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 OF LAW IN OPPOSITION TO DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT

Angiotech Pharmaceuticals Inc. ("Angiotech") opposes the cross motion for summary judgment filed by 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").

The PTO's cross motion and Angiotech's corresponding cross motion concern whether 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"). The PTO's cross motion should be denied for at least three reasons. First, the PTO's decision denying patent term extension to the '447 Patent is not entitled to any deference and

should be reviewed *de novo*. Second, the PTO's decision misconstrued the definition of "product" under Section 156 to exclude combination products like the ZILVER PTX, which combine both drug and device components. Finally, the PTO also misconstrued the plain language of the '447 Patent, which claims a method for biological stenting that may also include physical stenting using the ZILVER PTX.

The PTO's cross motion confirms its faulty analysis. The PTO also acknowledges that it has not previously addressed the issue of when Food and Drug Administration ("FDA") review of a combination product will support patent term extension under the Hatch-Waxman Act. In its Memorandum, the PTO explains that "[n]either the FDA [n]or the USPTO issued regulations guiding the determination of the regulatory review period or calculation of PTE for combination products as a stand-alone category." *See* Memorandum of Law in Support of Defendants' Cross Motion for Summary Judgment (Dkt. 22) ("PTO's Mem.") at 5. While the PTO cites a host of cases for its argument, these are also inapposite because the cases do not concern combination products or the specific statutory language at issue here. Because the PTO's treatment of the combination product here – the ZILVER PTX – is at odds with the Act, the PTO's cross motion for summary judgment should be denied and Angiotech's should be granted.

INTRODUCTION

Congress enacted the Hatch-Waxman Act for the express purpose of extending the lives of patents whose terms are consumed in part by the often-lengthy review and approval process of new drugs and products by the FDA. To achieve its purpose, the Act requires the FDA and the PTO to cooperate in the exercise of coequal, complementary authority – the FDA conducts reviews of products for safety and efficacy and the PTO extends the lives of patents claiming

products subject to the FDA's review. As amended by the Hatch-Waxman Act, the relevant provision of the Patent Act states in part:

> The term of a patent which claims . . . a method of using a product . . . shall be extended . . . if the product has been subject to a regulatory review period before its commercial marketing or use[.] . . . For purposes of this section: The term "product" means: Any medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act.

35 U.S.C. § 156.

In this case, the parties agree that the ZILVER® PTX Drug Eluting Peripheral Stent (the "ZILVER PTX") is a combination product that was subject to a regulatory review period before its first commercial marketing or use. As a combination product, the ZILVER PTX has both drug and device components; however, the PTO denied Angiotech's application for patent term extension of the '447 Patent on the ground that that the ZILVER PTX is merely a device, the ZILVER PTX was reviewed by the FDA as merely a device, and the '447 Patent does not claim structural elements of a device. The PTO's decision is arbitrary, capricious, and contrary to law because the decision misconstrued the nature of the ZILVER PTX, a combination product and not a mere device. Moreover, the decision violates the express language of the Hatch-Waxman Act and relies on several non-statutory factors. Finally, the decision ignores the drug component of the combination product reviewed and approved by the FDA, the ZILVER PTX, and the plain language of the '447 Patent.

The parties filed cross motions for summary judgment on April 20, 2016. Dkt. 18, 21. The PTO's cross motion, like its earlier decision, rests on three errors of law. First, contrary to the PTO's contention, the PTO's decision is not entitled to any deference and must be reviewed by this Court *de novo*. Second, the PTO fails to recognize that the statutory definition of "product" – "any medical device . . . subject to regulation" under the FDCA – includes the ZILVER PTX, a combination product subject to regulation under the FDCA that was reviewed

and approved by the FDA. Third, contrary to the PTO's contention, the '447 Patent need not recite any structural components of a device to be eligible for a patent term extension under the Hatch-Waxman Act. And the plain language of the '447 Patent claims a method for biological stenting that may also include physical stenting using the product approved by the FDA, the ZILVER PTX.

For each and all of these reasons, the PTO's cross motion for summary judgment should be denied, its decision should be overturned, and the matter should be remanded to the PTO with instructions to grant patent term extension under the Hatch-Waxman Act.

LOCAL CIVIL RULE 56(B) RESPONSE TO THE PTO'S STATEMENT OF UNDISPUTED MATERIAL FACTS ("SUMF")[1]

The '447 Patent

PTO's SUMF ¶ 1: On September 22, 1998, the USPTO issued the '447 patent, titled "Therapeutic Inhibitor of Vascular Smooth Muscle Cells." A600.[2] The '447 patent was originally assigned to the NeoRx Corporation. *Id*. Currently, the '447 patent is assigned to Boston Scientific Scimed, Inc., and is exclusively licensed to Plaintiff. A679.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 2: The '447 patent specification discloses "new therapeutic methods and therapeutic conjugates . . . for inhibiting vascular smooth muscle cells." A627. It also includes "methods for inhibiting stenosis" and "therapeutic methods and therapeutic dosage forms involving sustained release of therapeutic agent to target cells." A628. In short, the methods provided for by the '447 patent effectively constitute a so-called "biological stent." A600.

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1 The parties agree that judicial review of agency decision-making under the APA is confined to the administrative record of proceedings before the agency and, therefore, there can be no genuine issue of material fact here. *See* Memorandum of Law in Support of Defendants' Cross Motion for Summary Judgment (Dkt. 22) ("PTO's Mem.") at 6 n.3. Nevertheless, Angiotech provides its response to the PTO's statement of undisputed material facts as required under E.D. Va. Local Civil Rule 56(B).

2 All 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.

Angiotech's response: Undisputed, except to the extent that the '447 Patent discloses a method for both biological and physical stenting. A641 ('447 Patent, col. 30, lines 38-44).

The ZILVER PTX Product

PTO's SUMF ¶ 3: The Zilver PTX Stent is a "self-expanding nitinol stent coated on its outer surface with the drug paclitaxel." A714. [n.4: Nitinol is also known as nickel titanium. A587.] Among other uses, paclitaxel "applied locally reduces restenosis by inhibiting smooth muscle cell proliferation." A716. [n.5: Restenosis is the renarrowing of an artery over time, following medical treatments such as balloon angioplasty or stenting. A891.] Paclitaxel itself was first approved by the FDA in 1992. A707.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 4: On November 14, 2012, and pursuant to section 515 of the FDCA, the FDA approved Cook Medical Technologies, Inc.'s ("Cook Medical") Premarket Approval Application ("PMA") No. P100022, which granted permission for commercial marketing or use of the Zilver PTX Stent. A588, A713. The FDA indicated that the Zilver PTX Stent was the first permitted commercial marketing or use of the product. A693.

Angiotech's response: Undisputed.

Angiotech's Application for Patent Term Extension

PTO's SUMF ¶ 5: On December 7, 2012, Plaintiff filed a PTE application to extend the term of the '447 patent based on the FDA's regulatory review of the Zilver PTX Stent. A586-A673.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 6: Plaintiff sought PTE of the statutory maximum of five years. A596-A597.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 7: On March 25, 2015, the USPTO sent a Requirement for Information Pursuant to 37 C.F.R. § 1.750 ("RFI") to Plaintiff, which sought additional information from Plaintiff to demonstrate the manner in which at least one claim of the '447 patent "claims" a method of using the Zilver PTX Stent as that term is understood in 35 U.S.C. § 156(a). A689-A692. Specifically, the RFI directed Plaintiff to describe:

> (1) how the '447 patent claims a method of using the medical device subject to regulatory review under section 515 of the FFDCA, and consequently (2) that the amount of paclitaxel present in the ZILVER® PTX Drug Eluting Peripheral stent is administered, "in an amount and for a period of time effective to inhibit the

> contraction or migration of vascular smooth muscle cells" to achieve the recited "method of biological stenting."

A691.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 8: Plaintiff responded on June 19, 2015, identifying claim 12 of the '447 patent's eighteen claims as claiming a method of using the Zilver PTX Stent. A695-A771. Plaintiff had also identified claim 12 as claiming a method of using the Zilver PTX Stent in its original PTE application. A590-A591.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 9: In full, 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.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 10: The only definition for the term "biologically stenting" contained in the specification for the '447 patent reads as follows:

> The present invention also provides therapeutic methods and therapeutic dosage forms involving administration of free (i.e., non-targeted or non-binding partner associated) therapeutic agent to target cells. Preferably, the target cells are vascular smooth muscle cells and the therapeutic agent is an inhibitor of vascular smooth muscle cell contraction, allowing the normal hydrostatic pressure to dilate the vascular lumen. Such contraction inhibition may be achieved by actin inhibition, which is preferably achievable and sustainable at a lower dose level than that necessary to inhibit protein synthesis. Consequently, the vascular smooth muscle cells synthesize protein required to repair minor cell trauma and secrete interstitial matrix, thereby facilitating the fixation of the vascular lumen in a dilated state near its maximal systolic diameter. *This phenomenon constitutes a biological stenting effect* that diminishes or prevents the undesirable so recoil mechanism that occurs in up to 25% of the angioplasty procedures classified as successful based on an initial post-procedural angiogram.

A629 (emphasis added).

Angiotech's response: Undisputed that the cited text provides a definition of biological stenting in the '447 Patent. However, the following text in the '447 Patent also describes biological stenting:

> Methods are also provided for the direct and/or targeted delivery of therapeutic agents to vascular smooth muscle cells that cause a dilation and fixation of the vascular lumen by inhibiting smooth muscle cell contraction, thereby constituting a biological stent.

A600 (’447 Patent, Abstract).

> The invention also relates to the direct or targeted delivery of therapeutic agents to vascular smooth muscle cells that results in dilation and fixation of the vascular lumen (biological stenting effect).

A627 (’447 Patent, col. 1, lines 21-24).

> The therapeutic or prophylactic agent combined by, for example, local administration in protocols employing the aforementioned stabilizer/organizer may be either a cytotoxic agent (e.g., free cytotoxic agent, a cytotoxic conjugate, or a sustained dosage form incorporating a cytotoxic agent) or a cytostatic agent (e.g., free, targeted or sustained release formulations of an agent capable of generating a biological stenting effect, an anti-migratory agent, a cytoskeletal inhibitor, a metabolic inhibitor, an anti-proliferative agent or the like).

A643 (’447 Patent, col. 33, lines 33-43).

> Inhibition of cellular contraction (i.e., loss of vascular tone) may operate through two mechanisms to reduce the degree of vascular stenosis. First, inhibition of cellular contraction for a prolonged period of time limits the number of smooth muscle cells that migrate from the tunica media into the intima, the thickening of which results in vascular luminal stenosis. Second, inhibition of cellular contraction causes the smooth muscle wall to relax and dilate under normal vascular hydrostatic pressure (i.e., blood pressure). Therapeutic agents, such as the cytochalasins, inhibit smooth muscle cell contraction without abolishing the protein synthesis necessary for traumatized, post-angioplasty or other surgically- or disease-damaged, smooth muscle cells to repair themselves. Protein synthesis is also necessary for the smooth muscle cells to secrete matrix, which fixes or retains the lumen in a state near its maximum systolic diameter as the vascular lesion stabilizes (i.e., a biologically induced stenting effect).
>
> This biological stenting effect not only results in an expanded vessel luminal area and increased blood flow rate through the vessel, but also significantly reduces elastic recoil following angioplasty.

A644 (’447 Patent, col. 35, lines 46-67).

> Cytochalasins are exemplary therapeutic agents capable of generating a biological stenting effect on vascular smooth muscle cells. Cytochalasins are thought to inhibit both migration and contraction of vascular smooth muscle cells by interacting with actin. The cytochalasins interact with the ends of filamentous

> actin to inhibit the elongation of the actin filaments. Low doses of cytochalasins (e.g., cytochalasin B) also disrupt microfilament networks of actin. In vitro data indicate that after vascular smooth muscle cells clear cytochalasin B, the cells regenerate enough polymerized actin to resume migration within about 24 hours. In vivo assessments reveal that vascular smooth muscle cells regain vascular tone within 2 to 4 days. It is during this recuperative period that the lumen diameter fixation and biological stenting effect occurs.

A644 ('447 Patent, col. 36, lines 28-42).

> [T]he sustained release dosage form of the present invention, incorporating a cytochalasin or other anti-proliferative therapeutic agent, can be administered in combination with a free cytochalasin therapeutic agent. In this manner, the biological stenting effect, as well as an anti-proliferative or anti-migratory effect, can be achieved in a single administration protocol.

A644 ('447 Patent, col. 36, lines 59-65).

PTO's SUMF ¶ 11: Because the '447 patent was originally set to expire on September 22, 2015, Plaintiff also requested an interim extension pursuant to 35 U.S.C. § 156(e)(2). A772-A774.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 12: On September 17, 2015, the USPTO granted an interim extension for the '447 patent for a period of three months. A775-A776.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 13: On October 16, 2015, the USPTO denied Plaintiff's PTE application (the "Initial Decision"). A777-A850. The USPTO determined that the '447 patent does not claim the Zilver PTX Stent, or a method of using or manufacturing the Zilver PTX Stent, and thus was not eligible for PTE under 35 U.S.C. § 156(a). A778-A779.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 14: In the Initial Decision, the USPTO noted that Plaintiff identified only claim 12 as claiming the Zilver PTX Stent. A779. It further noted that the FDA had reviewed the Zilver PTX Stent under section 515 of the FDCA as a medical device and that both the FDA and Plaintiff referred to it as such at various points. A779-A780. Thus, the USPTO analyzed whether claim 12 claimed a method of using the Zilver PTX Stent by reciting "one or more structural elements" of the approved product. A780. The USPTO looked at the claim language in light of the '447 patent specification and considered Plaintiff's response to the RFI, but found no disclosure in the '447 patent of the use of any sort of stent medical device. A780-A783.

Angiotech's response: Undisputed to the extent that the FDA reviewed the ZILVER PTX under Section 515 of the FDCA as a device, but disputed to the extent the PTO attempts to characterize Angiotech's references to the ZILVER PTX as merely a device and not a combination product including both device and drug components.

PTO's SUMF ¶ 15: In addition, the USPTO observed that in its response to the RFI, Plaintiff appeared to "conflate[] the concept of claiming a method of using the product" with "whether making, using, offering to sell, or selling the [product] would, in theory, infringe claim 12." A783. However, the Initial Decision pointed out that the Federal Circuit rejected equating the two concepts in *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997). *Id*.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 16: Plaintiff then sought reconsideration of the USPTO's denial of its PTE application, as well as a second request for an interim extension. A851-A867. Plaintiff asserted that "[i]t is clear from the written description of the '447 Patent that claim 12 encompasses the local administration of drugs to the blood vessel wall." A854. Plaintiff then argued that the USPTO's Initial Decision "inappropriately ignores paclitaxel administration and solely focuses on the structural features of the ZILVER controlled-delivery system," and that there was "no authority that requires that . . . a method claim must include structural elements of the approved device." A858-A859.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 17: Separately, in seeming contradiction to this previous point, Plaintiff also argued that the use of the word "comprising" in claim 12 "indicates that other steps may be included." A859. Thus, Plaintiff reasoned, "there is nothing that precludes achieving biological stenting in conjunction with physical stenting." *Id*.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 18: Finally, in its request for reconsideration, Plaintiff sought to distinguish the USPTO's reliance on *Hoechst-Roussel Pharmaceuticals* in the Initial Decision, A860-A862, and it further contended that the denial of its PTE application was inconsistent with the USPTO's past decision to grant PTE for U.S. Patent No. 5,041,126 ("the '126 patent") based on the FDA's regulatory review of the Cook GRII™ Coronary Stent ("Cook Stent"), A862-A863.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 19: On December 11, 2015, the USPTO again denied Plaintiff's PTE application and concomitantly denied its second request for an interim extension (the "Final Decision"). A868-A904.

Angiotech's response: Undisputed.

The PTO's Decision

PTO's SUMF ¶ 20: After considering Plaintiff's PTE application and its request for reconsideration, the USPTO determined that, at bottom, the '447 patent does not claim a method of using the Zilver PTX Stent. A870. The Final Decision specifically incorporated the reasoning set forth in the Initial Decision, *id.*, and provided a detailed explanation for the denial of Plaintiff's PTE application.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 21: First, the USPTO rejected Plaintiff's attempt to re-characterize the Zilver PTX Stent as a drug product rather than a medical device by referring to it as a "ZILVER controlled delivery system." A870. The USPTO acknowledged that the Zilver PTX Stent was a product composed of both a drug component and a device component, but it also observed that the FDA considers such drug-eluting stents like the Zilver PTX Stent to be medical devices because "the uncoated stent functions to physically maintain vessel lumen patency, while the drug component has played a secondary role in preventing restenosis." *Id.* (quoting A881). For that reason, the USPTO noted, the FDA "reviewed and approved" the Zilver PTX Stent as a medical device under section 515 of the FDCA. *Id.*

Angiotech's response: Undisputed.

PTO's SUMF ¶ 22: The USPTO also pointed out that Plaintiff itself, the FDA, and the original sponsor of the PMA, Cook Medical, all described the Zilver PTX Stent in physical terms characteristic of a medical device. In the PTE application, Plaintiff described the Zilver PTX Stent as a "flexible, slotted tube made of nitinol, i.e., nickel titanium, and coated with paclitaxel." A870-A871. Both the FDA-approved labeling for the Zilver PTX Stent and the FDA's approval of PMA No. P100022 referred to it in physical terms. A871. And Cook Medical in its Patient Guide for the product described it as a "stent [that] expands and stays in place to keep the artery open after the catheter is withdrawn." *Id*. Thus, the USPTO concluded that "the approved product is a drug-eluting stent ('medical device') that acts to open an occluded vessel by physically expanding in the affected area." *Id.*

Angiotech's response: Undisputed, except to the extent that the cited description – a "stent [that] expands and stays in place to keep the artery open after the catheter is withdrawn" – is a general description of angioplasty and not a description of the ZILVER PTX. *See* A890. As

to the ZILVER PTX, the Patient Guide specifically states that "[t]he Zilver PTX stent uses a very small amount of paclitaxel, which is applied directly to the vessel wall." *See* A891.

PTO's SUMF ¶ 23: Second, the USPTO determined that the '447 patent does not claim a method of using the Zilver PTX Stent. The USPTO began by noting that because the FDA reviewed the Zilver PTX Stent under section 515 of the FDCA, the product at issue was a medical device. A872. Accordingly, it substituted the term "medical device" into 35 U.S.C. § 156(a) to reason that PTE should issue in this case only if the patent "claims . . . a method of using a [medical device]." A872. The USPTO then observed that a medical device, as defined by statute, "focuses on the structural features of the device . . . and specifically excludes a medical device that would 'achieve its primary intended purposes through chemical action within or on the body.'" A872-A873 (citing 21 U.S.C. § 321(h)). But, the USPTO continued, claim 12—i.e., the sole claim that Plaintiff identified in support of its PTE application—"does not recite any structural features of a medical device" and instead only "recites a method whereby the primary purpose ('biological stenting') is achieved via chemical action." A873. [n.6: In its Initial Decision, the USPTO noted that "[b]ased on the definition of 'biological stenting' in the '447 patent, it is understood that any patency effect is achieved through the targeted administration of an active pharmaceutical agent which inhibits vascular smooth muscle contraction and thereby allows the vessel to remain in a dilated state." A781.] As such, the USPTO stated that it did not find "sufficient support in the claim language of claim 12 or the written description of the '447 patent to find that claim 12 claims a method of using a drug-eluting stent, such as the [Zilver PTX Stent]." *Id.*

Angiotech's response: Undisputed, except to the extent the definition of a medical device under the FDCA (21 U.S.C. § 321(h)) is relevant to patent term extension decisions under the Hatch-Waxman Act (35 U.S.C. § 156).

PTO's SUMF ¶ 24: Along the same lines, the USPTO rejected Plaintiff's argument that the term "comprising" in claim 12 constitutes "open language" that "includes physical stenting in addition to biological stenting." A874. The USPTO explained that while it did not disagree that the term "comprising" indicated that "other steps may be included" in claim 12, "there is no written description of a drug-eluting stent found within the written description of the '447 patent document" showing that "the inventors of the subject matter described in the '447 patent actually invented or had possession of a drug-eluting stent." *Id.* At best, the USPTO recognized that the specification for the '447 patent contains one passing reference to a physical stent that "does not describe a method of using a drug-eluting stent." *Id*. This was insufficient to show that claim 12 claims a method of using the Zilver PTX Stent. *Id*. (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010)).

Angiotech's response: Undisputed, except to the extent the written description of the '447 Patent also states that "a therapeutically effective dosage of a therapeutic conjugate or

dosage form is useful in . . . vascular surgical procedures such as angioplasty, atheroectomy, placement of a stent (e.g., in a vessel), thrombectomy, and grafting." A641 ('447 Patent, col. 30, lines 38-44).

PTO's SUMF ¶ 25: Third, to the extent Plaintiff was arguing that the '447 patent claims the Zilver PTX Stent because the Zilver PTX Stent would potentially infringe the patent, the USPTO again rejected that argument as it did in its Initial Decision based on the Federal Circuit's decision in Hoechst-Roussel, which rejected equating the two concepts. A875-A876.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 26: And fourth, the USPTO rejected Plaintiff's contention that the denial of its decision in this case was inconsistent with the USPTO's past practices. A876-A877. In its request for reconsideration, Plaintiff identified the USPTO's past decision to grant PTE for the '126 patent based on the FDA's regulatory review of the Cook Stent. A862. Plaintiff had argued that, like claim 12 of the '447 patent, "[t]here are a nearly infinite number of stent configurations that could meet the requirements of [claim 1 of the '126 patent]" and yet PTE was granted based on the Cook Stent. *Id*. In rejecting this argument, the USPTO explained that unlike claim 12 of the '447 patent, claim 1 of the '126 patent "expressly" states a method of using a physical stent. A877. Indeed, both the USPTO and Plaintiff agreed that claim 1 of the '126 patent recited:

> 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.

A862, A876-A877.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 27: Because the USPTO found that the '447 patent was ineligible for PTE, it denied Plaintiff's second request for an interim extension. A877-A879.

Angiotech's response: Undisputed.

PTO's SUMF ¶ 28: Following the issuance of the Final Decision denying Plaintiff's PTE application, Plaintiff filed its Complaint in this Court on December 21, 2015, seeking judicial review of the USPTO's decision. [n.7: On December 22, 2015, the '447 patent expired.]

Angiotech's response: Undisputed.

ARGUMENT

The PTO's cross motion for summary judgment should be denied for three reasons. First, the PTO's decision denying patent term extension to the '447 Patent is not entitled to any deference and should be reviewed *de novo*. Second, the PTO's decision misconstrued the definition of "product" under Section 156 to exclude combination products like the ZILVER PTX, which combine both drug and device components. Finally, the PTO also misconstrued the plain language of the '447 Patent, which claims a method for biological stenting that may also include physical stenting using the ZILVER PTX.

I. The PTO's decision is not entitled to any deference because the Hatch-Waxman Act is unambiguous and the PTO concedes there are no pertinent agency regulations, policies, or pronouncements to support its litigating position.

Statutory interpretations in PTE proceedings, like the one here, are reviewed *de novo* and thus are not entitled to deference. For example, in *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 399 (Fed. Cir. 1990), the Federal Circuit gave "no deference to the [PTO's] surmise of Congress' intent in framing its definition" of "product" under Section 156. *See also Medicines Co. v. Kappos*, 731 F. Supp. 2d 470, 476 (E.D. Va. 2010) (stating that *Glaxo* "expressly rejected the PTO's claim for deference to its statutory interpretations in PTE proceedings"). As in *Glaxo*, the definition of "product" under Section 156 is the central issue here. And under settled precedent, the PTO's interpretation of that definition in its decision denying patent term extension to the '447 Patent is reviewed *de novo* and without deference.

The PTO concedes that *Chevron* deference does not apply. Rather, the PTO requests the lesser degree of deference afforded by *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), in which the weight given an agency's interpretation is limited to its "power to persuade." *See* PTO Mem. at 14-15. Because the Hatch-Waxman Act is unambiguous, however, the PTO's decision

interpreting that statute is not entitled even to *Skidmore* deference. *See Exelixis, Inc. v. Kappos*, 906 F. Supp. 2d 474, 483 (E.D. Va. 2012), *as amended* (Nov. 6, 2012) (Ellis, J.) ("*Skidmore* deference is unwarranted, when, as here, the statute is unambiguous."), *vacated and remanded sub nom. Exelixis, Inc. v. Lee*, 550 F. App'x 894 (Fed. Cir. 2014).

The PTO's concession that *Chevron* deference does not apply is correct. Because two different agencies (the FDA and the PTO) are charged with interpreting and applying the same statute (the patent term extension mechanism of the Hatch-Waxman Act) the PTO's interpretation here would not be entitled to *Chevron* deference, even assuming the language of the Act were ambiguous. *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *Rapaport v. United States Dep't of Treasury, Office of Thrift Supervision*, 59 F.3d 212, 216-17 (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.").

Skidmore deference also does not apply. As noted, under *Skidmore* "an agency's interpretation receives weight in proportion to its 'power to persuade.'" *Shipbuilders Council of Am., Inc. v. U.S. Dep't of Homeland Sec.*, 673 F. Supp. 2d 438, 453 (E.D. Va. 2009) (Ellis, J.). And this power is measured by "the thoroughness evident in its consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements." *Skidmore*, 323 U.S. at 140. Here, the PTO's decision has no "power to persuade" and the rationale offered to support its decision amounts to nothing more than a litigating position based on no prior agency practice.

In its Memorandum, the PTO makes an extraordinary concession that "[n]either the FDA [n]or the USPTO issued regulations guiding the determination of the regulatory review period or calculation of PTE for combination products as a stand-alone category." PTO's Mem. at 5. Thus, there is and can be no "consistency" between the PTO's decision denying patent term extension in this case and any "earlier and later pronouncements" by either the FDA or the PTO. *See Skidmore*, 323 U.S. at 140. For the same reason, the PTO's decision here does not "reflect" any of the "touchstones" warranting *Skidmore* deference. *See* PTO's Mem. at 15. The PTO's decision was not justified by any opinion letter, policy statement, agency manual, or enforcement guideline. *See id.* (quoting *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338, 349 (E.D. Va. 2009)). Nor does the decision reflect "consistent . . . agency-wide policy." *See Cathedral Candle Co. v. U.S. Int'l Trade Comm'n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005). Similarly, the PTO's reliance on inapposite "past precedent" to support its decision does not warrant *Skidmore* deference. *See* PTO's Mem. at 15, 22; Part II, below.

The PTO's interpretation of Section 156 in this case is unsupported by any agency practice. It appears to be nothing more than a litigating position concocted specially for this case to justify the result below. Accordingly, neither *Skidmore* nor *Chevron* apply to the PTO's decision, as the Supreme Court has "never applied the principle of [*Chevron*] to agency litigating positions that are wholly unsupported by regulations, rulings, or administrative practice." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988); *see also Hispanic Leadership Fund, Inc. v. Fed. Election Comm'n*, 897 F. Supp. 2d 407, 428 (E.D. Va. 2012) (Ellis, J.) ("[T]here is in this case no policy statement, regulation, or ruling that constitutes the basis for the [agency's] position in this litigation; instead there is only the position of the [the agency's counsel], which is

nothing more than the putative litigation position of the [agency] that is not entitled to any deference.").

Because the PTO's decision is not entitled to deference under any standard, whether the PTO's "treatment" of the ZILVER PTX "as a medical device is a reasonable construction of the statute," PTO's Mem. at 15, is an issue this Court must resolve *de novo*. And for the reasons explained below and in Angiotech's Memorandum in Support of Cross-Motion for Summary Judgment (Dkt. 19), that decision (the "treatment" by the PTO) should be declared arbitrary, capricious, and contrary to law.

II. The PTO's decision was arbitrary and capricious because Section 156's definition of "product" includes any medical device reviewed and approved by the FDA, including combination products like the ZILVER PTX.

Under the plain language of the statute, the PTO must extend the terms of patents that claim methods for using "products" that undergo regulatory review by the FDA. Section 156 defines "products" as "[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act." 35 U.S.C. § 156(f)(1)(B). In its decision denying patent term extension to the '447 Patent, however, the PTO improperly interpreted "*any* medical device" to mean *only* a device, thereby categorically excluding all products that combine both drug and device components from the definition of "products" under Section 156. The PTO provides no support for its blinkered and compartmentalized interpretation, which impermissibly narrows the statutory definition. The PTO's decision also relies on a number of impermissible bases, and its arguments rely exclusively on inapposite case law.

The PTO argues that Angiotech waived its contention that PTO's interpretation of Section 156's definition of "product" should include the product reviewed and approved by the FDA and described in the Premarket Approval Application ("PMA") – the ZILVER PTX. *See*

PTO's Mem. at 15-16 ("Plaintiff seems to contend instead that for purposes of § 156, the definition of the term 'product' should be taken from the FDA's practical description of the product that was actually reviewed and approved . . . Plaintiff did not reasonably, let alone clearly, make this argument before the [PTO] and has thus waived it.") (citing Compl. ¶¶ 48, 49, 55, 60). This is not correct. Throughout the patent term extension application process, Angiotech emphasized that the PTO should interpret "product" as defined in Section 156 to include the ZILVER PTX, the combination product reviewed and approved by the FDA. Angiotech explained that "claim 12 of the '447 Patent is 'a method of using a product' under 35 U.S.C. § 156, the product being the ZILVER [PTX]." A857-58. Quoting Section 156(a), Angiotech likewise explained to the PTO that "the '447 Patent 'claims . . . a method of using a product,' the product being the ZILVER [PTX] that was subject to a regulatory review period before its commercial marketing or use." *Id.* at A860. Angiotech has not waived its contention. This has always been Angiotech's contention.

The PTO also argues that Angiotech did not challenge the PTO's statement in its Request for Information that the "word 'product' as used in the statute is defined in 35 U.S.C. [§] 156(f)," A689, or the statement in its Initial Decision that the "term product is defined by statute to be, in the context of a review and approval of a PMA, 'any medical device,'" A779. Here, the PTO is correct. Angiotech did not challenge the PTO's statements because Angiotech agrees that a "product" under Section 156(a) includes "[a]ny medical device . . . subject to regulation under the Food, Drug, and Cosmetic Act" under Section 156(f)(1)(B). As explained during the patent term extension application process and in this action, however, Angiotech does dispute the PTO's narrow interpretation of "[a]ny medical device" to *exclude* combination products with

both drug and device components that, like the ZILVER PTX, were reviewed and approved by the FDA.

The PTO cites and quotes from numerous cases to support its decision. However, the cases are all distinguishable on their facts. The PTO's citations also in no way support a narrow interpretation of Section 156's definition of "product" to exclude patents claiming combination products like the ZILVER PTX from consideration for patent term extension. The cases do not concern combination products or the "[a]ny medical device" statutory language.

The PTO relies heavily on *Fisons plc v. Quigg*, No. CIV.A. 86-1804, 1988 WL 150851, at *1-3 (D.D.C. Aug. 19, 1988), *aff'd*, 876 F.2d 99 (Fed. Cir. 1989). There, the FDA approved three new drug products with the same active ingredient, cromolyn sodium. The PTO later denied plaintiff's applications to extend terms of patents claiming those drug products on the grounds that (i) under the plain language of Section 156(f) a "drug product" is defined as "the active ingredient of a new drug" and (ii) the drug products were not the first permitted commercial marketing or use of the active ingredient, cromolyn sodium. *Id.* at *1-3, *5 (citing 35 U.S.C. § 156(f)(2)(A)). This was the right decision. Yet, *Fisons* does not support the PTO's position in this case at all because the two cases concern entirely different "products" and thus entirely different definitions in the Hatch-Waxman Act.

The PTO overlooks these critical differences. Unlike the "product" in *Fisons*, the "product" at issue in this case is not a "drug product" narrowly defined by its active ingredient under sections 156(f)(1)(A) and 156(f)(2). Rather, here the "product" is "[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act," as defined under Section 156(f)(1)(B). Moreover, the "logical and simple interpretive exercise" the *Fisons* court found supported the PTO's position in that case supports Angiotech's position here:

> In the definitional provision of Section 156, the term "product" is defined as ["[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act."]. 35 U.S.C. § 156(f)(1)[(B)]. . . . Substituting this definition directly back into Section 156(a)(5)(A) yields the statement that a patent is ineligible for extension if it is not the first permitted commercial marketing or use of [any medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act].

See Fisons, 1988 WL 150851, at *5. Here, the application for patent term extension for the '477 Patent is based on the first permitted commercial marketing or use of the ZILVER PTX, a "medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act." *See* PTO's SUMF ¶ 4. Thus, under the language of the statute, the patent is eligible for patent term extension and the PTO's decision denying Angiotech's application for such extension was contrary to law.

Fisons is also distinguishable because, unlike the *Fisons* plaintiff, Angiotech does not dispute that the terms "product" and "approved product" in Section 156(a) have essentially the same meaning. In *Fisons*, the plaintiff argued that, because the last sentence of Section 156(a) provides that "the product" referred to in sections 156(a)(4) and (5) is "hereinafter in this section referred to as the 'approved product,'" the initial reference to "product" actually meant "approved product," or the patented product that underwent regulatory review. *Fisons*, 1988 WL 150851, at *5. But the court found that "[t]here would be no need for an additional definition if 'product' and 'approved product' were meant to be identities"; rather, "Congress merely intended to adopt a shorthand term for *those products already defined* in (a)(4) and (a)(5)." *Id.*

Not only does Angiotech not dispute the statute's use of "approved product" as a "shorthand term," *id.* at *5, or a "drafting device," *Fisons plc v. Quigg*, 876 F.2d 99, 101 (Fed. Cir. 1989), it does not assert that the operative meaning of "approved product" should be "borrowed from the FDA regulatory review process," as the PTO suggests. PTO's Mem. at 21 n.12. Indeed, it appears that it is the PTO that is relying in part on the FDA regulatory review

process to narrowly define "product" under Section 156(a), given its repeated references to the FDA's internal, administrative decision to review the ZILVER PTX in its center for reviewing medical devices under Section 515 of the FDCA and not the FDA center for reviewing new drug products under Section 505. *See* PTO's Mem. at 2-3, 6, 17, 18; SUMF ¶¶ 4, 7, 14, 21, 23.

As explained in Angiotech's Memorandum, *where* (or under *what* definition) the FDA chooses to conduct its review and approval process and *what* section of the FDCA governs that review are irrelevant to whether a patent should be granted a term extension, and any decision made on that basis is arbitrary, capricious, and contrary to law. Nothing in the FDCA permits the FDA – or, by extension, the PTO, when acting in its complementary capacity under the Hatch-Waxman Act – to ignore the device component of a combination product whose primary mode of action is that of a drug or to ignore the drug component of a combination product whose primary mode of action is that of a device. *See, e.g.*, 21 U.S.C. § 353(g)(2) ("Nothing . . . shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article."). Thus, Angiotech does not assert that the ZILVER PTX "should be treated as if it achieves its primary purpose through physical stenting *and/or* biological stenting as needed for purposes of evaluation whether the '447 patent claims the . . . 'product.'" PTO's Mem. at 22. Rather, the ZILVER PTX should be treated as a combination product whose purpose is physical *and* biological stenting, as the FDCA and the Hatch-Waxman Act direct.

Further, there is no dispute that the proper definition of "product" and "approved product" is provided in Section 156(f)(1)(B) – "[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act" – and not the FDCA or any FDA policy or publication governing the review process. For that reason, this Court's decision in *Glaxo*

Operations UK Ltd. v. Quigg, 706 F. Supp. 1224, 1232-33 (E.D. Va. 1989), *aff'd*, 894 F.2d 392 (Fed. Cir. 1990), which found that "'approved product' . . . plainly means a 'product,' as defined in Section 156(f), that has received FDA approval," also supports Angiotech's position here.

In sum, the statutory definition of "product" includes "any medical device" subject to review by the FDA, and that definition includes combination products like the ZILVER PTX, as Angiotech asserted before the PTO. The PTO's reliance on cases that concern the definition of "drug product" is unpersuasive, as is its reliance on *ad hoc* factors not included in the Hatch-Waxman Act to justify its too-narrow interpretation of Section 156. For all these reasons, the PTO's cross motion for summary judgment should be denied.

III. The PTO's decision was arbitrary and capricious because there is no requirement under the Hatch-Waxman Act that a patent claim recite the structural elements of an approved product combining both drug and device components, and the '447 Patent claims a method of biological and physical stenting using the ZILVER PTX.

The PTO's arbitrarily narrow interpretation of "product" under Section 156 fatally infects its analysis of whether claim 12 of the '447 Patent claims the ZILVER PTX, the combination product reviewed and approved by the FDA. The PTO denied Angiotech's application for patent term extension based on its erroneous 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. *See* A779-80. But the ZILVER PTX is not merely a device; rather, it is a combination product that provides a method of delivering paclitaxel to a blood vessel using a physical stent, a method that is claimed in the '447 Patent. *See* A891 ("The Zilver PTX stent uses a very small amount of paclitaxel, which is applied directly to the vessel wall.").

To be eligible for patent term extension, Section 156 requires only that a patent claim "*a method* of using a product," not "*all methods* of using a product." *See* 35 U.S.C. § 156(a). Thus,

when a combination production has more than one use, a patent need only claim one method to be eligible for patent term extension. Here, the ZILVER PTX has two uses, biological and physical stenting. And because the '447 Patent need only claim one of those uses, biological stenting, to be eligible for patent term extension, there is no requirement that it also recite any structural elements of the ZILVER PTX responsible for physical stenting.

Further, there is no requirement under Section 156 or any other provision of the Hatch-Waxman Act that a patent that claims a method of using an approved product also recite one or more structural elements of the approved product, as the PTO found in its decision denying a term extension of the '447 Patent. *See* A779-80. On the contrary, Section 156(a) only requires that the '447 Patent claim a method of using the "product," which, as explained above, includes the ZILVER PTX because it is included in Section 156(f)'s definition of "product": "[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act." 35 U.S.C. § 156(f)(1)(B).[3]

Finding no support in the Patent Act or the Hatch-Waxman Act for its position, the PTO falls back on the FDCA's definition of a "device." *See* PTO's Mem. at 23-24. Under the FDCA, "[t]he term 'device' . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . which does not achieve its primary

[3] In its Initial Decision denying patent term extension for the '447 Patent, the PTO asserted that Angiotech "conflated the concept of claiming a method of using the product (the medical device which was subject to regulatory review) with whether making, using, offering to sell, or selling the ZILVER® PTX Drug Eluting Peripheral Stent would, in theory, infringe claim 12 of the '447 Patent." A783. The PTO repeated this assertion in its Final Decision and repeats the assertion here. *See* A875-76; PTO's Mem. at 26, n.14. But like many of the authorities discussed above, the only support for the PTO's assertion, *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997), is distinguishable from the facts of this case. In *Hoechst*, the subject patent claimed a method of administering 1-hydroxy-tacrine rather than a method of administering the approved product, tacrine hydrochloride. *Id.* at 759 n.4. Here, by contrast, the '447 Patent claims a method of biological stenting that may also include physical stenting using the ZILVER PTX, the product approved by the FDA.

intended purposes through chemical action within or on the body of man or other animals." 21 U.S.C. § 321(h). But the "primary intended purposes" of the ZILVER PTX are no more relevant to the analysis under Section 156 than the FDA's determination as to the ZILVER PTX's "primary mode of action" when making its decision about which agency center should be charged with its review. *See* 21 U.S.C. § 353(g).

The PTO also continues to overlook the plain language of claim 12 of the '447 Patent, which indisputably "comprises" a method of administering paclitaxel. As the PTO concedes, the term "comprising" is a term of art in patent law that "creates a presumption that the body of [a] claim is open." *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001). And that presumption applies to claim 12, notwithstanding the PTO's attempt to rebut it using a creatively edited quotation from the Federal Circuit's decision in *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007). *See* PTO's Mem. at 25. The complete quote reveals that the term "comprising" at the beginning of a method claim like claim 12 indicates that the method may also include *steps* in addition to those explicitly recited:

> "Comprising" appears at the beginning of the claim—"comprising the steps of"—and indicates here that an infringing process could practice other steps in addition to the ones mentioned. Those six enumerated steps must, however, all be practiced as recited in the claim for a process to infringe. The presumption raised by the term "comprising" does not reach into *each of the six steps* to render every word and phrase therein open-ended—especially where, as here, the patentee has narrowly defined the claim term it now seeks to have broadened.

Dippin' Dots, 476 F.3d at 1343 (emphasis added). In its Memorandum, the PTO changed this quote to substitute the words "a claim" for "each of the six steps," thereby erroneously suggesting that "comprising" in claim 12 may not include other unrecited steps in addition to the biological stenting explicitly claimed, including the physical stenting of a blood vessel using the ZILVER PTX. PTO's Mem. at 25. But that is not what *Dippin' Dots* says, and the PTO's suggestion should be rejected.

The use of "comprising" in claim 12 to include both physical and biological stenting is consistent with the '447 Patent's specification, and the PTO has not shown otherwise. The '447 Patent states that "*a therapeutically effective dosage of a therapeutic conjugate or dosage form is useful in* . . . vascular surgical procedures such as angioplasty, atheroectomy, *placement of a stent (e.g., in a vessel),* thrombectomy, and grafting." A641 ('447 Patent, col. 30, lines 38-44) (emphasis added). Thus, the specification of the '447 Patent supports Angiotech's position that claim 12 recites a method that includes both biological stenting (administering paclitaxel) and physical stenting (through placement of a stent). Accordingly, claim 12 claims a method of using the ZILVER PTX, the product reviewed and approved by the FDA.

On one hand, the PTO's decision relies on the faulty premise that a "product" under Section 156 can only be a device, rather than "any medical device" that undergoes review by the FDA, including a product like the ZILVER PTX that combines both drug and physical components. On the other hand, the PTO's decision misconstrued (or ignored) language in the '447 Patent claiming a method for biological stenting that may also include physical stenting using the ZILVER PTX. Because neither the PTO's faulty interpretation of Section 156 nor its misconstruction of the '447 Patent supports its decision to deny patent term extension, the PTO's decision must be declared arbitrary, capricious, and contrary to law, and summary judgment must be entered in favor of Angiotech.

CONCLUSION

The PTO's decision is entitled to no deference and must be reviewed *de novo*. The statutory definition of "product" includes the ZILVER PTX, a combination product subject to regulation under the FDCA that was reviewed and approved by the FDA. Under the Hatch-Waxman Act, the '447 Patent need not recite any structural components of a device to be eligible

for patent term extension. And here, the '447 Patent's plain language demonstrates that it claims a method for biological stenting that may also include physical stenting using the product approved by the FDA, the ZILVER PTX. For each and all of these reasons, the PTO's decision should be declared unlawful, its cross motion for summary judgment should be denied, summary judgment should be entered for Angiotech, and the matter should be remanded to the PTO with instructions to approve an extension of the term of the '447 Patent.

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Respectfully submitted,

/s/

Damon W.D. Wright (VA Bar No. 40319)
Joshua Counts Cumby (VA Bar No. 82021)
VENABLE LLP
575 7th St NW
Washington, DC 20004
(202) 344-4000 telephone
(202) 344-8300 fax
dwdwright@venable.com
jccumby@venable.com
Counsel for Plaintiff
Angiotech Pharmaceuticals Inc.

CERTIFICATE OF SERVICE

I hereby certify that on May 11, 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:

Andrew S. Han
Assistant United States Attorney
Office of the United States Attorney
Justin W. Williams U.S. Attorney's Building
2100 Jamieson Ave.
Alexandria, VA 22314
Tel: (703) 299-3970
Fax: (703) 299-3983
Email: andrew.han@usdoj.gov

/s/
Joshua Counts Cumby (VA Bar No. 82021)
Counsel for Plaintiff
Angiotech Pharmaceuticals Inc.