IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

ANGIOTECH PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 1:15cv1673 (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.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT

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Pursuant to Local Rule 7(F)(1), Defendants Michelle K. Lee, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("USPTO"), and Drew Hirshfeld, Commissioner for Patents, through their undersigned counsel, hereby respectfully submit this memorandum of law in support of their cross motion for summary judgment in the above-captioned action.

INTRODUCTION

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act," or, hereinafter, "the Act"), Pub. L. No. 98-417, 98 Stat. 1585, as codified at 35 U.S.C. § 156, a patent term may be extended to compensate for the delay in marketing and use caused by the U.S. Food and Drug Administration' ("FDA") approval process for a product incorporating the subject patent. In this suit under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*, Plaintiff Angiotech Pharmaceuticals Inc. challenges the USPTO's decision to deny its application for a patent term extension ("PTE") for U.S. Patent No. 5,811,447 ("the '447 patent"). Plaintiff had applied for a five-year PTE for the '447 patent based on the regulatory review by the FDA of the ZILVER® PTX Drug Eluting Peripheral Stent ("Zilver PTX Stent"), a combination product composed of a physical stent coated with the restenosis-reducing drug paclitaxel. Because the '447 patent does not claim a method of using the Zilver PTX Stent, as a medical device, the USPTO's decision denying Plaintiff's PTE application should be affirmed.

To begin, the USPTO reasonably concluded that the Zilver PTX Stent is a medical device for purposes of evaluating PTE eligibility. Although the Zilver PTX Stent is composed of both a drug component and a device component, the FDA conducted its review of the Zilver PTX Stent as a medical device under section 515 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), *see* 21 U.S.C. § 360e, instead of as a new drug product under section 505 of the same—a

categorization that Plaintiff does not question. According to the plain language of § 156, a "product" for purposes of PTE eligibility, as relevant here, is unambiguously defined as a "medical device," and a "device" is further defined in the FDCA as a physical article that "does not achieve its primary intended purposes through chemical action," *see* 21 U.S.C. § 321(h).

Accordingly, the USPTO properly found that the '447 patent does not "claim" a medical device such as the Zilver PTX Stent. Plaintiff identified claim 12 of the '447 patent as claiming the product. But following established principles of claim construction, claim 12's recitation of a "method for biologically stenting a mammalian blood vessel" is insufficient to describe the structure of the Zilver PTX Stent or to enable its use or making. And the '447 patent specification provides no basis for reading claim 12 in a manner that claims a *method* of using or making the medical device at issue either. Because the structure of the Zilver PTX Stent is not claimed, the '447 patent does not claim the approved medical device and is therefore not eligible for PTE under § 156(a).

Because the USPTO's decision denying Plaintiff's PTE application was neither arbitrary nor capricious, Defendants' motion for summary judgment should be granted.

STATUTORY AND REGULATORY BACKGROUND

I. GENERAL PROVISIONS REGARDING PATENT TERM EXTENSION

In general, a patent in the United States expires twenty years from the date on which the application for the patent is filed. *See* 35 U.S.C. § 154(a)(2). For patents claiming certain drugs and medical devices, some of the patent term (i.e., the time during which the patent owner has exclusive rights over an invention) may be lost due to the FDA's approval process for products using the patent. *See Genetics & IVF Inst. v. Kappos*, 801 F. Supp. 2d 497, 500 (E.D. Va. 2011). Thus, Congress enacted the Hatch-Waxman Act, which, among other things, allowed the patent owner "to apply for a patent term extension 'to compensate for the delay in obtaining FDA

approval.'" *Meds. Co. v. Kappos*, 731 F. Supp. 2d 470, 471-72 (E.D. Va. 2010) (quoting *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996)).[1]

Specifically, Title II of the Hatch-Waxman Act concerns patent term extensions and is codified at 35 U.S.C. § 156. *See Glaxo I*, 706 F. Supp. at 1225 n.2. Pursuant to that statute, if certain conditions are met, "[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." 35 U.S.C. § 156(a); *see also* 37 C.F.R. § 1.710(a). As relevant here, those conditions are:

> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;
>
> (2) the term of the patent has never been extended under subsection (e)(1) of this section;
>
> (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use; [and]
>
> (5) . . . the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; . . . .

35 U.S.C. § 156(a). Section 156(a) further notes that "[t]he product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the 'approved product.'" *Id.*

[1] As summarized by the Federal Circuit, the Hatch-Waxman Act has two general purposes: "(1) to increase the availability of low-cost drugs by expanding a generic drug approval procedure; and (2) to further encourage new drug research by restoring some of the patent term lost while drug products undergo testing and await FDA pre-market approval." *Glaxo Operations UK Ltd. v. Quigg* ("*Glaxo II*"), 894 F.2d 392, 396 (Fed. Cir. 1990) (citing H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48), *aff'g Glaxo Operations UK Ltd. v. Quigg* ("*Glaxo I*"), 706 F. Supp. 1224 (E.D. Va. 1989).

The term "product" is defined as either a "drug product" (which itself is defined in § 156(f)(2)) or a "medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act." *Id.* § 156(f)(1). A "device," in relevant part, is:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> [. . .]
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h); *see also* 21 C.F.R. § 60.3(b)(13). And a "combination product" includes, among other things, "[a] product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity." 21 C.F.R. § 3.2(e).

II. FDA REVIEW AND THE DETERMINATION OF THE LENGTH OF PTE

In general, the FDA reviews a new drug product pursuant to section 505 of the FDCA, *see* 21 U.S.C. § 355, and reviews a Class III medical device[2] pursuant to section 515 of the same, *see id.* § 360e. For combination products, the FDA must first determine the "primary mode of action" of the combination product. *See id.* § 353(g)(1). A "mode of action" is defined as "the means by which a product achieves an intended therapeutic effect or action," of which there are three types: a biological product, a device, and a drug. *See* 21 C.F.R. § 3.2(k). The "primary

[2] Medical devices are categorized into three classes depending on the risks they present. *See* 21 U.S.C. § 360c. Class III devices receive the most federal oversight.

mode of action" is the "single mode of action of a combination product that provides the most important therapeutic action of the combination product"—that is, the "mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product." *Id.* § 3.2(m). If the FDA determines that the primary mode of action of a combination product is that of a drug, then the combination product is reviewed pursuant to section 505 of the FDCA like all new drugs. *See* 21 U.S.C. § 353(g)(1). Similarly, if the FDA determines that the primary mode of action of a combination product is that of a device, then it is reviewed pursuant to section 515 of the FDCA like all Class III medical devices. *See id.*

Whether the FDA reviews a product as a drug or as a device dictates the length of the "regulatory review period," which is the primary factor used for calculating the length of PTE to be issued for an eligible patent that is incorporated into the product. *See* 35 U.S.C. § 156(c) (calculating PTE length based on the "regulatory review period"); *id.* § 156(g) (defining "regulatory review period" based on the product category assigned by the FDA); *see also* 21 C.F.R. § 60.22 (determining regulatory review periods for drugs, additives, and medical devices); 37 C.F.R. § 1.775 (calculating PTE for drugs); *id.* § 1.777 (calculating PTE for medical devices). PTE is capped at no more than five years. *See* 35 U.S.C. § 156(g)(6)(A). Notably, the Hatch-Waxman Act does not specifically address combination products in this or any respect, nor have either the FDA or the USPTO issued regulations guiding the determination of the regulatory review period or the calculation of PTE for combination products as a stand-alone category.

STATEMENT OF UNDISPUTED MATERIAL FACTS[3]

I. THE PATENT: U.S. PATENT NO. 5,811,447

1. On September 22, 1998, the USPTO issued the '447 patent, titled "Therapeutic Inhibitor of Vascular Smooth Muscle Cells." A600. 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.

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.

II. THE PRODUCT: ZILVER® PTX DRUG ELUTING PERIPHERAL STENT

3. The Zilver PTX Stent is a "self-expanding nitinol stent coated on its outer surface with the drug paclitaxel."[4] A714. Among other uses, paclitaxel "applied locally reduces restenosis by inhibiting smooth muscle cell proliferation."[5] A716. Paclitaxel itself was first approved by the FDA in 1992. A707.

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

[3] The APA confines review of Executive Branch action by the Article III judiciary to the administrative record of proceedings before the pertinent agency. *See* 5 U.S.C. § 706; *Camp v. Pitts*, 411 U.S. 138, 142 (1973). As such, "there can be no genuine issue of material fact" in an APA action. *R.R. Donnelly & Sons v. Dickinson*, 123 F. Supp. 2d 456, 458 (N.D. Ill. 2000). The USPTO nevertheless provides this Court with a statement of undisputed material facts to explain the administrative proceedings in this action and to comply with Local Civil Rule 56(B).

[4] Nitinol is also known as nickel titanium. A587.

[5] Restenosis is the renarrowing of an artery over time, following medical treatments such as balloon angioplasty or stenting. A891.

("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.

III. PLAINTIFF'S APPLICATION FOR PTE

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.

6. Plaintiff sought PTE of the statutory maximum of five years. A596-A597.

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.

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.

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.

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).

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.

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

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.

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.

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.*

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.

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.*

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.

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.

IV. THE USPTO'S FINAL DECISION, AND PROCEDURAL HISTORY

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.

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.*

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.*

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.[6] 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.*

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)).

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.

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

[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.

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.

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.

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.[7]

STANDARD OF REVIEW

I. SUMMARY JUDGMENT

In an APA action, "the ordinary standard for summary judgment applies." *Genetics & IVF Inst.*, 801 F. Supp. 2d at 502. As such, a court should grant summary judgment if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). However, because the APA "confines

[7] On December 22, 2015, the '447 patent expired.

judicial review of executive branch decisions to the administrative record of proceedings before the pertinent agency[,] . . . there can be no genuine issue of material fact in an APA action, and the legal questions presented in [an APA] action are therefore ripe for resolution on cross-motions for summary judgment." *See Genetics & IVF Inst.*, 801 F. Supp. 2d at 502.

II. ADMINISTRATIVE PROCEDURE ACT

Under the APA, "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A). In undertaking this review, the district court "perform[s] only the limited, albeit important, task of reviewing agency action to determine whether the agency conformed with controlling statutes, and whether the agency has committed a clear error of judgment." *Holly Hill Farm Corp. v. United States*, 447 F.3d 258, 263 (4th Cir. 2006). The standard of review is "narrow," and does not authorize the district court "to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977).

ARGUMENT

The USPTO properly denied Plaintiff's application for PTE. At the threshold, the USPTO's thorough and well-reasoned Final Decision interpreting § 156 warrants, at a minimum, *Skidmore* deference.[8] *See generally Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). "*Skidmore*

[8] In this district, Judge Hilton has held that a PTE decision itself by the USPTO does not merit any *Chevron* deference due, in part, to the non-precedential nature of such decisions. *See Meds. Co.*, 731 F. Supp. 2d at 477 (discussing *Chevron, USA, Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)). Nonetheless, "'some deference' must be accorded to an agency's interpretive rule even if the rule is not entitled to full *Chevron* deference." *Cathedral Candle Co. v. U.S. Int'l Trade Comm'n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005) (quoting *Reno v. Koray*, 515 U.S. 50, 61 (1995)). Indeed, despite declining to apply *Chevron* deference to the USPTO's decision in *Medicines Co.*, Judge Hilton still afforded *Skidmore* deference to the USPTO's decision in his review in that case. *See Meds. Co.*, 731 F. Supp. 2d at 477.

deference can apply to agency interpretations not having the force of law, such as those contained in opinion letters, policy statements, agency manuals, and enforcement guidelines." *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338, 349 (E.D. Va. 2009) (citing *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000)), *aff'd sub nom., PhotoCure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010). "Such agency interpretations are 'entitled to respect . . . but only to the extent that those interpretations have the power to persuade.'" *Id.* (quoting *Christensen*, 529 U.S. at 587). Accordingly, how much deference to award depends on "the writer's thoroughness, logic, and expertise." *See id.* As the Federal Circuit has admonished, this does not mean that the standard "reduces to the proposition that 'we defer if we agree.'" *See Cathedral Candle Co.*, 400 F.3d at 1366. Rather, a court should defer to an agency interpretation of the statute that it administers:

> if the agency has conducted a careful analysis of the statutory issue, if the agency's position has been consistent and reflects agency-wide policy, and if the agency's position constitutes a reasonable conclusion as to the proper construction of the statute, even if [the court] might not have adopted that construction without the benefit of the agency's analysis.

Id.

In this case, the USPTO's Final Decision reflects all of these touchstones. First, to the extent Plaintiff adequately preserved the issue for judicial review, the USPTO's treatment of the Zilver PTX Stent under § 156 as a medical device is a reasonable construction of the statute. Second, the USPTO's conclusion that the '447 patent does not "claim" the Zilver PTX Stent is similarly supported by the relevant law.

I. THE USPTO'S TREATMENT OF THE ZILVER PTX STENT AS A "MEDICAL DEVICE" FOR PURPOSES OF § 156 IS NEITHER ARBITRARY NOR CAPRICIOUS

In its Complaint, Plaintiff's primary argument appears to be that the USPTO acted arbitrarily and capriciously when it defined the Zilver PTX Stent as a medical device for

purposes of § 156 based on the FDA's review of the product under section 515 of the FDCA. *See, e.g.*, Compl. ¶ 48 ("This determination [by USPTO] misconstrues the identity of the 'approved product' that is entitled to patent term extension under Section 156.").[9] 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—which, for the Zilver PTX Stent, was a product that "contains a physical stent component and drug component." *See, e.g.*, *id.* ¶ 49 (arguing that "the approved product is the product *defined in the PMA*" (emphasis added)). But this new argument by Plaintiff is untenable for several reasons.

To begin, Plaintiff did not reasonably, let alone clearly, make this argument before the USPTO and has thus waived it. In the PTE application, Plaintiff acknowledged that the FDA reviewed the Zilver PTX Stent under section 515 of the FDCA, A588, and it only compared claim 12 to a description of the Zilver PTX Stent taken from its *own* product literature, A590-A591. In the RFI response and the request for reconsideration, Plaintiff did attempt to compare claim 12 to the FDA's descriptions of the Zilver PTX Stent, A696-A699, A856-A859; however, Plaintiff did not actually challenge the USPTO's statement in the RFI that the "word 'product' as used in the statute is *defined in 35 U.S.C. [§] 156(f),*" A689 (emphasis added), or the statement in the 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 (emphasis added). Plaintiff thus deprived the USPTO of a proper opportunity to address this argument over how to define the "product"

[9] In another example, Plaintiff asserts: "The FDA recognized the ZILVER PTX as a combination product. . . . [H]owever, the PTO wrongly asserted that because the ZILVER PTX was reviewed by the FDA as a device, it incorrectly viewed the ZILVER PTX exclusively as a device . . . ." *Id.* ¶ 55. And elsewhere, Plaintiff argues: "[U]nlike the FDA, the PTO wants to put products and patents in discrete buckets as either about a device or about a drug, and ignore the secondary function of an approved combination product." *Id.* ¶ 60.

for purposes of § 156. At best, the USPTO—on its own initiative—chose to correct Plaintiff's suggested re-characterization of the Zilver PTX Stent "as a 'drug product' rather than a 'medical device.'" A870-A871 (noting that Plaintiff's reference to the Zilver PTX Stent as the "'ZILVER controlled-delivery system' does not change the nature of the product"). But this is simply insufficient to meet the administrative exhaustion requirements under the APA. Consequently, Plaintiff may not raise this argument for the first time under the APA in this Court. *See Lane Hollow Coal Co. v. Dir., Office of Workers' Comp. Programs*, 137 F.3d 799, 806 (4th Cir. 1998).

Nonetheless, even if Plaintiff had properly exhausted this argument, it falters on the merits. The plain language of the Hatch-Waxman Act support the USPTO's decision to treat the Zilver PTX Stent as a medical device for purposes of evaluating Plaintiff's PTE application under § 156. It is well-settled that "[a]s in any case of statutory construction, [the Court's] analysis begins with the language of the statute . . . . And where the statutory language provides a clear answer, it ends there as well." *Genetics & IVF Inst.*, 801 F. Supp. 2d at 503-04. Such is the case here: § 156 plainly defines the Zilver PTX Stent as a "medical device."

A. The Plain Language of § 156 Defines "Product" as a "Medical Device"

As explained in the Final Decision, in order for a patent (e.g., the '447 patent) to be eligible for PTE based on FDA review of a particular product (e.g., the Zilver PTX Stent), the patent must claim the product, a method of using the product, or a method of manufacturing the product. A871-A872. And per § 156, a product may be defined as a drug or it may be defined as a medical device. 35 U.S.C. § 156(f)(1). In this case, in accordance with 21 U.S.C. § 353, the FDA reviewed the Zilver PTX Stent as a medical device pursuant to section 515 of the FDCA,

and not as a new drug pursuant to section 505. A588.[10] Plaintiff does not challenge the FDA's decision to categorize and regulate the Zilver PTX Stent as a medical device. Therefore, consistent with the plain language definition of "product" as a "medical device" in § 156(f), and consistent with descriptions of the product as a medical device given by Plaintiff itself, the FDA, and Cook Medical, the USPTO also treated the Zilver PTX Stent as a medical device when considering Plaintiff's application for PTE. A870-A874. To that end,the USPTO emphasized that the statutory definition of a "medical device" focuses on the "structural features" of the device and "excludes" any device that would "achieve its primary intended purposes through chemical action." A873 (citing 21 U.S.C. § 321(h)).

Plaintiff challenges this construction by arguing, in essence, that the Court should ignore the statutory definitions and look elsewhere for the definition of "product." Specifically, Plaintiff argues that "[t]he approved product is the product *defined in the PMA*," which here is a "product that contains a physical stent component and a drug component identified as paclitaxel." *See* Compl. ¶¶ 49-50 (emphasis added). As Plaintiff apparently would have it, the USPTO's evaluation of its PTE application should have therefore considered the Zilver PTX Stent as providing either physical *and/or* biological stenting as necessary to satisfy the conditions for PTE. But Plaintiff does not identify any provision within § 156 or case law that is consistent with this understanding.

Indeed, in an analogous case concerning PTE for drug products, the district court (as affirmed by the Federal Circuit) agreed that a "product" for purposes of § 156 is limited to its statutory definition and not, as Plaintiff would have it, "the product defined in the PMA," *see*

[10] As the USPTO noted, the FDA has determined that drug-eluting stents like the Zilver PTX Stent primarily function "to physically maintain vessel lumen patency, *while the drug component has played a secondary role in preventing restenosis*." A870 (emphasis added).

Compl. ¶¶ 49-50. In *Fisons plc v. Quigg* ("*Fisons I*"), 1988 WL 150851 (D.D.C. Aug. 19, 1988), *aff'd, Fisons plc v. Quigg* ("*Fisons II*"), 876 F.2d 99 (Fed. Cir. 1989), the plaintiff-company ("Fisons") applied for PTEs on three newly patented drugs each containing a "new use or dosage form" for the same active ingredient of a drug that had previously been reviewed and approved by the FDA. Because PTE can issue only for "the first permitted commercial marketing or use of the *product*," *see* 35 U.S.C. § 156(a)(5)(A) (emphasis added), Fisons argued—much like Plaintiff here—that the term "product" should refer to any product "*that underwent regulatory review* regardless of whether it contained a previously patented [drug]." *See* 1988 WL 150851, at *4 (emphasis added). In other words, Plaintiff attempted to distinguish the three newly patented drugs from the previously approved drug (even though they all shared the same active ingredient) by focusing on the differences in the actual drug products reviewed by the FDA.

However, the district court rejected this definition of "product" based on the plain language of § 156. Using a "logical and simple interpretative exercise," the district court substituted the statutory definition of "product" given in § 156(f) "directly back" into § 156(a) to demonstrate that Fisons's proposed definition of "product" was inconsistent with the plain language of § 156. *See id.* Specifically, at the time the case was decided, § 156(f) defined the term "product" for purposes of drugs generally as the "active ingredient" of the drug. *See* 35 U.S.C. § 156(f)(1)(A), (2) (1988). Thus, substituting the term "active ingredient" in for the term "product," the district court concluded that a patent is ineligible for extension if it is not "the first permitted commercial marketing or use of the *active ingredient*" of a patented drug product. *See Fisons I*, 1988 WL 150851, at *5. As such, Fisons's attempt to define "product" in any other way—such as according to the FDA's general descriptions of the approved product—was inconsistent with the plain language of § 156. *See id.*

In this case, the USPTO engaged in precisely the *same* semantic exercise in evaluating Plaintiff's PTE application. The FDA reviewed the Zilver PTX Stent as a medical device, A872, which is included in the definition of "product" for purposes of § 156, *see* 35 U.S.C. § 156(f)(1)(B) (defining "product" as "[a]ny medical device . . . subject to regulation under the [FDCA]"). Therefore, the USPTO substituted "medical device" into § 156(a) to reason that PTE should issue only if the '447 patent "claims . . . a method of using a [medical device]." A872. As in *Fisons I*, the result of the semantic exercise is thus straightforward: the plain language of § 156 supports the USPTO's treatment of the Zilver PTX Stent as a medical device—which, by its statutory definition, necessarily has a physical structure, *see* 21 U.S.C. § 321(h)—for purposes of the Act. Any other definition of "product" in this regard is untenable: Plaintiff's assertion that the PMA for the Zilver PTX Stent or the FDA's general descriptions of it should *define* the patented product when evaluating a PTE application must be rejected.

B. The Plain Language of § 156 Defines "Approved Product" in the Same Way as "Product"

Separately, Plaintiff appears to also argue that the term "*approved* product" in § 156 has a different meaning than "product" and that "*approved* product is the product defined in the PMA." *See* Compl. ¶¶ 48-50 (emphasis added); *see also id.* ¶ 50 (asserting that "the PTO has no authority to redefine the product approved by the FDA in the PMA"). But other courts have rejected this reading of the Act as well.

To be sure, in *Fisons*, Fisons made virtually the same argument. *See Fisons I*, 1988 WL 150851, at *5 (acknowledging the plaintiff's argument that the USPTO's construction "fails to give effect to the language referring to 'approved product'" in the last sentence of § 156(a)).[11]

[11] That sentence reads: "The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the 'approved product.'" 35 U.S.C. § 156(a).

Fisons contended that "'approved product' . . . surely refers to the patented product that underwent regulatory review," and that thus "'product' must be read broadly to include whatever patented invention seeks benefit of the restoration provisions." *See id.* But the district court (as affirmed by the Federal Circuit) dismissed this argument, observing that there was no "direct support" for Fisons's argument. *See id.* at *5 n.35[12]; *see also Fisons II*, 876 F.2d at 100-01 (rejecting Fisons's contention that "the term 'product' [in § 156(a)] refers to *the particular drug product that the FDA approved*" (emphasis added)).

In *Glaxo I*, this Court addressed, and rejected, an almost identical argument made by the plaintiff-company ("Glaxo"). Glaxo argued that an "'approved product' . . . is self-evidently the product FDA approved." *See Glaxo I*, 706 F. Supp. at 1232. Based on the plain language of the statute, however, this Court disagreed with Glaxo and held that "'approved product' . . . plainly means a 'product,' *as defined in Section 156(f)*, that has received FDA approval." *See id.* at 1232-33 (Ellis, J.) (emphasis added), *aff'd, Glaxo II*, 894 F.2d 392.

Accordingly, to the extent Plaintiff contends that the reference to the "approved product" should refer to anything other than its statutory definition in § 156, the argument should be dismissed.

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Contrary to Plaintiff's arguments, it is actually Plaintiff—not the USPTO—who improperly seeks to "redefine" the "product" (or the "approved product") for purposes of

[12] The district court concluded that the structure of § 156(a) showed that "approved product" was merely a "shorthand term" for reading the statute," *id.* at *5, or, as the Federal Circuit described it, "merely a drafting device," *Fisons II*, 876 F.2d at 101. Moreover, the district court found that the legislative history of the Hatch-Waxman Act on this particular point "clearly implies that the term 'approved product' was intended to have a restrictive meaning in the context of the extension provisions *and not one borrowed from the FDA regulatory review process*." *See Fisons I*, 1988 WL 150851, at *5 n.37 (emphasis added)

§ 156(a). *See* Compl. ¶ 50. The plain language of § 156 is fundamentally consistent with the USPTO's consideration of the Zilver PTX Stent as a medical device, and not with Plaintiff's prescriptive contentions that the "product" or the "approved product" in § 156 should be defined simply by how the FDA describes the patented product during its regulatory. *Cf. Arnold P'ship v. Rogan*, 246 F. Supp. 2d 460, 465 (E.D. Va. 2003) (rejecting the plaintiff's argument that the USPTO's denial of its PTE application was improper because the USPTO's evaluation "is inconsistent with the realities of the FDA's practice"), *aff'd sub nom. Arnold P'ship v. Dudas*, 362 F.3d 1338 (Fed. Cir. 2004).[13] There is no basis to conclude, as Plaintiff asserts, that the Zilver PTX Stent should be treated as if it achieves its primary purpose through physical stenting *and/or* biological stenting as needed for purposes of evaluating whether the '447 patent claims the Zilver PTX Stent "product." By contrast, the USPTO's analysis is in line with past precedent and the statutory language itself and thus warrants a high level of *Skidmore* deference. The USPTO's decision on this front was neither arbitrary nor capricious and should be affirmed.

II. THE '447 PATENT DOES NOT "CLAIM" A METHOD OF USING THE ZILVER PTX STENT

The USPTO's determination that the '447 patent does not claim a method of using the Zilver PTX Stent was also neither arbitrary nor capricious. To be eligible for PTE, a patent must "*claim*[] a product, a method of using a product, or a method of manufacturing a product." 35 U.S.C. § 156(a) (emphasis added). Since its original application for PTE, Plaintiff has repeatedly

[13] Plaintiff also appears to suggest that the mere fact that the FDA undertook a review of the Zilver PTX Stent, despite having previously reviewed the physical component of the product (i.e., an uncoated Zilver Stent), necessarily means that *some* PTE is justified for *some* patent. *See* Compl. ¶ 53. But the legislative history of the Hatch-Waxman Act contradicts this notion. *See Fisons I*, 1988 WL 150851, at *6 (finding that legislative history showed that the Hatch-Waxman Act was intended, in part, to incentivize "research and development of *certain* products"—not all products—"which are subject to premarket government approval" (emphasis in original) (quoting H.R. Rep. No. 98-857, at 15 (1984))).

asserted that claim 12 of the '447 patent claims a method of using the Zilver PTX Stent. A590-A591, A695-A699, A857-A860; *see also* Compl. ¶¶ 28-32. Thus, having reasonably determined that the Zilver PTX Stent was a medical device for purposes of § 156(a), *see supra* Part I, the USPTO correctly identified the fundamental issue to be whether claim 12 "claims" a method of using the Zilver PTX Stent medical device—which in this case, it did not. A872.

As before, because this is a matter of statutory interpretation, the Court's analysis "begins with the language" of § 156. *Genetics & IVF Inst.*, 801 F. Supp. 2d at 503-04. To that end, the Federal Circuit has explained that the "term 'claims' has been used in patent litigation since the Patent Act of 1836 to define the invention that an applicant believes is patentable," or, in other words, it "provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." *Hoechst-Roussel*, 109 F.3d at 758 (quoting *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257-58 (Fed. Cir. 1989)). The claims in a patent specification must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." *Id.* (citing 35 U.S.C. § 112). For a patent to claim a product, a method of using a product, or a method of manufacturing a product, "the patentee must have satisfied numerous tests of patentability, including, *inter alia*, disclosure of the best mode of making the claimed product, and a description which would enable a person skilled in the art to make and use the claimed invention." *See id.* at 758-59 & n.2 (citing 35 U.S.C. § 112).

Here, the USPTO noted that claim 12 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." A873. Then, the USPTO noted

that the statutory definition of a medical device 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 of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.'" A873 (emphasis added) (quoting 21 U.S.C. § 321(h)). Comparing claim 12 to § 321(h), the USPTO found that the patent claim "does not recite any structural features of a medical device," and instead "recites a method whereby the primary purpose ('biological stenting') is achieved via chemical action." *Id.* While the USPTO agreed with Plaintiff that claim 12 "encompasses the local administration of drugs to the blood vessel wall"—that is, a desired use *of the '447 patent*—the USPTO also correctly explained that this "does not answer the question of whether claim 12 claims a method of using *a drug-eluting stent*." A873 (emphasis added).

To answer that question, the USPTO looked at the claim language in light of the '447 patent specification to determine the "metes and bounds" of the claim and found that it did not disclose the use of any sort of stent medical device, let alone the Zilver PTX Stent. A780, A873. For example, in its Initial Decision, which the USPTO incorporated into its Final Decision, A870, the USPTO noted that it could identify numerous references in the specification describing the patented biological stenting as being "achieved through the targeted administration of an active pharmaceutical agent," i.e., chemical action, but no references to a *physical* stent. A781. What is more, in the Final Decision, the USPTO noted that the "only recitation of 'stent' in the entire specification . . . *defines the patient population* that may benefit from a method of biological stenting" rather than describing a method of *using* a physical stent. A874 (emphasis added). Accordingly, although the '447 patent specification clearly disclosed the *goal* of preventing restenosis through the administration of paclitaxel, it did not indicate in

any way a "mode of administration of [paclitaxel] *via a drug-coated stent*." A783 (emphasis added). Consequently, the USPTO determined that there was insufficient 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 medical device like the Zilver PTX Stent. *See* A873 (emphasis added); *see also Ariad Pharms.*, 598 F.3d at 1351 (holding that the written description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed").

In contrast to its argument that a claim to biological stenting *alone* claims the use of the Zilver PTX Stent, Plaintiff also asserts that the term "comprises" in claim 12 "indicates that other steps may be included" and that therefore nothing in the claim "precludes achieving biological stenting in conjunction with physical stenting." *See* Compl. ¶ 69. But this argument is flawed as well. Although it is true that the word "'comprising' . . . creates a presumption that the body of the claim is open," *Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1350 (Fed. Cir. 2001), it "is not a weasel word with which to abrogate claim limitations," *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007). "The presumption raised by the term 'comprising' does not reach into [a claim] to render every word and phrase therein open-ended . . . ." *See id.* The claim must still be interpreted consistently with the specification. *See ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1320 (Fed. Cir. 2012) (rejecting a claim construction based on the ordinary meaning in industry practice because "the specification is not consistent with that meaning"); *see also Dippin' Dots*, 476 F.3d at 1342-43 (affirming the district court's limitation of the scope of a claim based on the patent's written description, despite the use of the word "comprising" in the claim); *Crystal Semiconductor*, 246 F.3d at 1350-51 (holding that "comprising" suggests a claim encompasses additional elements "unless the written description or the prosecution history clearly limits" the claim). As just explained, the

'447 patent specification does not disclose the use of any physical stent in the administration of paclitaxel to a blood vessel. As such, the use of the term "comprising" in claim 12 does not broaden the scope of the claim to include such products for determining PTE.[14]

All in all, because the '447 patent does not disclose any physical medical device, it does not claim a method of using the Zilver PTX Stent. And because the USPTO's decision reaching this conclusion is consistent with well-settled precedent, its denial of Plaintiff's PTE application was neither arbitrary nor capricious, and significant *Skidmore* deference is warranted. Thus, the USPTO's Final Decision should be affirmed.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court grant their Cross Motion for Summary Judgment.

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[14] Further, as the USPTO properly found in its Final Decision, even if the use of the Zilver PTX Stent may *infringe* the method recited in claim 12, "which method *comprises* administering to the blood vessel of a mammal a cytoskeletal inhibitor," that does not mean that claim 12 claims a method of using the Zilver PTX Stent for purposes of determining PTE. A876; *see also Hoescht-Roussel*, 109 F.3d at 759 ("[T]he concept of a 'claim' is different from the concept of infringement, and, as a result, the plain meaning of 'claims' is not the same as the plain meaning of infringement.").

Dated: April 20, 2016

Respectfully submitted,

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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 (NEF) to the following counsel of record:

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