UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

ANGIOTECH PHARMACEUTICALS INC.,	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NO. 1:15-cv-01673-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.	)	

PLAINTIFF ANGIOTECH PHARMACEUTICALS INC.'S MEMORANDUM IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

Plaintiff Angiotech Pharmaceuticals Inc. ("Angiotech") requests summary judgment 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 (together, "the PTO") on the ground that the PTO's Final Determination Denying Patent Term Extension Application Under 35 U.S.C. § 156 ("Final Decision") for U.S. Patent No. 5,811,447 ("the '447 Patent") violated the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or "Act") and was arbitrary, capricious, and contrary to law in violation of the Administrative Procedure Act ("APA").[1]

[1] The PTO's Answer included several defenses that are more typically raised by Fed. R. Civ. P. 12(b) motion (lack of subject matter jurisdiction, mootness, and lack of standing,). *See* Dkt. 11 at 1-2. After the PTO filed its Answer, Angiotech asked the PTO to identify any legal authority in support. The PTO declined to do so. As such, Angiotech will respond to those defenses, if raised, in its opposition to the PTO's cross-motion for summary judgment.

INTRODUCTION

With the Hatch-Waxman Act, Congress established a unitary mechanism for providing patent term extensions for drugs and medical devices in certain circumstances with the recognition that Food and Drug Administration ("FDA") review for safety and efficacy could consume a substantial amount of the period of patent protection granted under patent law. The Hatch-Waxman Act sets forth the patent term extension process and how the FDA and the PTO are required to work together. The FDA and the PTO jointly administer the Act. At the outset, the FDA exercises its pre-marketing approval authority to determine whether a drug or device may be sold to the public. Once the FDA has granted such approval, the PTO then determines whether the statutory criteria for patent term extension have been met and, if so, what term extension is appropriate. In making that decision, the PTO is required to respect the FDA's earlier conclusions in the patent term extension process.

Here, the PTO violated the Hatch-Waxman Act by ignoring the FDA's approval of a combination product, misconstruing the plain language of the Act as applied to that combination product, and overlooking language in the '447 Patent claiming a method for biological stenting using that product.

Angiotech manufactures the ZILVER® PTX Drug Eluting Peripheral Stent (the "ZILVER PTX"). The ZILVER PTX is used to administer a drug, paclitaxel, to the wall of blood vessels in the arteries. The administration of paclitaxel via the ZILVER PTX opens the blood vessels in a phenomenon known as "biological stenting." Biological stenting requires both the drug component of the ZILVER PTX, the paclitaxel coating, as well as its physical component, the stent, to deliver and administer the drug component. Accordingly, the ZILVER PTX was reviewed for safety and effectiveness and approved for sale in the United States by the

FDA as a "combination product"; that is, one that has both drug and physical components. FDA review consumed approximately eight years of the '447 Patent's 20-year term.

Angiotech also owns the '447 Patent which claims a method for biological stenting using the ZILVER PTX. Because Angiotech could not market the ZILVER PTX product until the FDA completed its lengthy review and approval of the product, Angiotech applied to the PTO for an extension of the '447 Patent's term under the Hatch-Waxman mechanism. The PTO denied Angiotech's application for patent term extension based on its findings that the ZILVER PTX is merely a device, that the FDA reviewed it as merely a device, and that the '447 Patent does not claim structural elements of the device.

The PTO's decision violated the literal language of the Hatch-Waxman Act, and otherwise was arbitrary, capricious, and contrary to law for three reasons:

First, the PTO's decision misconstrued the identity of the product approved by the FDA, the ZILVER PTX, which is a combination product that comprises both drug and device components – a physical stent with a paclitaxel coating.

Second, the PTO's decision is contrary to the language of the Hatch-Waxman Act and the Patent Act and relies on several non-statutory factors to deny a term extension to the '447 Patent.

Third, the PTO's decision ignored the drug component of the combination product approved by the FDA, the ZILVER PTX, and the plain language of the '447 Patent demonstrating that it claims a method of biological stenting using the ZILVER PTX.

For each and all of these reasons, the PTO's decision should be overturned and the matter remanded to the PTO with instructions to grant patent term extension under the Hatch-Waxman mechanism.

THE STATUTORY FRAMEWORK

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). For patents claiming certain drug and medical devices, some or all of the patent term may be consumed by the rigorous and often lengthy FDA approval process for new products ("approved products") that use those patents. The approval process often requires years to complete, greatly diminishing the commercial rights provided by the patent. Recognizing this problem and the prejudice to patent owners caused by the administrative delay, Congress enacted Title II of the Hatch-Waxman Act. That provision establishes a unitary mechanism under which the term of a patent covering an approved product or its use may be extended up to five years. The length of the extension depends on how long the product was under FDA review.

Consistent with its prior delegations of authority to the FDA and the PTO, Congress in the Hatch-Waxman Act amended both the Food, Drug, and Cosmetic Act ("FDCA") and the Patent Act. The Hatch-Waxman mechanism 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 are intended to protect the intellectual property rights of manufacturers like Angiotech whose products are subject to the lengthy FDA approval process.

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). Likewise, 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). Thus, Section 355 of the FDCA and Section 156 of the Patent Act constitute a unitary mechanism that provides a remedy to patent owners: an extended patent term to offset the loss of effective patent life during the period of review of an approved product. By following this statutory scheme and granting patent term extensions, the PTO fulfills Congress's intent to protect the intellectual property rights of drug manufacturers who are required to seek FDA approval.

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. 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. 35 U.S.C. § 156(d)(1).

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. Based upon the FDA's findings and an examination of the patent at issue, 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, then is responsible for determining the length of the applicable 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. 52 Fed. Reg. 17,830 (May 12, 1987).

LOCAL RULE 56(B) LISTING OF UNDISPUTED FACTS

The Claims of the '447 Patent

1. The PTO issued the '447 Patent on September 22, 1998. A600-64[2] (the '447 Patent).

2. 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." A664 ('447 Patent, col. 76, lines 41-46).

3. The '447 Patent's written description encompasses the administration of a drug to the wall of a blood vessel. A873; *see also* A627 ('447 Patent, col. 2, lines 19-22, 56-59); A644 ('447 Patent, col. 36, lines 43-45, 52-54); A653 ('447 Patent, col. 54, lines 41-46.).

4. The ZILVER PTX has two complementary functions: (i) physical stenting to expand a blood vessel, and (ii) biological stenting to prevent narrowing of arteries. A870-71.

5. The ZILVER PTX administers the drug paclitaxel to the wall of a blood vessel. A840, 843, 875.

6. Paclitaxel is a cytoskeletal inhibitor that acts on microtubule and microfilament networks within a cell. A636 ('447 Patent, col. 19, lines 6-9).

[2] Citations are to the consecutively paginated administrative record entered on the docket as Dkt. 16-2, 16-3, 16-4, 17-1, 17-2, and 17-3.

7. Paclitaxel inhibits the contraction or migration of smooth muscle cells in the wall of a blood vessel. A628 ('447 Patent, col. 3, lines 30-36); *see also* A647 ('447 Patent, col. 42, lines 32-38) ("[E]mbodiments of the present invention involve the administration of [paclitaxel, which] is believed to stabilize vascular smooth muscle cells against division by binding to microtubules and inhibiting the organization and ordering of the microtubule network. Cell migration may also be inhibited by this mechanism.").

8. Product literature attached to and cited in the PTO's decisions (the "Zilver Product Literature") also describes the ZILVER PTX and indicates that paclitaxel binds to microtubules in cells, inhibits the microtubules molecular disassembly, and that this can prevent smooth muscle cell migration and the narrowing of arteries (restenosis), and thus maintain the openness of the arteries. A794-95; A876 (citing A785-850, A885-900).

9. The administration of paclitaxel to smooth muscle cells in a blood vessel wall allows the cells to synthesize the protein required to repair minor cell trauma and dilates the blood vessel to its maximal systolic diameter. A780; A629 ('447 Patent, col. 5, lines 35-50). This phenomenon is known as "biological stenting." *Id.*; *see also* A627 ('447 Patent, col. 1, lines 18-24) ("The invention . . . relates to the direct . . . delivery of therapeutic agents [drugs] to vascular smooth muscle cells that results in dilation and fixation of the vascular lumen (biological stenting effect).").

10. The device component (a self-expanding nitinol stent) and the drug component (paclitaxel) of the ZILVER PTX function together to inhibit the contraction or migration of the smooth muscle cells in the wall of a blood vessel to achieve biological stenting of the blood vessel. A780; A629 ('447 Patent, col. 5, lines 35-50).

11. The self-expanding nitinol stent acts to support the paclitaxel coating and apply and maintain it in direct contact with the wall of a blood vessel. A780; A840; A875.

12. The paclitaxel coating acts to inhibit the contraction or migration of the smooth muscle cells in the wall of a blood vessel. A794-95; A628 ('447 Patent, col. 3, lines 30-36).

The FDA's Approval of the ZILVER PTX

13. Before the FDA independently reviewed and approved the ZILVER PTX, it reviewed and approved the "Zilver Vascular Stent," which, unlike the ZILVER PTX, is not coated with paclitaxel and provides only physical (rather than biological) stenting. A782.

14. The ZILVER PTX substantially improved on the uncoated Zilver Vascular Stent by providing both physical and biological stenting, as biological stenting is more effective in maintaining the openness of the blood vessel than "bare" stenting (that is, stenting that does not use a paclitaxel-coated stent). A782; A812; A814.

15. In June 2010, Pre-Market Approval ("PMA") application No. P100022 was filed with the FDA for the ZILVER PTX. A672.

16. The FDA requires PMA applications when the device component of a drug-eluting stent like the ZILVER PTX provides the primary mode of action. When a 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).

17. The ZILVER PTX is considered by the FDA to be a combination product that contains both drug and device components. A870 (citing the FDA's publication "Combination Products: Jurisdictional Update: Drug-Eluting Cardiovascular Stents" (A881)); 21 U.S.C. § 353(g).

18. For internal administrative and jurisdictional purposes, the FDA review for combination products "is assigned based on the Agency's determination of the product[s'] 'primary mode of action,'" which the FDA has determined to be "that of the device component." A881-82 (Combination Products, Jurisdictional Update: Drug-Eluting Cardiovascular Stents). Accordingly, review for the ZILVER PTX was assigned to the FDA's Center for Devices and Radiological Health ("CDRH"). *Id.*

19. The FDA review of drug eluting stents does not ignore the drug component of the stent. "Although the agency has determined that these products are subject to premarket review and approval solely under the medical device provisions of the Act, the agency . . . may apply other drug requirements to the products as appropriate. The CDRH review staff have discussed application of drug requirements in the context of specific applications." *Id.*

20. On November 14, 2012, the FDA approved the PMA for the ZILVER PTX. A693; A883-84.

21. The FDA-approved labeling for the ZILVER PTX describes the approved device as "a self-expanding stent made of nitinol and coated with the drug paclitaxel." A780; A871.

The PTO's Decision on Patent Term Extension

22. 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 review of the ZILVER PTX. A586-673.

23. 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 review period of the ZILVER PTX. A686-88.

24. In response to the PTO's request for assistance, on May 11, 2015, the FDA confirmed that the ZILVER PTX had been subject to FDA review under 21 U.S.C. § 360e and that approval of PMA No. P100022 represented the first permitted commercial marketing or use of the ZILVER PTX. A693-94; *see also* A883-84.

25. On October 16, 2015, the PTO issued its initial decision denying Angiotech's patent term extension application ("Initial Decision"). A777-850.

26. In relevant part, the PTO's Initial Decision provides:

> In this case, the [ZILVER PTX] was reviewed and approved under section 515 of the [FDCA] and, as such, is a medical device. Clearly Applicant agrees that the approved product is a medical device since the [patent term extension] application described the approved product, the [ZILVER PTX], 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]. In other words, the claimed method must recite one or more structural elements of the [ZILVER PTX], which is described by applicant as, "a flexible, slotted tube made of nitinol, *i.e.*, nickel titanium, and coated with paclitaxel."

A779-80.

27. On November 16, 2015, Angiotech requested reconsideration on the PTO's Initial Decision. A851-67.

28. On December 11, 2015, the PTO issued its Final Decision denying Angiotech's request for reconsideration of the Initial Decision, its request for an interim extension, and its application for patent term extension. A868-904.

29. The PTO's Final Decision incorporated its Initial Decision and further provided:

> FDA reviewed and approved the [ZILVER PTX] as a "medical device" under section 515 of the [FDCA]; [the] FDA did not consider the stent a "drug product" under section 505 of the [FDCA]. Thus, the approved "medical device" is a drug-eluting stent . . . [The] FDA has indicated that drug-eluting stents, which comprise both a device component and a drug component, are "medical devices" to be reviewed under section 515 of the [FDCA].

A870.

30. Although the PTO's Final Decision described the ZILVER PTX as a "medical device," the PTO noted that the "FDA has indicated that drug-eluting stents [like the ZILVER PTX] . . . comprise both a device component and a drug component." A870.

STANDARD

The APA provides the applicable standard of judicial review of a final agency decision. *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 395 n.4 (Fed. Cir. 1990). Under the APA, agency action may be set aside if the court finds that the agency action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In making this determination, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts,* 411 U.S. 138, 142 (1973). The parties agree that the administrative record sets forth the undisputed facts and that this action may be resolved as a matter of law under Fed. R. Civ. P. 56.

ARGUMENT

The PTO's decision denying a patent term extension for the '447 Patent was arbitrary and capricious for three reasons. First, the PTO ignored the FDA's approval of the ZILVER PTX as a combination product that combines drug *and* device components. Second, the PTO's decision is contrary to the Hatch-Waxman Act's plain language and the FDA's interpretation of the relevant language found at Section 355 of the FDCA and Section 156 of the Patent Act. Finally, the PTO's decision overlooked the plain language of the '447 Patent, which claims a method of biological stenting using the ZILVER PTX. For each and all of these reasons, this Court should enter summary judgment in favor of Angiotech.

I. The PTO's decision was arbitrary and capricious because it ignored the fact that the FDA approved the ZILVER PTX as a combination product with both drug and device components.

The PTO's decision denying a patent term extension for the '447 Patent misconstrued the identity of the product approved by the FDA. In its Final Decision, the PTO arbitrarily described the ZILVER PTX as a "medical device." A870. However, under Section 515 of the FDCA, the approved product *is the product defined in the PMA.* Here, the product defined in the PMA is the ZILVER PTX, a combination product that comprises both drug and device components – a physical stent with a paclitaxel coating. Although the PTO's Initial and Final decisions noted that the paclitaxel coating is a component of the ZILVER PTX, those same decisions mistakenly and exclusively focused on the physical stenting component of the ZILVER PTX.

The PTO's decisions are contrary to the FDA's description of the approved product in the PMA, which is administratively determinative and which the PTO has no authority to second-guess. Under the Act, the FDA reviews and approves a patented product and the PTO, in turn, determines whether that product satisfies the criteria to extend the product's patent term to offset the loss of effective patent life resulting from the delay required for FDA review and approval. *See* 21 U.S.C. § 355(b)(1); 35 U.S.C. § 156(a). In making its decisions concerning patent term extensions, the PTO is bound by the FDA's determination as to the product it approved.

Importantly, the ZILVER PTX was reviewed and approved by the FDA even though the agency had previously reviewed and approved the uncoated Zilver Vascular Stent. Separate review of the ZILVER PTX was required by the FDA's authorizing statute and governing regulations because, as the FDA correctly recognized, the structure and function of the ZILVER PTX – unlike the Zilver Vascular Stent – comprises both physical and drug components. This separate review and approval of the ZILVER PTX resulted in delay, and it is because of this

delay that Angiotech seeks a patent term extension. By denying Angiotech such relief, the PTO is depriving an innocent party of its rights and subjecting that party to a substantial financial loss, based on the PTO's disagreement with the FDA about the FDA's interpretation and application of the FDA's own authorizing statute as to when a separate review and approval is required.

That Section 355 of the FDCA speaks to methods of using a "drug," and Section 156 of the Patent Act speaks to methods of using a "product," is irrelevant to this analysis. First, there is no dispute that the approved product – the ZILVER PTX – is a combination product that includes both drug and device components. Second, the subtle difference in the statutory language is irrelevant because the meanings of the two provisions are identical. These two provisions were adopted in the same statute, the Hatch-Waxman Act, in which the clear intent of Congress was to create a workable mechanism for extension of patent life when defined criteria were present. In enacting this mechanism, Congress reflected the underlying structure of its prior delegations: the power to approve drugs and devices is delegated to one agency (the FDA) and the power to issue patents and patent term extensions is delegated to another agency (the PTO). Like two halves of a locket, the two nearly-identical provisions must fit and function for the mechanism that Congress enacted to fit and function as Congress intended. The fact that similar provisions appear in two different titles of the U.S. Code has no significance, but reflects Congress' decision to create this mechanism while preserving consistency with the prior delegations of authority to different agencies.

The structure and legislative history of the Hatch-Waxman Act suggest that Congress intended to create one implementing mechanism in one statute that would operate in the same manner in both agencies. Nothing in the language, the structure, or the legislative history suggests that the mechanism was to work in different ways in the two agencies. *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 [in two complementary statutes] is a strong indication that they are to be interpreted alike."). And the canons of construction suggest that in interpreting these two provisions, their language should be treated in a consistent manner because the clear intent of Congress was to create one workable mechanism, responsibility for whose operation was divided between two agencies. *See* 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 . . .").

The PTO's decision denying patent term extension for the '447 Patent was arbitrary and capricious because it ignored the reasoning that necessitated regulatory review and the FDA's complementary decision to approve the ZILVER PTX. As the FDA determined, and the PTO noted, the ZILVER PTX is a combination product comprising both drug and device components, and the FDA's approval of the ZILVER PTX is binding on the PTO. If this were not so, the intent of Congress in delegating coequal, complementary authority on the FDA and the PTO to administer the Hatch-Waxman Act would be frustrated. For this reason alone, summary judgment should be entered in favor of Angiotech.

II. The PTO's decision was arbitrary and capricious because it is contrary to the plain meaning of the Hatch-Waxman Act.

The FDA approved the ZILVER PTX as a combination product that provides both physical stenting and biological stenting. But the PTO arbitrarily and mistakenly determined, in essence, that only the physical stent was approved and, because the '447 Patent does not

expressly claim the physical structure of the stent, the '447 Patent was not eligible for a patent term extension. Unlike the FDA, the PTO seemed not to grasp the concept of a combination product, and its decision here is contrary to the plain meaning of the Hatch-Waxman Act.

The PTO's interpretation of the Hatch-Waxman Act throws up barriers that do not exist in the Act. 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). 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).

Here, the ZILVER PTX provides a method of using a drug (*i.e.*, delivering paclitaxel to a blood vessel) for purposes of Section 355 of the FDCA. Likewise, the '447 Patent claims a method for using the ZILVER PTX (*i.e.*, for delivering paclitaxel to a blood vessel) 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. A780 (emphasis added). With this assertion, the PTO has introduced a new requirement nowhere to be found in the plain language of Section 156 of the Patent Act – that "the claimed method must recite one or more structural elements" of the approved product. The PTO's new requirement is not included anywhere in the

statute. The statute requires only that the patent claim a method of using the product, and the '447 Patent claims a method of using the ZILVER PTX.

The PTO's determination is contrary to the plain language of the Hatch-Waxman Act in other respects. In interpreting Section 156 and denying patent term extension, the PTO relied in part on the fact that the FDA assigned the review of the ZILVER PTX combination product to the CDRH, the internal division of FDA that reviews products that are primarily devices. *See* A870. But *where* a product is reviewed within the FDA is irrelevant under the Hatch-Waxman Act, which makes it clear that approval of a combination product must take account of both the device and drug components regardless of which agency center is primarily responsible for review. *See* 21 U.S.C. § 353(g). Where a product is reviewed within the FDA is also not a statutory criterion and has no role to play in the proper interpretation of Section 156. Rather than have the PTO speculate about a product or what the FDA may have considered, Section 156 requires that the PTO examine only the FDA's findings and conclusions in its final decision on approval. Importantly, in its decision, the FDA never suggested that the identity of the internal division of the FDA that reviewed the ZILVER PTX was in any way meaningful to its analysis or somehow made the paclitaxel and biological stenting more or less a component of the combination product's structure and function. The PTO cannot justify its interpretation of the FDA decision on factors on which the FDA never relied. The PTO must rest its patent term extension decision on the criteria set forth in Section 156 and not on which internal division the FDA chooses to have review a product as a matter of convenience.

By failing to understand or ignoring the Hatch-Waxman Act's application to combination products, the PTO is interpreting differently than the FDA the similar language found in Section 355 of the FDCA and Section 156 of the Patent Act. 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 drug and device 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 decided that a patent term extension is not warranted if the product was primarily reviewed as a device and the patent primarily concerns a drug.

In other words, the PTO has wrongly determined to restrict 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. Unlike the FDA, the PTO wants to put products and patents in discrete categories as either only about a device or only about a drug. But that ignores the complementary functions of an approved combination product, like the ZILVER PTX, even where, as here, the fact that the complementary function exists is what made separate regulatory review necessary.

The Hatch-Waxman Act provides the same protections regardless of whether a product or patent concerns a device, a drug, or a combination of both. The FDA understands this. When faced with a combination product, the FDA evaluates both the drug and device components of that product. By contrast, the PTO's decision suggests that the FDA approves drugs, approves devices, but does not approve products comprising both drugs and devices. The Hatch-Waxman Act is not ambiguous. And even if it were, because different interpretations by different agencies of the same statute are not entitled to *Chevron* deference, the PTO's interpretation is not entitled to *Chevron* deference. *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *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."). In sum, the FDA recognizes that the Hatch-Waxman Act applies to a combination product. The PTO does not. The PTO's contrary interpretation is at odds with the Hatch-Waxman Act and should receive no deference.

The ability to obtain a patent term extension is based upon the requirement of regulatory approval. And it is the FDA, and not the PTO, that determines when regulatory approval of a product is required. The FDA determined that the ZILVER PTX was a product subject to regulatory review before commercial marketing or use and that the subsequent approval "represent[ed] the first permitted commercial marketing or use of the product." A693. Thus, the FDA's application of Section 355 of the FDCA is determinative, and the PTO's conflicting interpretation and application of Section 156 should be set aside. By failing to recognize that the Hatch-Waxman Act applies with equal force to products and patents that concern both drugs and devices, the PTO's decision was arbitrary and capricious and should be declared unlawful.

III. The PTO's decision was arbitrary and capricious because 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.

Applying Section 156 of the Patent Act, patent term extension should have been granted here because the patent recites a method of using the approved product, a biological stent. To deny patent term extension, however, the PTO effectively viewed the ZILVER PTX as being no different than the uncoated Zilver Vascular Stent, a physical stent. Because the PTO determined

that the ZILVER PTX was a device for physical stenting and the '447 Patent recited a method of biological stenting, the PTO determined that the '447 Patent did not recite a method of using the approved product. In reaching this conclusion, the PTO ignored the drug component of the combination product and misconstrued the plain language of the '447 Patent. Accordingly, its decision should be declared invalid.

The PTO acted arbitrarily and capriciously in concluding that the patent did not recite a method of using the ZILVER PTX. To the contrary, as the FDA correctly found when it approved the PMA, the drug (paclitaxel) and device (stent) components of the ZILVER PTX function together to achieve biological stenting, the very method claimed in the '447 Patent. As the PTO itself noted, the stent acts to support the paclitaxel coating and apply and maintain it in direct contact with the wall of a blood vessel. A780; A875; *see also* A840 (Zilver Patient Guide). The paclitaxel coating, in turn, acts to inhibit the contraction or migration of the smooth muscle cells in the blood vessel wall. A794-95; A628 ('447 Patent, col. 3, lines 30-36). Thus, the PTO was bound to determine that the ZILVER PTX functions not only by physical stenting but also by *biological* stenting as claimed in the '447 Patent.

The ZILVER PTX is a combination product and was not simply the Zilver Vascular Stent. The FDA had previously approved the uncoated Zilver Vascular Stent. The FDA determined that the ZILVER PTX needed separate FDA approval because of its drug component, and the approval of the ZILVER PTX represented the "first permitted commercial marketing or use of the product." A693. 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. *See* A664 ('447 Patent, col. 76, lines 41-46).

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* A627 ('447 Patent, 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 smooth muscle cells in the blood vessel wall for an extended duration.

The PTO simply ignored the drug-delivery features of the ZILVER PTX, asserting that "patency [blood vessel 'openness'] 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," where the term "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 in the '447 Patent substantially improved on the uncoated Zilver Vascular Stent by providing both physical *and* biological stenting. *See* A814 ("stenting with the paclitaxel-coated [ZILVER PTX] is

significantly more effective in maintaining primary patency than stenting with the same bare (uncoated) stent.").

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. *See* 35 U.S.C. § 156(a) ("The 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.") (emphasis added). By ignoring the drug component of the combination product and the plain language of the '447 Patent demonstrating that it claims a method of biological stenting using the approved combination product, the ZILVER PTX, the PTO's decision was arbitrary and capricious and should be overturned.

CONCLUSION

The PTO's decision denying patent term extension was arbitrary, capricious, and contrary to law. The PTO's decision (i) failed to respect the FDA's approval of the ZILVER PTX as a combination product that combines drug *and* device components, (ii) was based on criteria not found in the Hatch-Waxman Act and at odds with the FDA's interpretation and application of the Act, and (iii) overlooked the biological stenting found in the ZILVER PTX and the plain language of the '447 Patent, which confirm that the '447 Patent claims a method of using the ZILVER PTX. For each and all of these reasons, the PTO's decision should be declared unlawful, summary judgment should be entered in Angiotech's favor, and the matter should be remanded to the PTO with instructions to approve an extension of the term of the '447 Patent.

April 20, 2016 Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2016, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of electronic filing to the following counsel of record:

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