UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

ANGIOTECH PHARMACEUTICALS INC.,	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NO. 1:15-cv-01673-TSE-TCB**
	)	
MICHELLE K. LEE,	)	
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and	)	
DREW HIRSHFELD,	)	
Commissioner for Patents,	)	
Defendants.	)	

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

Plaintiff Angiotech Pharmaceuticals Inc. ("Angiotech") requests summary judgment against Michelle K. Lee, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and Drew Hirshfeld, Commissioner for Patents (together, "the PTO").

Angiotech's cross-motion and the PTO's corresponding cross-motion concern whether the PTO's Final Determination Denying Patent Term Extension Application Under 35 U.S.C. § 156 ("Final Decision") for U.S. Patent No. 5,811,447 ("the '447 Patent") violated the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or "Act") and was arbitrary, capricious, and contrary to law in violation of the Administrative Procedure Act ("APA").

Angiotech's cross-motion should be granted for at least three reasons. First, Section 156 does not require a patent to recite "structural features" of a "device" to be eligible for patent term extension. Second, where or how the FDA decides to review a product is not dispositive of whether that product is eligible for patent term extension. Third, because the '447 Patent claims a method of biological stenting that can also include physical stenting using the ZILVER PTX, the '447 Patent claims a method for using the ZILVER PTX and is, therefore, eligible for patent term extension.

Because the PTO's decision has no plausible basis in any authority, considers (and relies on) a number of irrelevant factors, and constitutes a clear error of judgment, it is arbitrary and capricious. Accordingly, Angiotech's cross-motion for summary judgment should be granted, and the PTO's cross-motion should be denied.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

A court reviewing an agency decision under the APA must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quotations and citations omitted). "Agency action is arbitrary and capricious 'if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *Green v. Nat'l Archives & Records Admin.*, 992 F. Supp. 811, 820-21 (E.D. Va. 1998) (Ellis, J.) (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43). Where an agency considers "irrelevant factors or make[s] a clear error in judgment,"

its decision is arbitrary and capricious. *Shipbuilders Council of Am., Inc. v. U.S. Dep't of Homeland Sec.*, 673 F. Supp. 2d 438, 460 (E.D. Va. 2009) (Ellis, J.).

Here, the PTO's Final Decision denying a patent term extension to the '447 Patent is arbitrary and capricious for several reasons. The PTO's decision lacks support in the plain language of Section 156, the provision of the Patent Act that, as amended by the Hatch-Waxman Act, Congress adopted to govern patent term extension decisions. The PTO's decision also has no plausible basis in the FDCA, the statute under which the FDA reviewed and approved the ZILVER PTX. The PTO's argument "cherry picks" provisions from that statute in an attempt to create a justification for its decision, without regard to the text or operation of that law. Moreover, the FDCA provisions the PTO relies upon are irrelevant to patent term extension decisions, confirm its faulty logic, and inevitably condemn its decision as a clear error in judgment. And because the PTO has conceded that "[n]either the FDA [n]or the USPTO [has] issued regulations guiding the determination of the regulatory review period or calculation of PTE for combination products as a stand-alone category," Memorandum of Law in Support of Defendants' Cross Motion for Summary Judgment (Dkt. 22) ("PTO's Mem.") at 5, its decision also has no plausible basis in any agency practice. Accordingly, the PTO's decision is entitled to no deference under any standard. *See* Memorandum of Law in Opposition to Defendants' Cross Motion for Summary Judgment (Dkt. 25) ("Angiotech's Opp'n") at 13-16.

In addition to having no legal or logical support, the PTO's decision also flies in the face of the policy and purpose of the Hatch-Waxman Act. The statute was enacted to protect the intellectual property rights of manufacturers like Angiotech whose products are subject to the lengthy FDA approval process. In the opening pages of its Opposition, the PTO commits a fatal legal error by arguing that its decision is based on the notion that combination products like the

ZILVER PTX are categorically *excluded* under the Hatch-Waxman Act from eligibility for patent term extensions. Memorandum of Law in Opposition to Plaintiff's Cross Motion for Summary Judgment (Dkt. 24) ("PTO's Opp'n") at 2. But the PTO offers no support whatsoever for this unprecedented conclusion from the language of the statute, case law, or the legislative history of the Hatch-Waxman Act.

Angiotech's cross-motion for summary judgment should be granted for three reasons:

First, Section 156 does not require a patent to recite "structural features" of a "device" to be eligible for patent term extension; rather, Section 156 requires only that a patent claim a method of using a product subject to regulatory review by the Food and Drug Administration ("FDA"), like the ZILVER PTX.

Second, the FDA's decision about where to review the ZILVER PTX based on its "primary mode of action" is an internal, administrative decision about which agency center should be charged with the responsibility for reviewing certain products. The FDA's decision on this procedural point is in no way determinative of the issue whether a patent claims a method of using a product or in any way relevant to the PTO's decision as to whether a patent is eligible for patent term extension. In denying patent term extension to the '447 Patent, the PTO's decision gave dispositive weight to where the FDA reviewed the ZILVER PTX and was, therefore, erroneous as a matter of law.

Third, because the '447 Patent claims a method of biological stenting that also "comprises" physical stenting via the use of the ZILVER PTX, the '447 Patent claims a method for using the ZILVER PTX consistent with Section 156 and is, therefore, eligible for patent term extension.

Because the PTO's decision has no plausible basis in any applicable legal authority and is based on a number of unlawful and irrelevant factors, the decision constitutes a clear error of judgment, is arbitrary and capricious, and should be overturned. Accordingly, Angiotech's cross-motion for summary judgment should be granted, and the PTO's cross-motion should be denied.

ARGUMENT

I. The PTO relied on irrelevant provisions of the FDCA to require that the '447 Patent claim "structural features" of a "device"; instead, the PTO should have applied the plain language of Section 156, which requires only that the '447 Patent claim a method of using the ZILVER PTX.

Section 156 of the Patent Act, as amended by the Hatch-Waxman Act, provides in relevant part that "[t]he term of a patent which claims . . . a method of using a product . . . shall be extended in accordance with this section . . . if the product has been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156(a)(4).[1] Section 156 defines "product" to mean "[a] drug product" or "[a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act." *Id.* at § 156(f). The definition of "[a]ny medical device" includes a combination product that combines both drug and device components because it includes a "medical device." And a combination product is subject to regulatory review by the FDA under the Food, Drug, and Cosmetic Act ("FDCA") before its first commercial marketing or use. *See* 21 U.S.C. § 353(g) ("Regulation of combination products").[2]

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[1] Section 156 also provides that "[t]he 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). It is undisputed that "product" and "approved product" have essentially the same meaning for purposes of the analysis here. *See* Memorandum of Law in Opposition to Defendants' Cross Motion for Summary Judgment (Dkt. 25) ("Angiotech's Opp'n") at 19 ("Angiotech does not dispute that the terms 'product' and 'approved product' in Section 156(a) have essentially the same meaning.").

[2] In pertinent part, Section 353 provides that

Thus, "[t]he term of a patent which claims . . . a method of using a [combination] product . . . shall be extended in accordance with this section . . . if the [combination] product has been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156(a)(4). The PTO fails to recognize this.

Here, there is no dispute that the combination product subject to regulatory review by the FDA under the FDCA is the ZILVER PTX. *See* Angiotech's Local Rule 56(B) Listing of Undisputed Facts (Dkt. 19) at ¶ 17 ("The ZILVER PTX is considered by the FDA to be a combination product that contains both drug and device components."); PTO's Mem. at 2 ("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

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> (1) The Secretary shall in accordance with this subsection assign an agency center to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of--
>
> > (A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction,
> >
> > (B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction, or
> >
> > (C) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.
>
> (2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

21 U.S.C. §§ 353(g)(1), (2).

paclitaxel."). It follows, then, that "[t]he term of a patent which claims . . . a method of using [the ZILVER PTX] . . . shall be extended." 35 U.S.C. § 156.

The PTO seeks to avoid the inevitable conclusion that results from application of the plain language of Section 156. But all its arguments fail.

First, the PTO argues that the term of a patent claiming a method of using a combination product like the ZILVER PTX can only be extended if the patent "recites the structural features" of a "device." *See* PTO's Opp'n at 3, 7, 15, 17, 19, 20. As explained in Angiotech's Memorandum in Support of Cross-Motion for Summary Judgment, however, there is no requirement in Section 156 that a patent recite the structural features of an approved product. *See* Dkt. 19 ("Angiotech's Mem.") at 15-16. Rather, Section 156 requires only that the patent claim "a method of using a product."

The PTO's argument is fatally flawed because it relies on statutory language borrowed from the FDCA, which it seeks to substitute for the plain language of Section 156. The PTO reasons that, because the FDA reviewed the ZILVER PTX as a "device" and not a "drug," the PTO "properly noted that the statutory definition of a medical 'device' focuses on the 'structural' features of the device . . . Thus, under § 156, the '447 patent must recite a method of using the Zilver PTX Stent by the structural features of that medical device." PTO's Opp'n at 15 (citing 21 U.S.C. § 321(h)). However, the FDA did *not* review the ZILVER PTX as only a device – it reviewed the ZILVER PTX as a combination product. And the statute requires the FDA to consider all aspects of a combination product, not only the aspects related to the primary mode of action as the PTO asserts. *See* 21 U.S.C. § 353(g)(2) ("Regulation of combination products") ("Nothing in this subsection shall prevent the Secretary from using any agency resources of the

Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.").

The PTO erred in relying on a definition not included in the Hatch-Waxman Act generally or Section 156 specifically to deny patent term extension to the '447 Patent. And the PTO repeatedly commits this legal error in an attempt to justify that decision:

- [T]he 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"* [*see* 21 U.S.C. § 321(h)] *as having physical structure*. PTO's Opp'n at 3 (emphasis added).

- 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)*). PTO's Opp'n at 7 (emphasis added).

- [T]he 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. PTO's Opp'n at 9 (emphasis added).

- 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)*). PTO's Opp'n at 15 (emphasis added).

- 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)*). PTO's Opp'n at 19 (emphasis added).

The PTO's decision here essentially rests on a statutory provision that is not applicable to the patent term extension decision. Section 321(h) of Title 21, a provision of the FDCA, does not govern patent term extension decisions; the Hatch-Waxman Act and Section 156 do. And contrary to the PTO's assertions, the "plain language of the Hatch-Waxman Act" does *not*

"support[] the USPTO's decision to treat the Zilver PTX as a medical device for purposes of evaluating Plaintiff's PTE application under § 156, and not as a combination product." PTO's Opp'n at 6. No provision of the Hatch-Waxman Act provides any justification for excluding combination products like the ZILVER PTX from Section 156's definition of "product." And the PTO has not cited any prior authority that construes the Hatch-Waxman Act to justify the categorical exclusion of combination products from eligibility for patent term extension.

As explained in Angiotech's Opposition, the PTO's reliance on decisions affirming denials of patent term extension for patents claiming drug products is misplaced and wholly unpersuasive because those decisions turn on the definition of "drug product" in 35 U.S.C. § 156(f)(2), which applies only to drug products and not to combination products like the ZILVER PTX. *See* Angiotech's Opp'n at 18-19; PTO's Opp'n at 7-19, 12. For example, *Fisons plc v. Quigg*, No. CIV.A. 86-1804, 1988 WL 150851, at *1-3 (D.D.C. Aug. 19, 1988), *aff'd*, 876 F.2d 99 (Fed. Cir. 1989) concerned the FDA's approval of three new drug products with the same active ingredient, cromolyn sodium. And *Arnold P'ship v. Rogan*, 246 F. Supp. 2d 460, 462 (E.D. Va. 2003), *aff'd sub nom. Arnold P'ship v. Dudas*, 362 F.3d 1338 (Fed. Cir. 2004) pertained to a patent that claimed "[a] pharmaceutical composition which comprises hydrocodone or a pharmaceutically acceptable acid addition salt thereof and ibuprofen or a pharmaceutically acceptable acid additional salt thereof." Neither *Fisons* nor *Arnold* concerned a combination product having both drug and device aspects like the ZILVER PTX.

Affirming the PTO's position here would lead to consequences that are not only unsupported by the language of the statute, but contrary to the statute's purpose and wholly unintended by the proponents of the Hatch-Waxman Act. The PTO unambiguously concedes that under its construction, "§ 156's definition of a 'product' for purposes of PTE eligibility

includes a 'medical device,' *but not a 'combination product.'*" PTO's Opp'n at 2 (emphasis added). From the PTO's point of view, then, patents claiming combination products or methods for using them are categorically excluded from eligibility for patent term extensions. As demonstrated above, the plain language of the statute does not support such a drastic result, and the PTO has not advanced any rational basis to support this irrational outcome. For all these reasons, summary judgment should be entered in favor of Angiotech, and the PTO's cross-motion for summary judgment should be denied.

II. The PTO gave dispositive weight to the FDA's determination of the "primary mode of action" of the ZILVER PTX, despite the fact that this determination is irrelevant to whether the ZILVER PTX is eligible for patent term extension under Section 156.

In addition to unlawfully and arbitrarily relying on the FDCA to justify its faulty reading of Section 156 and its denial of patent term extension to the '447 Patent, the PTO also erroneously seeks to justify its decision by focusing on *where* or *how* the FDA conducted its review, and not on *what* the FDA reviewed, as required by Section 156.

Again, as noted above, there is no dispute that the "product" the FDA reviewed – the "product . . . subject to a regulatory review period before its commercial marketing or use," 35 U.S.C. §§ 156(a), (f) – is the ZILVER PTX, a combination product that includes both drug and device components. *See* Angiotech's Mem. at ¶ 17; PTO's Mem. at 2. Nor can there be any dispute that Section 353 of the FDCA governs the regulation of combination products and requires the Secretary of Health and Human Services to "assign an agency center to regulate products that constitute a combination of a drug, device, or biological product" by "determin[ing] the primary mode of action of the combination product." 21 U.S.C. § 353(g)(1). Importantly, the statute requires the FDA to consider all aspects of a combination product, not merely the primary mode of action. Section 353 goes on to state that "[n]othing in this

subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article," notwithstanding the Secretary's determination of a combination product's "primary mode of action." 21 U.S.C. § 353(g)(2). But the PTO unlawfully gave the "primary mode of action," and thus the place of review within the FDA, dispositive weight when it denied patent term extension to the '447 Patent.

The FDA's decision under Section 353 of the FDCA to assign review of a combination product to a particular agency center, or its determination of the combination product's "primary mode of action" in making that assignment, is irrelevant to the decision required by the statute: whether a patent that claims a method of using a combination product is eligible for patent term extension under Section 156. Yet the PTO repeatedly invokes Section 353 to support its requirement – a requirement not included in Section 156 – that the '447 Patent recite "structural features" of a "device." For example, the PTO argues that

> 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. . . . 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."

PTO's Opp'n at 13 (citing 21 U.S.C. § 353(g)(1)). But Section 353, much less Section 156, "dictates" no such thing. Section 353 merely requires the FDA to make an initial or interim decision about which agency center should be charged with responsibility for reviewing combination products.

Elsewhere, the PTO argues that

> when reviewing a combination product, the FDA by statute first determines the 'primary mode of action.' . . . And this 'primary mode of action,' whether a biological product, a device, or a drug, . . . dictates whether the FDA reviews the product as a device . . . That review, in turn, guides the USPTO's PTE review.

PTO's Opp'n at 17 (citing 21 U.S.C. § 353(g)(1)). The PTO also argues that "[b]y 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." *Id.* at 18 n.15. Nowhere does the PTO explain, however, why the FDA's internal allocation of responsibility to review a combination product as a device "guides" its review of patent term extension applications, or why its "consistency" with the FDA's determination as to which agency center should review a combination product like the ZILVER PTX has any bearing whatsoever on its decision denying patent term extension to the '447 Patent under the terms of the Hatch-Waxman Act. The PTO is misconstruing the Hatch-Waxman Act by adding requirements for patent term extension that do not exist.

The purpose of the FDA's interim decision is solely to regulate its management and organization, as is made clear by 21 C.F.R. § 3.1, which implements 21 U.S.C. § 353(g) (equivalently, Section 503(g) of the FDCA):

> This regulation *relates to agency management and organization* and has two purposes. The first is to implement section 503(g) of the act . . . by specifying how FDA will determine the organizational component within FDA designated to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug and a device[.] . . . This determination will eliminate, in most cases, the need to receive approvals from more than one FDA component for such combination products. The second purpose of this regulation is to *enhance the efficiency of agency management and operations* by providing procedures for determining which agency component will have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute. Nothing in this section prevents FDA from using any agency resources it deems necessary to ensure adequate review of the safety and effectiveness of any product, or the substantial equivalence of any device to a predicate device.

21 C.F.R. § 3.1 (emphasis added). There is no indication whatsoever that 21 U.S.C. § 353(g) or its implementing regulation have any purpose beyond the efficient organization and management of the FDA's internal procedures.

The PTO's heavy reliance on the locus of the FDA's review of the ZILVER PTX and the FDA's internal, administrative decision-making about which agency centers have jurisdiction to review which combination products has no support in the plain language of Section 156, the Hatch-Waxman Act, or the FDCA. Moreover, the PTO acknowledges that its reliance on the FDA's jurisdictional decision-making *ignores* the very nature of combination products like the ZILVER PTX, which the PTO seems determined to treat as drug products or devices in mutually exclusive categories, when combination products are a well-known category that combine elements of both. *See* PTO's Opp'n at 13 ("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.'") (emphasis in original).

The PTO's reliance on the FDA's jurisdictional decisions and its refusal to consider patent term extension for combination products is also squarely at odds with its acknowledgement that it "must account for the FDA's 'findings and conclusions' during the latter agency's regulatory review of a combination product." *Id.* at 17. Further, no provision of the Hatch-Waxman Act provides that combination products as an entire class are excluded from the scope of the patent term extension mechanism. Because the PTO's willful ignorance is unsupported (and unsupportable), the PTO's Final Decision denying the '477 Patent a term extension is arbitrary, capricious, and contrary to law. The PTO's decision should be overturned and summary judgment should be entered in Angiotech's favor.

III. The PTO's decision was arbitrary and capricious because the '447 Patent claims both biological stenting and physical stenting using the ZILVER PTX.

As explained above, there is no requirement under Section 156 that a patent claim "structural features" of a "device" to be eligible for patent term extension. *See* Part I, above. On the contrary, a patent need only "claim[] . . . a method of using a product." 35 U.S.C. § 156(a). And a "product," as defined under Section 156, includes a product that combines both drug and device components like the ZILVER PTX. Otherwise, such products, which are subject to regulation by the FDA under the FDCA, are categorically excluded from eligibility for patent term extension. The proponents of the Hatch-Waxman Act did not intend this result and, more importantly, the plain language of the statute does not support it.

Because there is no dispute that the ZILVER PTX underwent regulatory review by the FDA under the FDCA, then to be eligible for patent term extension, the '477 Patent need only "claim[] . . . a method of using [the ZILVER PTX]." 35 U.S.C. § 156(a). Importantly, there is no requirement that the claim include *all* methods by which the device operates – only *a* method. Thus, the '477 Patent satisfies the requirement for claiming a method of use because it claims a method for biological stenting using the ZILVER PTX, a conclusion the PTO concedes given that it "does not disagree that the [ZILVER PTX] does administer paclitaxel to the blood vessel of a mammal." A875.

The PTO argues that the "proper inquiry" here is "whether the '447 patent claims a method of using the Zilver PTX Stent *medical device*," and that that inquiry turns on whether claim 12 of the '447 Patent "recite[s] any structural features of a medical device," given the FDCA's definition of "device." PTO's Opp'n at 18-19 (emphasis in original) (citing 21 U.S.C. § 321(h) ("The term 'device' . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . which does not

achieve its primary intended purposes through chemical action within or on the body of man or other animals.").

Again, however, the PTO's reasoning relies on a false premise. The definition of "device" in Section 321 of the FDCA is not relevant to the truly "proper inquiry" here: whether the '447 Patent claims a method of using the ZILVER PTX. As explained in Angiotech's Opposition, the "primary intended purposes" of the ZILVER PTX under Section 321 are no more relevant to the determination whether a patent term extension should be granted under Section 156 than the FDA's determination as to the ZILVER PTX's "primary mode of action" when making its decision about which agency center should be charged with its review under Section 353. Angiotech's Opp'n at 22-23. Moreover, nothing in Section 321 changes the fact that the text of Section 156 does not require a patent to recite "structural features" of a "device" to be eligible for patent term extension. *See* Part I, above.

The '447 Patent indisputably claims a method of administering paclitaxel to the wall of a blood vessel. *See* PTO's Opp'n at 19 ("[T]he USPTO agree[s] . . . that claim 12 'encompasses the local administration of drugs to the blood vessel wall'") (quoting A873). And because claim 12 of the '447 Patent uses the transitional term "comprising," as a matter of black letter patent law, the method recited in claim 12 may also include additional, un-recited steps, including the physical stenting of a blood vessel using the ZILVER PTX. *See Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007).[3]

[3] In its opposition, the PTO once again creatively edits its quotation from *Dippin' Dots* in an unsuccessful attempt to rebut the presumption created by the use of the term "comprising" at the beginning of a method claim. *See* Memorandum of Law in Opposition to Plaintiff's Cross Motion for Summary Judgment (Dkt. 24) at 20. In *Dippin' Dots*, the Federal Circuit actually stated that "[t]he presumption raised by the term 'comprising' does not reach into *each of the six steps* to render every word and phrase therein open-ended." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (emphasis added). In its Opposition, however, the PTO

The use of "comprising" in claim 12 to include both physical and biological stenting is consistent with the '447 Patent's specification. The '447 Patent states that "*a therapeutically effective dosage of a therapeutic conjugate or dosage form is useful in* . . . vascular surgical procedures such as angioplasty, atheroectomy, *placement of a stent (e.g., in a vessel),* thrombectomy, and grafting." A641 ('447 Patent, col. 30, lines 38-44) (emphasis added). Thus, the specification of the '447 Patent confirms Angiotech's position that claim 12 recites a method that includes both biological stenting (administering paclitaxel) and physical stenting (through placement of a stent).

For the same reason, the PTO's reliance on *ArcelorMittal*, *Dippin' Dots*, and *Crystal Semiconductor* is misplaced. *See* PTO's Opp'n at 20-21. In *ArcelorMittal*, the Federal Circuit found that an interpretation of a claim term that was inconsistent with the patent's specification could not be correct, notwithstanding the consistency of the interpretation with the ordinary and customary meaning of the term in the relevant industry. *ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1320 (Fed. Cir. 2012). Here, Angiotech is not advancing an interpretation of claim 12 that relies on an ordinary or customary meaning within an industry, much less a meaning that is inconsistent with the specification of the '447 Patent.

Similarly, in *Crystal Semiconductor*, the Federal Circuit found that a method claim using the term "comprising" encompasses more than what is recited "unless the written description or the prosecution history clearly limits [the claim] to its recited elements." *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1350-51 (Fed. Cir. 2001). But

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changed this quote to substitute the words "a claim" for "each of the six steps," thereby erroneously suggesting that "comprising" in claim 12 may not include other unrecited steps in addition to the biological stenting explicitly claimed, including the physical stenting of a blood vessel using the ZILVER PTX. But again, that is not what *Dippin' Dots* actually says, and the PTO's suggestion should be rejected.

there is nothing in the written description of the ’447 Patent that “clearly limits” claim 12 and excludes physical stenting using the ZILVER PTX. Nor is Angiotech attempting to broaden the scope of claim 12 to include unrecited steps that have no support in the ’447 Patent’s written description, as was the case in *Dippin’ Dots*, 476 F.3d at 1343. Accordingly, *ArcelorMittal*, *Dippin’ Dots*, and *Crystal Semiconductor* are inapposite and do not support the PTO’s denial of patent term extension for the ’447 Patent.

The ’447 Patent claims a method of biological stenting that can include physical stenting using the ZILVER PTX. This is all that is required under the law for it to be eligible for patent term extension under Section 156. And for this reason, the PTO’s Final Decision was arbitrary, capricious, and contrary to law. That decision should be overturned, and summary judgment should be entered in Angiotech’s favor.

CONCLUSION

For each and all of these reasons, summary judgment should be entered for Angiotech, the PTO’s decision should be declared unlawful, its cross-motion for summary judgment should be denied, and the matter should be remanded to the PTO with instructions to approve an extension of the term of the ’447 Patent.

May 25, 2016

Respectfully submitted,

/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 to the following counsel of record:

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