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.	)	
	)	

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

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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 opposition to Plaintiff's Cross Motion for Summary Judgment ("Plaintiff's Motion") (Dkt. Nos. 18-19) in the above-captioned action.

INTRODUCTION

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") pursuant to the Hatch-Waxman Act.[1] Plaintiff's PTE application was based on the regulatory review by the U.S. Food and Drug Administration ("FDA") of the ZILVER® PTX Drug Eluting Peripheral Stent ("Zilver PTX Stent"). The FDA reviewed the Zilver PTX Stent, a combination product composed of a physical stent coated with the restenosis-reducing drug paclitaxel, as a medical device. Yet, according to Plaintiff, the USPTO's determination that the '447 patent was ineligible for PTE because it does not claim a method of using a medical device like the Zilver PTX Stent was arbitrary and capricious in contravention of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.* Plaintiff's contention finds no support in any statute, regulation, or relevant case law.

In general, Plaintiff asks this Court to ignore the plain language of 35 U.S.C. § 156—where the provisions of the Hatch-Waxman Act concerning PTE are codified. Instead, in order to analyze the USPTO's decision, Plaintiff would have this Court look to various documents filed with or created by the FDA, especially the original Premarket Approval Application ("PMA")

[1] The official name of the Hatch-Waxman Act is the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

for the Zilver PTX Stent,[2] or to inapposite provisions within the Federal Food, Drug, and Cosmetic Act ("FDCA"). Not only is Plaintiff's position illogical, its assertions are largely conclusory and, tellingly, do not rely on a single authority interpreting § 156 or addressing patent claim construction.

First, Plaintiff contends that the USPTO erred when it treated the Zilver PTX Stent as a medical device for purposes of § 156, because the Zilver PTX Stent is a combination product comprising both a drug component and a device component. Plaintiff notes that the PMA for the Zilver PTX Stent and other FDA literature generally describes drug-eluting stents, including the Zilver PTX Stent, in this manner. However, Plaintiff concomitantly concedes that the FDA conducted its regulatory review of the Zilver PTX Stent as a medical device under section 515 of the FDCA, *see* 21 U.S.C. § 360e. A588. In so doing, the FDA necessarily determined as a threshold matter that, although the Zilver PTX Stent is a combination product, its "primary mode of action" was as a device. *See id.* § 353(g)(1). And by statute, the "primary mode of action" dictates the FDA's regulatory review of a combination product. *See id.* Plaintiff fails to identify any authority to suggest that the USPTO's decision to also treat the Zilver PTX Stent as a device as opposed to a combination product was unreasonable. To the contrary, § 156's definition of a "product" for purposes of PTE eligibility includes a "medical device," but not a "combination product."

Second, Plaintiff argues that the USPTO's conclusion that the '447 patent must recite at least one structural element of the Zilver PTX Stent in order to claim a method of using that product finds no basis in the statute. Like the first argument, however, this argument is nothing more than an attempt by Plaintiff to redefine the Zilver PTX Stent as a "drug," rather than as a

[2] Cook Medical Technologies, Inc.'s ("Cook Medical") submitted the original PMA for the Zilver PTX Stent. A588, A713.

"device." But the USPTO properly determined that the Zilver PTX Stent was a medical device (for purposes of PTE evaluation), and properly relied on the FDCA's statutory definition of a medical "device" as having physical structure. Thus, the USPTO reasonably required that the '447 patent recite the structural features of the Zilver PTX Stent. Because the '447 patent does not claim a method of using the Zilver PTX Stent as statutorily defined—namely, a device—the USPTO's decision to deny Plaintiff's PTE application was fully consistent with the Hatch-Waxman Act.

Finally, Plaintiff contends that the USPTO's decision "overlooked" the drug component of the Zilver PTX Stent, which the '447 patent claimed. However, this contention misses the point. By statute, the FDA's regulatory review of a combination product comprising a device component and a drug component, like the Zilver PTX Stent, is dictated by *only one* of those components—i.e., whichever component the FDA determines is the "primary mode of action" of the combination product. *See* 21 U.S.C. § 353(g)(1). In this case, the FDA decided that the "primary mode of action" for the Zilver PTX Stent was a device, and it thus reviewed the Zilver PTX Stent pursuant to section 515 of the FDCA as a device. The drug component or "biological stenting" features of the Zilver PTX Stent were not "overlooked." The USPTO, in turn, evaluated Plaintiff's application to extend the '447 patent based on the FDA's determination and properly found that the patent does not claim a medical device, like the Zilver PTX Stent, because claim 12 does not recite any structural features of such a device in light of the specification. Plaintiff's attempt to salvage its case by arguing that the term "comprising" in claim 12 of the '447 patent does not preclude the possibility of physical stenting is unavailing, as the Federal Circuit has rejected such overly broad interpretations of that term.

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

COUNTER-STATEMENT OF FACTS

Defendants respectfully refer this Court to their memorandum of law in support of Defendants' Cross Motion for Summary Judgment ("Defendants' Motion") (Dkt. No. 22), and specifically incorporate both the Statutory and Regulatory Background, and the Statement of Undisputed Material Facts stated therein. *See* Defs.' Mot. at 12-13. Defendants submit a specific counter-statement of only those facts set forth in Plaintiff's Motion that it either disputes or believes requires clarification.

1. With respect to paragraph 11 of Plaintiff's "Local Rule 56(B) Listing of Undisputed Facts": As provided in the Device Description section of Cook Medical's product literature for the Zilver PTX Stent, the "self-expanding nitinol stent" component of the Zilver PTX Stent is best described as "designed to impart an outward radial force upon the inner lumen of the vessel, establishing patency in the stented region." A786; *see also* A780, A875. To the extent Plaintiff suggests that the sole or primary purpose of the "self-expanding nitinol stent" is instead to "support the paclitaxel coating" or to "apply and maintain it" directly to the blood vessel, the portions of the record cited by Plaintiff do not support this statement.

2. With respect to paragraph 18: The FDA has explained that "review responsibility" for a combination product "is based on the Agency's determination of the product's 'primary mode of action.'" A881-A882 (citing 21 U.S.C. § 353(g); 21 C.F.R. § 3.4). To the extent Plaintiff suggests that the FDA's assignment of the review of a combination product based on its primary mode of action is solely for "internal administrative and jurisdictional purposes," the portions of the record cited by Plaintiff do not support this statement.

ARGUMENT

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

Plaintiff first alleges that the "PTO arbitrarily described the ZILVER PTX [Stent] as a 'medical device.'" Pl.'s Mot. at 12. In its view, because the PMA for the Zilver PTX Stent "defined" it as a "combination product," the "approved product" for purposes of assessing PTE is the Zilver PTX Stent *as a combination product,* and the USPTO thus "mistakenly . . . focused on the physical stenting component of the ZILVER PTX." *See id.* Significantly, however, Plaintiff fails to cite any authority holding that the "product" or the "approved product" for purposes of evaluating a PTE application under § 156 is defined by the FDA's description of a product as set forth in a PMA.[3] Nor can it. The plain language of § 156 clearly defines the Zilver PTX Stent, in light of the FDA's regulatory review, as a "medical device." And the term "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).

As an initial matter, Plaintiff did not properly raise this argument before the USPTO and has thus waived it. In its PTE application, Plaintiff acknowledged that the FDA reviewed the Zilver PTX Stent as a medical device under section 515 of the FDCA, A588, and Plaintiff only compared claim 12 of the '447 patent to a description of the Zilver PTX Stent taken from its own product literature, A590-A591. In its response to the USPTO's Requirement for Information

[3] To the extent Plaintiff suggests that the terms "product" and "*approved* product" in § 156 have different meanings, this Court and others have rejected this argument. *See, e.g.*, *Fisons plc v. Quigg* ("*Fisons I*"), 1988 WL 150851, at *5 (D.D.C. Aug. 19, 1988), *aff'd*, *Fisons plc v. Quigg* ("*Fisons II*"), 876 F.2d 99 (Fed. Cir. 1989); *see also Glaxo Operations UK Ltd. v. Quigg* ("*Glaxo I*"), 706 F. Supp. 1224, 1232-33 (E.D. Va. 1989) (Ellis, J.) (holding that "'approved product' . . . plainly means a 'product,' *as defined in Section 156(f),* that has received FDA approval" (emphasis added)), *aff'd*, *Glaxo Operations UK Ltd. v. Quigg* ("*Glaxo II*"), 894 F.2d 392 (Fed. Cir. 1990).

("RFI") and its 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 never challenged 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 October 16, 2015, 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 on how to define the "product" 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 insufficient to meet the requirement that an individual or entity must present an argument or position to an administrative agency before a federal court may pass on the same under the APA. As such, 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 raised this argument below, it falters on the merits. The plain language of the Hatch-Waxman Act supports the USPTO's decision to treat the Zilver PTX Stent as a medical device for purposes of evaluating Plaintiff's PTE application under § 156, and not as a combination product. 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. v. Kappos*, 801 F. Supp. 2d 497, 503-04 (E.D. Va. 2011). Such is the case here: § 156 defines the

"product," i.e., the Zilver PTX Stent, as a "medical device," and Plaintiff's arguments to the contrary should be rejected.

A. The Plain Language of § 156 and Case Law Support Defendants' Interpretation of "Product" as a "Medical Device"

As explained in the USPTO's December 11, 2015, 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; *accord* 35 U.S.C. § 156(a). Per § 156, and as relevant here, a product is defined either as a drug *or* 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.[4] 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" in § 156(f)(1) as a "medical device" (consistent with Plaintiff's, the FDA's, and Cook Medical's descriptions of the product as a medical device), the USPTO also treated the Zilver PTX Stent as a medical device for purposes of PTE. A870-A874. The USPTO accordingly 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)).

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 in that section and not, as Plaintiff would have it, "the product defined in the PMA."

[4] 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).

See Pl.'s Mot. at 12. In *Fisons*, the plaintiff-company ("Fisons") applied for PTEs on three newly patented drug products 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, Fisons attempted to distinguish the three newly patented drug products from the previously approved drug product (even though they all shared the same active ingredient) by focusing on the differences in how the FDA described those drug products during its review.

However, based on the plain language of § 156, the district court rejected this definition of "product." 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, the district court rejected Fisons's attempt to define "product" in a way inconsistent with the plain language of § 156—including according to the FDA's descriptions of the approved product. *See id.*

In this case, the USPTO engaged in precisely the same statutory construction exercise in evaluating Plaintiff's PTE application. The FDA reviewed the Zilver PTX Stent as a medical device, A872, which is one 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 the term "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 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 PTE eligibility. Any other definition of "product" is untenable.

B. Plaintiff's Attempt to Redefine the "Product" for Purposes of § 156(a) Should Be Rejected

Plaintiff challenges the USPTO's construction of the term "product" in § 156(a) by ignoring the statutory definitions contained in § 156(f) and looking elsewhere for the definition of "product." Specifically, Plaintiff argues that "the approved product is the product *defined in the PMA*," which here is a "combination product that comprises both drug and device components." *See* Pl.'s Mot. at 12 (emphasis in original). As Plaintiff would have it apparently, the USPTO's evaluation of its PTE application should have considered the Zilver PTX Stent as a drug *and* a device simultaneously 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. Nor does Plaintiff even attempt to reconcile its proposed definition with the fact

that the statutorily defined categories of "product" in § 156(f) do not include a "combination product."[5]

Plaintiff primarily relies on inapplicable provisions of the FDCA to support its argument. For example, Plaintiff summarily asserts that section 515 of the FDCA—pursuant to which the FDA reviewed the Zilver PTX Stent—defines the "approved product" as the "product defined in the PMA." *See id.* However, section 515 of the FDCA does not contain any reference to, let alone a definition of, the "approved product" in § 156; rather, section 515 of the FDCA solely concerns premarket approval of Class III medical devices.[6] *See, e.g.*, 21 U.S.C. § 360e(a) (requiring a "class III device" to have an "approval under this section of an application for premarket approval"). In fact, section 515 of the FDCA does not refer to § 156 at all (or to any provision of the Patent Act for that matter). Although—or perhaps because—section 515 of the FDCA is the provision under which the FDA reviewed the Zilver PTX Stent, that section does not provide any support for Plaintiff's argument that the USPTO should have somehow simultaneously considered both the drug component and the device component of the Zilver PTX Stent when it assessed Plaintiff's PTE application.

Elsewhere, Plaintiff attempts to divert the analysis by defining the Zilver PTX Stent according to another provision within the FDCA: 21 U.S.C. § 355. *See* Pl.'s Mot. at 12 (citing 21 U.S.C. § 355(b)(1) for the proposition that "the FDA reviews and approves a patented product"); *id.* at 13 (arguing that "[t]hat Section 355 of the FDCA speaks to methods of using a 'drug,' and

[5] Indeed, neither § 156 nor its implementing regulations provide for calculating PTE based on the FDA's review of a "combination product." *See* 35 U.S.C. § 156(c), (g) (calculating PTE length for eight product categories, but not combination products); 37 C.F.R. § 1.775 (calculating PTE for drugs); *id.* § 1.777 (medical devices); *see also* 21 C.F.R. § 60.22 (calculating regulatory review periods for drugs, additives, and medical devices).

[6] 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.

Section 156 of the Patent Act speaks to methods of using a 'product,' is irrelevant to this analysis"). But critically, § 355 is the codification of *section 505* of the FDCA concerning premarket regulatory review of *new drug products*—not devices or combination products. *See generally* 21 U.S.C. § 355. Plaintiff does not explain why section 505 of the FDCA should govern the USPTO's treatment of the Zilver PTX Stent. Nor does Plaintiff explain how this argument can be reconciled with its concession that the FDA properly determined that the Zilver PTX Stent should be reviewed as a medical device under section 515 of the FDCA. *See* Pl.'s Mot. at 10 (recognizing that the Zilver PTX Stent "had been subject to FDA review under 21 U.S.C. § 360e"); *see also* A588 (stating, in the original PTE application: "The federal statute under which regulatory review took place for the Zilver® PTX® Drug Eluting Peripheral Stent is Section 515 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360(e) [*sic*]."). Plaintiff's reliance on § 355 is meaningless in this regard.

Further, even though § 156 already defines the "product" for purposes of PTE, Plaintiff argues that its proposed definition of "product" based on FDA practice should trump the plain language of § 156 because Congress intended for the FDCA and the Patent Act to be interpreted identically for purposes of PTE applications. *See, e.g.*, Pl.'s Mot. at 13 (arguing that the "subtle difference in the statutory language is irrelevant because the meanings of the two provisions are identical"). However, Plaintiff cites to no relevant case law in support of this premise,[7] and its bare assertion that the "structure and legislative history of the Hatch-Waxman Act suggest that Congress intended to create one implementing mechanism in one statute that would operate in

[7] The few cases that Plaintiff cites stand only for the general proposition and canon of construction that similar language in statutes should be interpreted in the same way. *See id.* at 13-14. However, these cases did not concern the Hatch-Waxman Act, and they were decided in the distinguishable context of the interpretation of fee-shifting statutes. *See, e.g., In re Crescent City Estates, LLC*, 588 F.3d 822, 829 (4th Cir. 2009) ("As the Supreme Court has explained, fee-shifting statutes' similar language is a strong indication that they are to be interpreted alike.").

the same manner in both agencies" is entirely conclusory. *See id.* In actuality, to the extent parties have sought to ignore an express provision within § 156 in favor of the FDCA, courts have reached quite the opposite conclusion. *Cf., e.g., Arnold P'ship v. Rogan* ("*Arnold I*"), 246 F. Supp. 2d 460, 465 (E.D. Va. 2003) (holding that the "plain language of § 156 and the overall structure of the Act demonstrate that *Congress was not concerned with the FDA's practice*" (emphasis added)), *aff'd sub nom. Arnold P'ship v. Dudas* ("*Arnold II*"), 362 F.3d 1338 (Fed. Cir. 2004); *Fisons I*, 1988 WL 150851, at *5 n.37 (finding that the legislative history of the Hatch-Waxman Act "clearly implies that the term 'approved product' [in § 156] was intended to have a restrictive meaning in the context of the extension provisions *and not one borrowed from the FDA regulatory review process*" (emphasis added)); *see also Arnold II*, 362 F.3d at 1342 (rejecting the argument that § 156 should be interpreted "in harmony" with the FDA's practices, and noting that "the Patent Act and the Food, Drug, and Cosmetic Act do not exhibit a perfect overlap of policies and protections").[8]

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Plaintiff's argument focusing on the FDA's recognition of the Zilver PTX Stent as a combination product ultimately misses the point. In its Final Decision the USPTO did not disagree that the Zilver PTX Stent is a "combination product comprising both drug and device

[8] Plaintiff also suggests that the mere fact that the FDA undertook a review of the Zilver PTX Stent, despite having previously reviewed just the physical component of the product (i.e., an uncoated Zilver Stent), necessarily means that *some* PTE is justified for *some* patent. *See* Pl.'s Mot. at 12-13. But nothing in § 156 dictates that PTE is warranted every time the FDA requires review of a patent, and the legislative history of the Hatch-Waxman Act contradicts this notion as well. *See, e.g.*, *Fisons I*, 1988 WL 150851, at *6, 10 (finding that legislative history showed that the 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))); *id.* at *10 (observing that the legislative history contains "clear indications of intent to restrict the types of patents eligible for restoration").

components." *See* Pl.'s Mot. at 14. However, for a combination product, the FDA must *by statute* first determine its "primary mode of action," 21 U.S.C. § 353(g)(1), of which there are three types: a biological product, a device, and a drug, 21 C.F.R. § 3.2(k). The "primary mode of action" is the "*single* mode of action of a combination product that provides the most important therapeutic action of the combination product." *Id.* § 3.2(m) (emphasis added). 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, and 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* 21 U.S.C. § 353(g)(1). Accordingly, the regulatory review period for which a patented combination product may potentially recover PTE is dictated by a *single* mode of action, i.e., its "primary mode of action."[9]

In this case, that mode of action for the Zilver PTX Stent is as a medical device. Plaintiff does not dispute the FDA's initial decision to categorize, review, and regulate the Zilver PTX Stent as a medical device. *See, e.g.*, 588 (stating, in the PTE application, that the FDA reviewed the Zilver PTX Stent pursuant to section 515 of the FDCA). Thus, *irrespective of whether the Zilver PTX Stent includes a drug component,* for purposes of § 156, the USPTO properly considered it to be a medical device under that statute's definition of "product." Because Plaintiff's arguments (to the extent they are properly preserved) find no support in either the

[9] Contrary to Plaintiff's suggestion, the FDA itself has observed that its regulatory review of a combination product is controlled by the primary mode of action. For example, an FDA document concerning drug-eluting stents that the USPTO attached to its Final Decision (and to which Plaintiff cites, *see* Pl.'s Mot. at 9) states that the FDA has "determined that [drug-eluting stents] are subject to premarket review and approval *solely under the medical device provisions of the [FDCA]*." A881 (emphasis added).

plain language of § 156 or the legislative history of the Hatch-Waxman Act, its motion for summary judgment should be denied.

II. THE PLAIN LANGUAGE OF § 156 CONTEMPLATES THAT THE '447 PATENT MUST RECITE A STRUCTURAL ELEMENT IN ORDER TO "CLAIM" A METHOD OF USING THE ZILVER PTX STENT

Next, Plaintiff argues that the USPTO has "introduced a new requirement nowhere to be found in the plain language of Section 156 of the Patent Act—that 'the claimed method must recite one or more structural elements' of the approved product." *See* Pl.'s Mot. at 15. This argument, however, is yet another attempt by Plaintiff to redefine the Zilver PTX stent as a "drug" product capable of biological stenting, instead of as a medical "device" as reviewed by the FDA.[10] Contrary to Plaintiff's view, § 156 as applied in this case necessarily contemplates that the '447 patent must recite a structural element of the Zilver PTX Stent in order to claim a method of using that product.

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).[11] In *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997), the Federal Circuit made clear that to claim a method of using a product, a patent must still claim the particular product itself. *See id.* at 759 (affirming the denial of PTE because the plaintiff's patent failed to claim the active ingredient of the approved drug or a method of using the active ingredient of the approved drug, and claimed instead a chemically distinct product and a method of using that chemically distinct product).

[10] In fact, Plaintiff appears to recognize that "the '447 Patent does not expressly claim the physical structure of the [Zilver PTX] stent." *See id.* at 14-15.

[11] As before, to interpret this provision, the Court's analysis "begins with the language" of § 156. *Genetics & IVF Inst.*, 801 F. Supp. 2d at 503-04.

Here, the "product" is the Zilver PTX Stent. The FDA reviewed the Zilver PTX Stent as a medical device under section 515 of the FDCA, even while recognizing it as a combination product that included a drug component for biological stenting. Accordingly, consistent with the express definition of a "product" as a medical "device," the USPTO treated the Zilver PTX Stent as a medical device for purposes of § 156(a). *See supra* Part I. The USPTO then properly 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.'" A873 (quoting 21 U.S.C. § 321(h)). Thus, under § 156, the '447 patent must recite a method of using the Zilver PTX Stent by the structural features of that medical device. Plaintiff's assertion that there is no statutory support for this requirement is simply not true. *See* Pl.'s Mot. at 15.

Plaintiff ignores this straightforward statutory scheme and instead resorts (again) to inapplicable portions of the FDCA to demonstrate that this allegedly "new" requirement of a structural recitation of the patented product is inconsistent with § 156. Plaintiff first notes that "Section 355 of the FDCA and Section 156 of the Patent Act contain very similar language." *See id.* According to Plaintiff, it follows from this that because the Zilver PTX Stent "provides a method of using a drug . . . for purposes of section 355 of the FDCA," and because the '447 patent claims a method for using the drug component of the Zilver PTX Stent, that the '447 patent is entitled to PTE. *See id.* But this argument suffers from the fundamental flaw (as previously discussed, *see supra* pp. 10-11) that 21 U.S.C. § 355 is the codification of *section 505* of the FDCA concerning premarket regulatory review of *new drug products*—not devices or

combination products. *See generally* 21 U.S.C. § 355.[12] Section 505 of the FDCA (i.e., § 355) is ultimately irrelevant to this case, especially given Plaintiff's repeated acknowledgment that the FDA conducted its review of the Zilver PTX Stent as a medical device under section 515 of the FDCA. *See* A588; Pl.'s Mot. at 10.

Despite this acknowledgment, Plaintiff nevertheless alleges—without any supporting authority—that "*where* a product is reviewed within the FDA is irrelevant under the Hatch-Waxman Act." *See* Pl.'s Mot. at 16 (emphasis in original). Plaintiff presses this point by averring that "the Hatch-Waxman Act . . . makes clear that approval of a combination product must take account of both the device and drug components regardless of which agency center is primarily responsible for review." *Id.* (citing 21 U.S.C. § 353(g)). As an initial matter, however, § 353(g) (which concerns the FDA's regulation of combination products) was not enacted as part of the Hatch-Waxman Act; it was originally enacted as part of the Safe Medical Devices Act of 1989, Pub. L. No. 101-629, 104 Stat. 4511.[13] More importantly, Plaintiff can cite to no authority for the erroneous position that the Hatch-Waxman Act requires that "both the device and drug components" of a combination product be considered for purposes of evaluating a PTE application.

Plaintiff does correctly observe, at least generally, that the USPTO must rely on "the FDA's findings and conclusions" in rendering a final decision on a PTE application. *See* Pl.'s

[12] This argument is also flawed because the legislative history of the Hatch-Waxman Act and case law directly contradict the notion that the FDCA and § 156 were intended to be read *identically*. *See supra* pp. 11-12. On a related note, Plaintiff's contention that any difference between the USPTO's and the FDA's interpretations of the Hatch-Waxman Act should not be afforded *Chevron* deference is irrelevant. Defendants have already noted that *Chevron* deference is inapplicable to this specific context concerning the agency's statutory interpretations contained in PTE decisions. *See* Defs.' Mot. at 14 (citing *Meds. Co. v. Kappos*, 731 F. Supp. 2d 470, 471-72 (E.D. Va. 2010)).

[13] Notably, neither § 156 nor its implementing regulations include any express reference to "combination products."

Mot. at 16. To that end, as previously explained, *see supra* pp. 12-13, when reviewing a combination product, the FDA by statute first determines the "primary mode of action." 21 U.S.C. § 353(g)(1). And this "primary mode of action," whether a biological product, a device, or a drug, 21 C.F.R. § 3.2(k), dictates whether the FDA reviews the product as a new drug under section 505 of the FDCA or as a device under section 515 of the FDCA. *See* 21 U.S.C. § 353(g)(1). That review, in turn, guides the USPTO's PTE review. *See, e.g.*, 35 U.S.C. § 156(f)(1)(B) (defining "product" as "[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act").[14] Thus, it is true that the USPTO must account for the FDA's "findings and conclusions" during the latter agency's regulatory review of a combination product, but certainly not to the untenable extent advocated for by Plaintiff.

However it is framed, Plaintiff's challenge to the USPTO's determination that the '447 patent must recite a structural element of the Zilver PTX Stent in order to "claim" a method of using that product is unavailing. The product in this case—the Zilver PTX Stent—was reviewed by the FDA as a medical device, which is statutorily defined by its structural features. Thus, to be eligible for PTE, the '447 patent must claim a method of using a structural device, like the Zilver PTX Stent. Plaintiff's reliance on inapplicable portions of the FDCA to redefine the Zilver PTX Stent as a drug product does not demonstrate otherwise. Plaintiff's motion should accordingly be denied.

[14] In light of this statutory mandate, Plaintiff's assertion that the "FDA never suggested that the identity of the internal division of the FDA that reviewed the ZILVER PTX was in any way meaningful to its analysis or somehow made the paclitaxel and biological stenting more or less a component of the combination product's structure and function" is illogical. *See* Pl.'s Mot. at 16. By determining the "primary mode of action" of the Zilver PTX Stent, the FDA by definition decided that the "structure" of the Zilver PTX Stent is the "*single* mode of action . . . that provides the *most important* therapeutic action" of that combination product. *See* 21 C.F.R. § 3.2(m) (emphasis added). Therefore, the "paclitaxel and biological stenting" component of the Zilver PTX Stent, although part of the product, is in fact "less a component" and inconsequential to the USPTO's consideration of Plaintiff's PTE application.

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

Finally, Plaintiff argues that the USPTO erred in finding that the '447 patent does not claim a method of using the Zilver PTX Stent. According to Plaintiff, the USPTO wrongly "ignored the drug component" of the Zilver PTX Stent,[15] and the '447 patent claims a method of using a biological stent. *See* Pl.'s Mot. at 18-20. Therefore, Plaintiff asserts, the USPTO should have concluded that the '447 patent claims the Zilver PTX Stent. *See id.* This line of argument, however, again hinges on Plaintiff's incorrect assumption that it was unreasonable for the USPTO to treat the Zilver PTX Stent as a medical device for purposes of § 156. *Cf. id.* at 14-15 (acknowledging that "the '447 Patent does not expressly claim the physical structure of the [Zilver PTX] stent"). As explicated above, Plaintiff's assumption finds no support in either the plain language of § 156 or case law.

The proper inquiry, as the USPTO identified, is not whether the '447 patent claims a method of biological stenting via use of a drug, as Plaintiff argues, but whether the '447 patent claims a method of using the Zilver PTX Stent *medical device*. A872. Specifically, since its original application for PTE, Plaintiff has repeatedly 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, the question narrows to whether *claim 12* claims a method of using the Zilver PTX Stent medical device. It does not.

[15] To be clear, the USPTO did not "ignore" the fact that the Zilver PTX Stent included a drug component. The USPTO acknowledged that the Zilver PTX Stent was composed of both a drug component and a device component, but it also observed that the FDA has indicated that such drug-eluting stents are "'medical devices' to be reviewed under section 515 of the [FDCA]" because the drug component has played a "secondary" role in preventing restenosis. A870. The "primary mode of action" of the Zilver PTX Stent was as a device. *See* 21 U.S.C. § 353(g)(1). By treating the Zilver PTX Stent as a medical device for purposes of § 156, the USPTO proceeded in a manner entirely consistent with the FDA's regulatory determinations regarding that combination product.

In the Final Decision, 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. The USPTO then 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 physical medical device like the Zilver PTX Stent. *See* A873; *see also Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (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 (like claim 12) *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 patent "precludes achieving biological stenting in conjunction with physical stenting." *See* Pl.'s Mot. at 20. But setting aside for the moment the fact that this argument effectively admits that the '447 patent does not affirmatively recite any structural features of a medical device, the argument itself 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. The use of the term "comprising" in claim 12 thus does not broaden the scope of the claim to include such products for determining PTE.

Accordingly, Plaintiff has not demonstrated that the '447 patent discloses any physical medical device. Plaintiff has also not demonstrated that it was improper for the USPTO to treat the Zilver PTX Stent as a medical device for purposes of § 156. Therefore, the '447 patent does not claim a method of using the Zilver PTX Stent, and Plaintiff's motion should be denied.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court deny Plaintiff's Cross Motion for Summary Judgment.

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Respectfully submitted,

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By: /s/

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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 (NEF) to the following counsel of record:

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