probable intent of the legislature . . .").

62. Moreover, interpretations by multiple agencies of the same statute are not entitled to *Chevron* deference. *See, e.g., Rapaport v. United States Department of Treasury, Office of Thrift Supervision*, 59 F.3d 212, 216 (D.C. Cir. 1995) (no deference is owed to a single agency's interpretation of a statute where multiple agencies are charged with its administration); *1185 Ave of Americas Associates v. Resolution Trust Corp.*, 22 F.3d 494, 497 (2d Cir. 1994) ("Where Congress has entrusted more than one federal agency with the administration of a statute a reviewing court does not owe as much deference as it might otherwise give if the interpretation were made by a single agency similarly entrusted with powers of interpretation.").

63. The PTO's decision is in conflict with the Hatch-Waxman Act and its statutory scheme. With the Hatch-Waxman Act, Congress sought to provide the same relief to similar

patent owners for similar administrative delays using similar language in statutes administered by agencies under the same statutory scheme. The FDA and PTO were charged with jointly implementing the Hatch-Waxman Act and thus fulfilling Congress' intent to extend patent terms to offset the loss of effective patent life during regulatory review.

64. The FDA understands that, when faced with a combination product, it must evaluate both the device and drug components of that product. By contrast, the PTO's decision denying patent term extension rests on the false notion that the drug component was not evaluated or approved at all. The PTO's decision frustrates the very purpose of Section 156 – to provide a remedy to patent owners, an extended patent term, to offset the loss of effective patent life during the period of regulatory review of a new approved product.

65. By failing to recognize that the Hatch-Waxman Act applies with equal force to products and patents that concern both devices and drugs, the PTO's decision was arbitrary and capricious.

The PTO Overlooked The Drug Component Of The ZILVER PTX And The Plain Language Of The '447 Patent Demonstrating That It Claims A Method Of Using That Product

66. Applying Section 156 of the Patent Act, patent term extension should have been granted because the patent recites a method of using the approved product. In denying patent term extension, however, the PTO effectively viewed the ZILVER PTX as being no different than the uncoated ZILVER Stent. Because the PTO determined that the '447 Patent did not recite a method of using a physical stent, the PTO thus determined that the '447 Patent did not recite a method of using the approved product. With this analysis, the PTO ignored the drug component of the combination product and misconstrued the plain language of the '447 Patent.

67. The ZILVER PTX is a combination product and was not simply the ZILVER Stent. The FDA had previously approved the uncoated ZILVER Stent. The ZILVER PTX

needed separate FDA approval because of its drug component. The ZILVER PTX provides a "method for biologically stenting a mammalian blood vessel"; it "administer[s] to the blood vessel of a mammal a cytoskeletal inhibitor"; and administration of the cytoskeletal inhibitor (paclitaxel) is "in an amount and for a period of time effective to inhibit the contraction or migration of the vascular smooth muscle cells." This is exactly what is described and claimed in the '447 Patent.

68. At Claim 12, the '447 Patent recites "[a] method for biologically stenting a mammalian blood vessel, which method comprises administering to the blood vessel of a mammal a cytoskeletal inhibitor in an amount and for a period of time effective to inhibit the contraction or migration of the vascular smooth muscle cells." Claim 12 thus specifies a method identifying where to administer a drug ("administering to the blood vessel of a mammal") and the result of that administration ("to inhibit the contraction or migration of the vascular smooth muscle cells"). *See* col. 1, lines 21-24 (explaining that the result is "dilation and fixation of the vascular lumen (biological stenting effect)"). Accordingly, Claim 12 of the '447 Patent recites "a method of using a product," namely the ZILVER PTX, to administer the substance (the paclitaxel coating, a cytoskeletal inhibitor) to the target vascular smooth muscle cells for an extended duration.

69. In denying patent term extension, the PTO ignored the drug-delivery features of the ZILVER PTX, asserting that "patency is achieved whether or not a cytoskeletal inhibitor (paclitaxel) is included in the stent system" and stating that "in the '447 Patent, patency is achieved by the pharmaceutical agent alone (*i.e.*, 'biological stenting[']), rather than by a physical stent." This overlooks the plain language of the '447 Patent, which "comprises" a method of "administering . . . a cytoskeletal inhibitor," "comprising" indicates that other steps

may be included. There is also nothing that precludes achieving biological stenting in conjunction with physical stenting. Indeed, the ZILVER PTX claimed by the '447 Patent substantially improved on the uncoated ZILVER Stent by providing both physical *and* biological stenting.

70. As a matter of law, Section 156 of the Patent Act does not require that the patent claim every use of an approved product, only "a" use of the product. Here, the ZILVER PTX has two uses – (i) physical stenting to expand a blood vessel and (ii) biological stenting to minimize restenosis. A claim directed to either use provides sufficient basis for patent term extension. In its analysis of the ZILVER PTX, however, the PTO arbitrarily chose to focus on only one of those uses: physical stenting. By ignoring that the ZILVER PTX provides biological stenting to minimize restenosis, the PTO was arbitrary and capricious.

71. In denying patent term extension, the PTO also asserted that Claim 12 reads on products or commercial embodiments in addition to the ZILVER PTX. However, this is not a valid basis for denying patent term extension. On many occasions in the past, the PTO has granted patent term extensions where numerous product configurations satisfied the elements of method claims claiming FDA-approved products. Indeed it would be unusual for a patent claim to only be directed to a single product, as such a narrow claim would be easy for competitors to avoid. By asserting a ground to deny patent term extension to Angiotech that is inconsistent with the PTO's decisions in the past, the PTO was arbitrary and capricious.

72. By way of example, the PTO granted patent term extension for U.S. Patent No. 5,041,126 (the '126 patent") on the basis of the regulatory review period for the Cook GRII™ Coronary Stent. Claim 1 of the '126 patent recites "[a] method for inserting a stent which comprises: (a) engaging a stent, having a longitudinal length, around a balloon catheter, (b)

locating the catheter and stent within a passageway, and (c) inelastically expanding the stent, while maintaining the longitudinal length of the stent, by inflating the balloon catheter within the stent to inelastically deform the stent until the stent engages the passageway." In the application for patent term extension, the applicant asserted that "[c]laim 1 [of the '126 patent] reads on the method for use of the Cook GRII™ Coronary Stent." There are a nearly infinite number of stent configurations that could meet the requirements of claim 1 of the '126 patent, far more than just the FDA-approved Cook GRII™ Coronary Stent. Yet the PTO granted patent term extension for the '126 patent.

73. By ignoring the drug component of the combination product and the plain language of the '447 Patent demonstrating that it claims a method of using the approved combination product, the PTO was arbitrary and capricious.

COUNT I

74. Angiotech repeats and incorporates by reference the allegations set forth above.

75. The decision of Defendants to deny Angiotech's application for patent term extension for the '447 Patent was unlawful and violated 35 U.S.C. § 156.

76. Defendant's construction of 35 U.S.C. § 156 is contrary to law and frustrates the purpose of the Drug Price Competition and Patent Term Restoration Act.

COUNT II

77. Angiotech repeats and incorporates by reference the allegations set forth above.

78. The decision of Defendants to deny Angiotech's application for patent term extension for the '447 Patent was arbitrary and capricious and should be set aside under the Administrative Procedure Act, 5 U.S.C. §§ 701-06.

RELIEF REQUESTED

WHEREFORE, Angiotech prays that the Court:

1. Issue a declaratory judgment that Defendants acted unlawfully in denying Angiotech's application for patent term extension;

2. Issue a declaratory judgment that Angiotech's application for patent term extension satisfies the requirements of 35 U.S.C. § 156;

3. Issue an order setting aside the Defendants' denial of Angiotech's application for patent term extension;

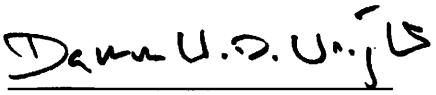
4. Issue an order compelling Defendants to comply with the requirements of 35 U.S.C. § 156 and to take action to extend the term of the '447 Patent in accordance with the provisions of 35 U.S.C. § 156;

5. Award Angiotech its costs and reasonable attorney's fees; and

6. Grant other and further relief as may be just and proper.

December 21, 2015

Respectfully submitted,



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