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.	)	

REPLY 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 USPTO, and Drew Hirshfeld, Commissioner for Patents, through their undersigned counsel, hereby respectfully submit this reply memorandum of law in support of their cross motion for summary judgment in the above-captioned action.

INTRODUCTION

For the first time since filing its PTE application, Plaintiff expressly agrees with Defendants that the Zilver PTX Stent "product" should be defined and treated as a "medical device" pursuant to 35 U.S.C. § 156(f). Plaintiff insists this position is not new by arguing that the definition of "medical device" includes a "combination product" with both drug and device components, such as the Zilver PTX Stent. As such, Plaintiff alleges that the USPTO's determination that the definition of "medical device" as a physical article does not include use of just the drug component of a "combination product" was arbitrary and capricious. However, like Plaintiff's previous arguments, this new argument is unsupported by any statute, regulation, or decisional authority, and thus fails to show that the USPTO's Final Decision denying Plaintiff's PTE application for the '447 patent was unsound.

First, contrary to Plaintiff's assertion, the USPTO unmistakably articulated its treatment of the Zilver PTX Stent "product" as a "medical device" per § 156(f) in both its Initial Decision and its Final Decision. Moreover, because of its thoroughness and logical soundness, the decision to deny Plaintiff's PTE application based on the USPTO's interpretation of § 156 warrants, at a minimum, *Skidmore* deference. Plaintiff misunderstands the requirements of *Skidmore* deference; therefore, its arguments against its application should be rejected. In any event, even if *Skidmore* deference is not applied here, the USPTO's decisions were reasonable.

Second, although Plaintiff purports to have always agreed with the USPTO's position defining the "product" in this case to be a "medical device," it was not until Plaintiff's opposition memorandum in this Court that this "agreement" was clearly set forth. To the extent Plaintiff now relies on this new premise to argue that the definition of the term "medical device" includes a "combination product" with both drug and device components, that argument has been waived because Plaintiff failed to properly present it to the USPTO during administrative proceedings. Irrespective of any waiver, however, Plaintiff does not actually identify any statute, regulation, or decisional authority that equates the term "medical device" in § 156 with any use of the drug component of a "combination product." Nor does Plaintiff identify any reason why it was arbitrary or capricious for the USPTO to treat the Zilver PTX Stent as a "medical device" based on the FDA's determination pursuant to 21 U.S.C. § 353(g) that the primary mode of action of the Zilver PTX Stent was a medical device to be reviewed under section 515 of the FDCA. The USPTO's analysis in this regard was proper and should be affirmed.

Third, Plaintiff's contention that the USPTO should not have relied on 21 U.S.C. § 321(h) for the definition of "medical device" in § 156 fails for the same reason: Plaintiff has identified no basis (other than its own conclusory assertions) for defining "medical device" otherwise. Because § 321(h) defines a medical "device" primarily by its structure, it was reasonable for the USPTO to conclude that the '447 patent needed to recite some structural article to claim a medical device like the Zilver PTX Stent and be eligible for PTE. Moreover, the term "comprising" in claim 12 of the '447 patent does not operate in the boundless manner that Plaintiff argues for, as the presumption of "openness" inherent in that term must nonetheless be read in light of (and therefore limited by) the patent specification.

To summarize, none of Plaintiff's arguments demonstrate that the USPTO's denial of Plaintiff's PTE application was arbitrary or capricious. As set forth in § 156, a patent may be eligible for PTE if it claims a product, a method of using a product, or a method of manufacturing a product. By definition, a product is either a drug product or a medical device, and a medical device is characterized by having structural elements. Here, the FDA reviewed the Zilver PTX Stent as a medical device. The FDA did so because, although the Zilver PTX Stent is a combination product composed of both drug and device components, the FDA determined that its primary mode of action is a medical device. As such, the USPTO reviewed the '447 patent (specifically claim 12, as designated by Plaintiff) for whether it claimed a method of using a medical device. Finding that the '447 patent did not recite any structural elements of the Zilver PTX Stent, the USPTO correctly denied Plaintiff's PTE application.

Accordingly, Plaintiff's arguments should be rejected, and Defendants' cross motion for summary judgment should be granted.

ARGUMENT

I. THE USPTO'S DECISION TO TREAT THE ZILVER PTX STENT AS A "MEDICAL DEVICE" FOR PURPOSES OF § 156 IS CLEARLY SET FORTH IN THE FINAL DECISION AND WARRANTS *SKIDMORE* DEFERENCE

In opposing Defendants' summary judgment motion, Plaintiff argues that no deference is due to the USPTO's interpretation of § 156 on which it based its Final Decision denying Plaintiff's PTE application. Specifically, Plaintiff asserts that the USPTO's interpretation is "nothing more than a litigating position concocted specially for this case to justify the result below." Pl.'s Opp'n, at 15. But this assertion rings hollow in light of the administrative record,

which includes the agency's statutory interpretation of § 156, and which is due *Skidmore* deference.[1]

As Defendants summarized in their opening memorandum, the USPTO's Initial Decision (which was expressly incorporated into the Final Decision) and its Final Decision clearly explicated the rationale for denying Plaintiff's PTE application that Plaintiff contends was "concocted" for this litigation. *See* Defs.' Mot., at 8-12. In the Initial Decision, the USPTO set forth relevant portions of the text of § 156, including § 156(f), which defines the "product" upon which a PTE application is based as either a "drug product" or a "medical device." A779. The USPTO noted that, in this case, the "term product is defined by statute to be, in the context of a review and approval of a PMA, 'any medical device.'" *Id.* Then, in both the Initial Decision and the Final Decision, the USPTO observed that the FDA had reviewed the Zilver PTX Stent as a medical device under section 515 [i.e., 21 U.S.C. § 360e] of the FDCA. *Id.*; A872. From that, the USPTO determined that PTE should be afforded if the '447 patent claimed "a [medical device], a method of using a [medical device], or a method of manufacturing a [medical device]." A872 (alterations in original). Based on the definition of "medical device" in 21 U.S.C. § 321(h), the USPTO concluded that for the '447 patent to claim a method of using a medical device like the Zilver PTX Stent, it must recite some structural element of that product. *Id.* And, because the '447 patent did not recite any such structural element, it was not eligible for PTE. A872-A873. Accordingly, the USPTO's construction of § 156 in this case reflects the same position it has held since the infancy of Plaintiff's PTE application.

[1] Importantly, irrespective of whether *Skidmore* deference is applied in this case, the USPTO's denial of Plaintiff's PTE application was neither arbitrary nor capricious for the reasons set forth in Defendants' opening memorandum, and as set forth in this reply memorandum.

Not only is the USPTO's reasoning readily discernible from its written decisions, the USPTO grounded its analysis in the plain text of § 156 and the FDCA. Plaintiff even appears to acknowledge (at least in part) that throughout the administrative process, the USPTO looked to § 156(f) for the definition of the term "product" for purposes of adjudicating Plaintiff's PTE application. *See* Pl.'s Opp'n, at 17 (agreeing with the USPTO's analysis of the term "product" in the RFI and the Initial Decision). Given the logical progression of the USPTO's reasons for denying Plaintiff's PTE application, deference is owed to its interpretation of § 156 as a basis for its Final Decision. *See generally Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

In arguing against the application of *Skidmore* deference, Plaintiff misunderstands that doctrine.[2] First, Plaintiff contends that no deference is due because the USPTO stated that there are no regulations "guiding the determination of the regulatory review period or the calculation of PTE for combination products as a stand-alone category," and thus there can be no "consistency" among the USPTO's "earlier and later pronouncements" on this issue. *See* Pl.'s Opp'n, at 15. But *Skidmore* deference does not require that an agency's "pronouncements" on an issue be in the form of formal regulations; indeed, even the more substantial *Chevron* doctrine is not so cabined, *see United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). Further, "consistency with earlier and later pronouncements" is just one of several touchstones to be considered in applying *Skidmore* deference—all of which are present here. *See Skidmore*, 323 U.S. at 140 (holding that the weight of an agency's judgment depends on its "thoroughness," the "validity of its reasoning," and its "power to persuade"). Regardless, in *this* case, as just

[2] Despite Defendants' acknowledgment that *Chevron* deference is inapplicable in this case, *see* Defs.' Mot., at 14 n.8, Plaintiff still cites several authorities concerning *Chevron* deference, *see* Pl.'s Opp'n, at 14-15 (citing, for example, *Rapaport v. U.S. Dep't of Treasury, Office of Thrift Supervision*, 59 F.3d 212 (D.C. Cir. 1995); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988)). All such cases are inapposite here.

discussed, the USPTO has in fact been consistent in its construction of § 156 in its Initial and Final Decisions. To that end, the critical language in § 156 upon which the USPTO's decisions turn is the term "product," not "*combination* product"; therefore, the absence of regulations concerning the evaluation of PTE for a "combination product" is irrelevant to whether *Skidmore* deference should apply here.[3]

Second, Plaintiff contends that no deference is due here because the USPTO's decision "was not justified by any opinion letter, policy statement, agency manual, or enforcement guideline." *See* Pl.'s Opp'n, at 15. But none of these are required for *Skidmore* deference to apply. As Defendants stated in their opening memorandum, "*Skidmore* deference can apply to agency interpretations not having the force of law, such as those *contained in* opinion letters, policy statements, agency manuals, or enforcement guidelines." Defs.' Mot., at 14-15 (emphasis added) (quoting *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338, 349 (E.D. Va. 2009)). In other words, *Skidmore* deference does not require that an agency's statutory interpretation be "justified by" opinion letters and the like, as Plaintiff argues; rather, *Skidmore* deference may apply to an agency's statutory interpretation "contained in" such documents. *See, e.g., Shipbuilders Council of Am., Inc. v. U.S. Dep't of Homeland Sec.*, 673 F. Supp. 2d 438, 452-53 (E.D. Va. 2009) (Ellis., J.) (applying *Skidmore* deference to an agency's letter rulings). In this case, it is the USPTO's well-reasoned construction of § 156 "contained in" its Final Decision denying Plaintiff's PTE application that warrants *Skidmore* deference.[4]

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[3] As further discussed in this reply memorandum, *see infra* pp. 9-10,14, the absence of regulations guiding the determination of the regulatory review period or the calculation of PTE for "combination products" as a stand-alone category controverts *Plaintiff's* position, as Plaintiff cannot point to any authority for defining the term "medical device" to include *any* use of a "combination product."

[4] Notably, this Court has observed that "in the Federal Circuit, *Skidmore* deference carries more force than in the other circuits." *See Exelixis, Inc. v. Kappos*, 906 F. Supp. 2d 474, 483 n.21

In sum, contrary to Plaintiff's assertions, the USPTO's basis for denying its PTE application has been consistent since the beginning of the administrative process. The USPTO's analysis is also clearly stated, thoroughly reasoned, and well-supported by the plain language of § 156 and the FDCA. For these reasons, and in light of the USPTO's particular expertise in this highly technical area of patent law, *Skidmore* deference is merited, and the USPTO's denial of Plaintiff's PTE application should be affirmed.

II. PLAINTIFF'S NEW ARGUMENT THAT THE DEFINITION OF "MEDICAL DEVICE" INCLUDES A "COMBINATION PRODUCT" WITH BOTH DRUG AND DEVICE COMPONENTS FINDS NO BASIS IN ANY STATUTE, REGULATION, OR CASE LAW

For the first time since Plaintiff submitted its application for PTE for the '447 patent based on the FDA's review of the Zilver PTX Stent, Plaintiff changes course from its prior position regarding the definition of "product" in § 156 and argues that "the statutory definition of 'product' includes 'any medical device,'" and that the definition "includes combination products" with both drug and device components. *See* Pl.'s Opp'n, at 21.[5] It is in this sense that Plaintiff explains that it "dispute[s] the PTO's narrow interpretation of '[a]ny medical device' to *exclude* combination products." *See id.* at 17-18 (emphasis in original). However, to the extent this new argument by Plaintiff can even be considered at this stage (and it cannot), *see Hollow Coal Co. v. Dir., Office of Workers' Comp. Programs*, 137 F.3d 799, 806 (4th Cir. 1998), it does nothing more than highlight that there is no statutory provision, regulation, or decisional authority that supports Plaintiff's interpretation of § 156.

(E.D. Va. 2012) (Ellis, J.), *vacated and remanded on other grounds sub nom. Exelixis, Inc. v. Lee*, 550 F. App'x 894 (Fed. Cir. 2014).

[5] It is somewhat unclear whether Plaintiff means to argue that the definition of "product" in § 156 includes "combination products," or whether it means to argue that the definition of "medical device" includes "combination products." Either way, Plaintiff identifies no authority supporting its proposed definition.

To begin, Plaintiff contends that it has not waived this argument because "[t]hroughout the patent term extension application process, Angiotech emphasized that the PTO should interpret 'product' as defined in Section 156 to include the ZILVER PTX." *See* Pl.'s Opp'n, at 17 (citing A857-A858, A860). But whether the "product" to be analyzed under § 156 in this case is the "Zilver PTX Stent" is not the relevant inquiry; that conclusion is self-evident. A587. Instead, the relevant inquiry is whether the *term* "product" in § 156 in this case should be defined as a "medical device," as provided for in § 156(f)—it is *this* inquiry that Plaintiff failed to adequately challenge during the administrative process.[6]

Plaintiff maintains that it did not challenge the USPTO's construction of the term "product" as "medical device" per § 156(f) during the administrative process because it "agrees" with that statement. *See* Pl.'s Opp'n, at 17. However, there is no evidence of this in the administrative record. Indeed, despite the USPTO plainly stating in its Initial Decision that the "term product is defined by statute to be, in the context of a review and approval of a PMA, 'any medical device,'" A779, Plaintiff never referred to the Zilver PTX Stent as a "medical device" in its Request for Reconsideration, and it never contended that the definition of a "medical device" included a "combination product." A851-A865. Plaintiff opted instead to refer to the Zilver PTX Stent by the ambiguous label of a "controlled-delivery system." *E.g.*, A852.

Furthermore, Plaintiff's Complaint belies its assertion that it ever agreed or accepted that the "product" for purposes of § 156 in this case should be defined as a "medical device." For

[6] Indeed, the breadth of Plaintiff's attempt to avoid waiver here reaches far beyond any reasonable construction of its position during administrative proceedings. Plaintiff effectively posits that because it generally asserted that the Zilver PTX Stent is the "product" at issue, *any* argument that it seeks to advance in pursuit of that generic conclusion (and in pursuit of a grant of its PTE application) is cognizable in this Court, regardless of whether it provided the USPTO an opportunity to address that particular argument during administrative proceedings. That is not the law.

example, Plaintiff alleges that section 505 of the FDCA (i.e., 21 U.S.C. § 355)—which concerns new *drug products*—and § 156 should be read in tandem, and that as a result, "[h]ere, the ZILVER PTX [Stent] provides a method of using a *drug* for purposes of [section 505] of the FDCA." *See* Compl. ¶¶ 57-58 (emphasis added); *see also id.* ¶¶ 25-27 (alleging that section 505 of the FDCA and § 156 should be read together). Tellingly, nowhere in the Complaint does Plaintiff allege that section 515 of the FDCA (i.e., 21 U.S.C. § 360e)—which concerns medical devices, and which governed the FDA's review of the Zilver PTX Stent—should be read in tandem with § 156. In another example, the Complaint alleges that "[i]n the case of a product approved in a PMA under Section 515 of the FDCA, the approved product" for purposes of § 156 "is the product *defined in the PMA*." *See id.* ¶¶ 48-49 (emphasis added). This allegation regarding the putative source for the definition of "product" in § 156 stands in sharp contrast to Plaintiff's stance newly put forth in its opposition.

But even if Plaintiff did not waive this argument, it has yet to identify any authority to suggest that the statutory definition of a "medical device" includes the use of the drug portion of a "combination product." Nor can it. As explained in Defendants' opening memorandum, per § 156, a "product" may be defined as a "drug product" or it may be defined as a "medical device." *See* Defs.' Mot., at 17-18 (citing 35 U.S.C. § 156(f)(1)). The definitions provided in § 156(f) do *not* refer to or include a "combination product" as defined by Plaintiff. Accordingly, because the FDA reviewed the Zilver PTX Stent as a medical device pursuant to section 515 of the FDCA, the USPTO properly treated the Zilver PTX Stent "product" as a "medical device." And, by statute, a medical "device" is defined primarily by its structural features, which "does not achieve its primary intended purposes through chemical action." *See* 21 U.S.C. § 321(h); 21 C.F.R. § 60.3(b)(13). Like § 156(f), the definition of "device" in 21 U.S.C. § 321(h) does not

include any reference to a "combination product" with both drug and device components either. As such, the plain language of § 156 and the FDCA undermines any attempt by Plaintiff to expand the definition of "medical device" to include any use, and particularly the use of the drug component, of a "combination product."

Nevertheless, Plaintiff argues that the USPTO "improperly interpreted '*any* medical device' to mean *only* a device, thereby categorically excluding all products that combine both drug and device components from the definition of 'products' under Section 156." *See* Pl.'s Opp'n, at 16 (emphasis in original). However, Plaintiff fails to explain how or why the term "any" should expand the definition of "medical device" beyond its statutory definition in 21 U.S.C. § 321(h) to include products that may be treated primarily as a "drug product" for purposes of PTE.[7] Doing so would only render Congress's separation of "drug products" and "medical devices" into two distinct categories of "products" in § 156(f) meaningless.

Moreover, Plaintiff misunderstands that the USPTO did not "categorically exclud[e] all products that combine both drug and device components" from the definition of "product" in § 156. In this case, there is no dispute that the Zilver PTX Stent is the "product" on which Plaintiff's PTE application is based. The USPTO simply treated the Zilver PTX Stent as a medical device *for purposes of evaluating Plaintiff's PTE evaluation*, consistent with both the

[7] Plaintiff's attempt to turn *Fisons plc v. Quigg*, 1988 WL 150851 (D.D.C. Aug. 19, 1988), *aff'd*, *Fisons plc v. Quigg*, 876 F.2d 99 (Fed. Cir. 1989), against Defendants' argument suffers for the same reason. *See* Pl.'s Opp'n, at 18-19. Plaintiff's substitution of the term "any medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act" for the term "product" in § 156(a), similar to what the district court did in *Fisons*, still does not explain how or why the term "any medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act" includes the use of "combination products" primarily as drugs in its definition. In addition, Plaintiff's attempt to distinguish *Fisons* and Defendants' other cited authority based on the fact that those cases involved drug products misses the point. In each case, the courts adhered strictly to the plain language of the statutory definitions of the terms in § 156—which Plaintiff fails to do here.

plain language of § 156(f) and the FDA's review under section 515 of the FDCA. The USPTO denied PTE because the '447 patent did not claim the Zilver PTX Stent as a medical device—not because it "categorically exclud[ed]" the Zilver PTX Stent from being considered at all.[8]

Plaintiff also contends that the FDA's decision to review the Zilver PTX Stent as a medical device under section 515 of the FDCA is irrelevant. *See* Pl.'s Opp'n, at 20 ("As explained in Angiotech's Memorandum, *where* (or under *what* definition) the FDA chooses to conduct its review and approval process and *what* section of the FDCA governs that review are irrelevant to whether a patent should be granted a term extension . . . ."). This contention is untenable on its face. The entire purpose of § 156 is to compensate for the loss of patent term caused by the FDA's regulatory review of a product claimed by a patent. Consequently, if, as here, the FDA reviews a product *as a medical device*, then (assuming all other factors of eligibility are satisfied) it follows that PTE may issue for a patent that claims the product *as a medical device*. *Compare* 35 U.S.C. § 156(g)(1)(B) (calculating the "regulatory review period" for a "new drug" based on key dates of the FDA's review under section 505 of the FDCA), *with id.* § 156(g)(3)(B) (same for a "medical device" based on key dates of the FDA's review under section 515 of the FDCA). Plaintiff's assertions to the contrary are wholly conclusory.

Plaintiff's argument that the term "any medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act" in § 156(f) includes a "combination product" used primarily as a drug product is not only illogical with respect to § 156, it is also irreconcilable with the FDCA and its implementing regulations. The FDCA directs the FDA to regulate

[8] Separately, Plaintiff argues that "[n]othing in the FDCA permits the FDA—or, by extension, the PTO . . . to ignore the drug component of a combination product whose primary mode of action is that of a device." *See* Pl.'s Opp'n, at 20. Yet Plaintiff also points to no provision in the FDCA or elsewhere that permits the USPTO to *expand* the plain language definition of "product" set forth in § 156(f). The USPTO's adherence to the plain language of the statute and consistency with the FDA's determinations were entirely reasonable.

"combination products" according to their "primary mode of action." 21 U.S.C. § 353(g).[9] A "mode of action" may be a biological product, a device, or a drug. *See* 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). Thus, Plaintiff's argument that a "combination product" with both drug and device components may be treated according to either of the *two* modes of action improperly ignores the FDA's statutory mandate, which requires the FDA to determine the *one* "primary mode of action" of a "combination product" and review the product pursuant to the appropriate section of the FDCA. The USPTO's more reasoned construction of § 156 and reliance on the FDA's decision to review the Zilver PTX Stent as a medical device avoids that tortured result.

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Plaintiff has waived its assertions regarding its interpretation of "product" in § 156 as a "medical device," and thus its interpretation of "medical device" to include a "combination product" with both drug and device components should be rejected at the threshold. To the extent it has not been waived, Plaintiff's argument nonetheless lacks merit because there is no statute, regulation, or decisional authority that expands the plain language definitions of those terms in the manner Plaintiff seeks. By contrast, the USPTO's Final Decision construing "product" as a "medical device" as that term is defined in the FDCA is consistent with § 156. Accordingly, judgment in favor of Defendants is warranted.

[9] Significantly, the presence of the term "combination products" in the FDCA demonstrates Congress's clear understanding of that term. Accordingly, the *absence* of the term "combination products" in § 156 demonstrates that Congress did *not* intend for such products to be potentially eligible for PTE based on any possible use of such products.

III. CLAIM 12 OF THE '447 PATENT DOES NOT RECITE ANY STRUCTURAL ELEMENT OF THE ZILVER PTX STENT

Plaintiff insists that the '447 patent claims a method of using the Zilver PTX Stent, despite the fact that claim 12 (the sole patent claim on which it relies) does not recite any structural element of a medical device like the Zilver PTX Stent. Plaintiff notes that § 156 "requires only that a patent claim '*a method* of using a product,' not '*all methods* of using a product.'" *See* Pl.'s Opp'n, at 21 (emphasis in original). Thus, Plaintiff argues, because the '447 patent claims biological stenting—i.e., "a" method of using the Zilver PTX Stent—§ 156 is satisfied. *See id.* at 21-22. But Plaintiff's analysis is incomplete. While it is true, as Plaintiff emphasizes, that § 156 requires that a patent claim "*a* method of using a product" in order to be eligible for PTE, § 156 concomitantly requires that a patent claim "a method of using a *product*." *See* 35 U.S.C. § 156(a) (emphasis added). As discussed earlier and in Defendants' opening memorandum (and as Plaintiff apparently now concedes), the Zilver PTX Stent "product" in this case is properly treated as a "medical device" for PTE eligibility purposes based on the FDA's regulatory review. Therefore, because a "medical device" is statutorily defined as having structure, the '447 patent must claim some structural article of the Zilver PTX Stent to claim "a method of using a *product*." *See Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 759 (Fed. Cir. 1997) (holding that to claim a method of using a product under § 156, a patent must also claim the particular product itself).[10]

[10] Plaintiff contends that *Hoechst-Roussel Pharmaceuticals* is distinguishable by the mere fact that the case concerned a drug product. *See* Pl.'s Opp'n, at 22 n.3. However, the principles underlying the Federal Circuit's decision in that case are nonetheless generally applicable in the § 156 context. There, the plaintiff sought PTE for a patent that claimed both the compound 1-hydroxy-tacrine and a method of using 1-hydroxy-tacrine, based on the FDA's review of a drug product whose active ingredient was the chemically distinct compound tacrine hydrochloride. *See Hoechst-Roussel Pharms., Inc.*, 109 F.3d at 757. Despite similar uses for the two compounds, the Federal Circuit affirmed the USPTO's denial of PTE because the patent at issue did not claim "tacrine hydrochloride, or a method of using *that ingredient*" and instead

Although Plaintiff now recognizes that the "product" for purposes of § 156 in this case should be defined as "[a]ny medical device . . . subject to regulation under the [FDCA]," Plaintiff nevertheless criticizes the USPTO's reliance on the statutory definition of "device" that is contained in the FDCA at 21 U.S.C. § 321(h) to impose a requirement that a structural article be claimed. *See* Pl.'s Opp'n, at 22-23 ("[T]he PTO falls back on the FDCA's definition of a 'device.'"). But, as before, Plaintiff has still not identified any other statutory provision, regulation, or other authority that provides an alternative definition for a medical "device," nor has Plaintiff explained why any such alternative definition should supersede § 321(h). Instead, it is Plaintiff who continues to "fall[] back" on its mere conclusory assertions that the USPTO's reliance on § 321(h) for the definition of medical "device" is unreasonable.

Tacitly conceding that the plain language of the '447 patent does not actually recite any structural articles of a medical device like the Zilver PTX Stent, Plaintiff contends that the use of the term "comprises" in claim 12 saves its PTE application by, essentially, opening claim 12 to every single possible step that may or may not be involved in the method recited. *See* Pl.'s Opp'n, at 23. As Defendants explained in their opening memorandum, however, the word "comprising is not a weasel word with which to abrogate claim limitations." Defs.' Mot., at 25-26 (quoting *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007)). The claim must still be interpreted consistently with the patent specification. *See ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1320 (Fed. Cir. 2012). And here, there is nothing within claim 12, even when read in light of the specification, to suggest that claim 12 should be read openly to recite a medical device.

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claimed "1-hydroxy-tacrine and the method of using *that product*." *See id.* at 759 (emphasis added). In other words, irrespective of the fact that the relevant "product" was a "drug product" as opposed to a "medical device," the court held that the "product" itself must be claimed when a patent is alleged to claim "a method of using a product."

Plaintiff alleges that Defendants mischaracterized the holding in *Dippin' Dots*, and that that case somehow supports its interpretation of the term "comprising." *See* Pl.'s Opp'n, at 23.[11] To that end, Plaintiff alleges that the language of the Federal Circuit's decision reads: "The presumption raised by the term 'comprising' does not reach into *each of the six steps* to render every word and phrase therein open-ended . . . ." *See id.* (emphasis in original) (quoting *Dippin' Dots, Inc.*, 476 F.3d at 1343). But this language does not alter Defendants' point, nor does it buttress Plaintiff's argument. That a claim may contemplate additional "steps" in a method of using a product by its use of the term "comprising" speaks nothing of whether the claim recites the product itself.

Indeed, in *Dippin' Dots*, the claim at issue recited a "method of preparing and storing a free-flowing, frozen alimentary dairy product, comprising [six] steps." *See Dippin' Dots, Inc.*, 476 F.3d at 1340. One of the six enumerated steps in the claim language referred to the freezing of the dairy product into "beads," which the patent specification defined as having a "smooth, spherical appearance." *Id.* at 1343. The Federal Circuit held that despite the use of the term "comprising," the claim at issue did not recite a method of producing "irregular or odd shaped particles" of the dairy product "such as popcorn." *See id.* In other words, the term "comprising" did not encompass a method of producing or using every single possible shape of frozen dairy product, but was limited to the language of the claim in light of the specification. Similarly, in this case, the term "comprising" does not encompass every single possible method of stenting, as there is nothing in claim 12—let alone any "steps" in claim 12—or in the '447 patent's specification that recites a method of using a medical device like the Zilver PTX Stent.

[11] Plaintiff conspicuously fails to address Defendants' other cited authority supporting the same proposition. *See* Defs.' Mot., at 25-26 (citing *ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314 (Fed. Cir. 2012), and *Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336 (Fed. Cir. 2001)).

Contrary to Plaintiff's assertion, the '447 patent specification at column 30, lines 38-44 does not expand the plain language of claim 12 to recite a method of using the physical structure of a medical device like the Zilver PTX Stent, but instead only discloses the resulting chemical action of a dosage of the therapeutic agent (i.e., drug). *See* Pl.'s Opp'n, at 24. In full, that portion of the '447 patent reads:

> In one representative embodiment, a therapeutically effective *dosage* of a therapeutic conjugate or *dosage form* is useful in treating vascular trauma *resulting from* disease (e.g., atherosclerosis, aneurysm, or the like) *or* vascular surgical procedures such as angioplasty, atheroectomy, placement of a stent (e.g., in a vessel), thrombectomy, and grafting.

A641 (emphasis added). In the Final Decision, the USPTO addressed this precise portion of the specification and lucidly explained why this recitation does not describe a method of using a medical device like the Zilver PTX Stent:

> The only recitation of "stent" in the entire specification (aside from the term "biological stenting") defines the patient population that may benefit from a method of biological stenting. . . . At most, [this recitation] contemplates that **after** vascular trauma, for example, **after** placement of a stent, an infusion catheter could be used to administer a drug product to the vessel.

A874 (emphasis in original). When the complete context of this portion of the '447 patent specification is considered, it is clear that Plaintiff's contention that "the specification of the '447 Patent supports Angiotech's position that claim 12 recites a method that includes both biological stenting (administering paclitaxel) and physical stenting (through placement of a stent)," *see* Pl.'s Opp'n, at 24, is erroneous and should be rejected.

Accordingly, Plaintiff has failed to establish that the USPTO acted arbitrarily or capriciously in relying on the definition of medical "device" in the 21 U.S.C. § 321(h) to require that the '447 patent claim a structural article like the Zilver PTX Stent in order for PTE to issue. Plaintiff has also failed to establish that claim 12, even when read in light of the '447 patent specification, recites a method of using a medical device like the Zilver PTX Stent. Because the

USPTO's decision to deny Plaintiff's PTE application was reasonable and the underlying rationale was readily discernible from its written decisions, the USPTO's Final Decision should be affirmed.

CONCLUSION

For the foregoing reasons, and the reasons set forth in Defendants' Cross Motion for Summary Judgment and accompanying Memorandum of Law, Defendants respectfully request that this Court grant their Cross Motion for Summary Judgment.

Dated: May 25, 2016

Respectfully submitted,

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By: /s/

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CERTIFICATE OF SERVICE

I hereby certify that on May 25, 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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