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

ANGIOTECH PHARMACEUTICALS INC.,	)	
Plaintiff,	)	
	)	**Case No. 1:15-cv-1673**
v.	)	
	)	
MICHELLE K. LEE, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

In this Administrative Procedure Act ("APA")[1] case, plaintiff Angiotech Pharmaceuticals Inc., the exclusive licensee of U.S. Patent No. 5,811,447 ("the '447 patent") and the agent of the '447 patent's owner for purposes of this action, challenges the United States Patent and Trademark Office's ("PTO")[2] final decision denying a patent term extension for the '447 patent. In addition to holding the rights to the '447 patent, plaintiff also manufactures the ZILVER® PTX Drug Eluting Peripheral Stent ("Zilver PTX"), a medical device that physically and biologically stents arteries. The '447 patent claims a method of biological stenting to prevent the narrowing of mammalian arteries, and in plaintiff's view, the '447 patent claims a method of biological stenting using the Zilver PTX. Because the Zilver PTX could not be marketed until the completion of a lengthy review and approval process by the Food and Drug Administration ("FDA"), plaintiff seeks a patent term extension for the '447 patent pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-

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[1] 5 U.S.C. § 500 *et seq.*

[2] Defendants in this action are (i) Michelle K. Lee, Director of the PTO, and (ii) Drew Hirshfeld, Commissioner for Patents. This Memorandum Opinion refers to the defendants collectively as the PTO.

Waxman Act.[3] The PTO denied plaintiff's application for a term extension on the ground that the '447 patent does not claim a method of using the Zilver PTX and therefore does not qualify for a term extension under the Hatch-Waxman Act. This action followed.

The parties filed cross-motions for summary judgment, which have now been fully briefed and argued. Accordingly, the motions are now ripe for disposition.

I.

A.

At the outset, a brief overview of the pertinent statutory and regulatory framework is useful. The FDA oversees the review and market approval of new drugs and medical devices pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA").[4] The nature of FDA review of a new drug or medical device depends on the nature of the product; for example, a new drug receives a review that differs from the review of a new medical device. *See* 21 U.S.C. § 355 (new drugs), § 360e (certain medical devices). Yet, some products—known as combination products—have therapeutic attributes "that are physically, chemically, or otherwise combined or mixed and produced as a single entity." 21 C.F.R. § 3.2(e). When reviewing a combination product, the FDA first determines the product's "primary mode of action," which refers to the one means by which the product achieves its intended therapeutic effect that makes the greatest contribution to the product's overall therapeutic effect. *See* 21 U.S.C. § 353(g)(1) (regulation of combination products); 21 C.F.R. § 3.2(k) (defining "mode of action"), § 3.2(m) (defining "primary mode of action"). A combination product can have one of three primary modes of action—drug, device, or biological product—and the FDA reviews a combination product in

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[3] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in relevant part at 35 U.S.C. § 156).

[4] 21 U.S.C. § 301 *et seq.*

accordance with the product's primary mode of action. *See* 21 U.S.C. § 353(g)(1). For example, a combination product with the primary mode of action of a device is reviewed by the FDA as if the product were a device, whereas a combination product with the primary mode of action of a drug is reviewed by the FDA as if the product were a drug. *See id.*

FDA review of a new drug or medical device is often a lengthy process, not uncommonly requiring years to complete. The time-consuming nature of this process can impose certain significant costs on the holders of patents claiming new drugs or medical devices. Specifically, federal law generally provides a twenty-year term for a patent, starting from the date on which the patent application is filed. *See* 35 U.S.C. § 154(a)(2). This general rule places patents claiming FDA-regulated drugs or medical devices (or methods of using or manufacturing such drugs or medical devices) at a disadvantage, as many years of the patent's term can pass while the product awaits FDA approval. Because the patent owner cannot market the claimed product commercially without FDA approval, several years of the patent monopoly can be entirely unprofitable. *See, e.g., Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224, 1225 (E.D. Va. 1989) (observing that FDA review and approval "often require[s] years to complete, thereby diminishing the commercial rights provided by the patent"), *aff'd*, 894 F.2d 392 (Fed. Cir. 1990). Thus, an important policy concern in this area is that inventors may well not have sufficient incentive to expend the resources necessary to develop new drugs and medical devices, as patents claiming medical innovations subject to FDA review may have an effective life of less than the standard twenty years owing to the time consumed by the FDA review and approval process.

Title II of the Hatch-Waxman Act represents Congress's solution to this problem by seeking to ease the tension between ensuring safe drugs and medical devices on the one hand and

incentivizing the development of new drugs and medical devices on the other. The mechanism for doing so involves extending the terms of certain patents claiming products (or methods of using or manufacturing products) subject to FDA review and approval. *See Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 396 (Fed. Cir. 1990) (The Hatch-Waxman Act "encourage[s] new drug research by restoring some of the patent term lost while drug products undergo testing and await FDA pre-market approval."). Thus, once the FDA's regulatory review of a product has concluded, the owner of a patent "which claims [the] product, a method of using [the] product, or a method of manufacturing [the] product" can apply to the PTO for an extension of the patent's term pursuant to the Hatch-Waxman Act. *See* 35 U.S.C. § 156(a). If the product and the patent meet certain statutory criteria, the PTO "shall" extend the term of the patent. *Id.* In other words, term extensions are mandatory for patents that qualify under § 156.

The PTO's final decision on a patent term extension application is an "agency action" subject to judicial review under the APA. As such, the PTO's final decision on whether to grant or to deny a patent term extension application may be "set aside" if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

B.[5]

The '447 patent—titled "Therapeutic Inhibitor of Vascular Smooth Muscle Cells"—issued on September 22, 1998. *See* U.S. Patent No. 5,811,447, at [45], [54] (filed May 25, 1995). As relevant here, claim 12 of the '447 patent recites "[a] method for biologically stenting a

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[5] The facts recited here are derived from the administrative record of the proceedings before the PTO, and the administrative record defines the scope of the review. *See* 5 U.S.C. § 706 (limiting the scope of review to "the whole record or those parts of it cited by a party"). In an APA action, summary judgment is merely "the mechanism for deciding, as a matter of law, whether the agency action is...consistent with the APA." *Hyatt v. U.S. Patent & Trademark Office*, --- F. Supp. 3d ---, 2015 WL 7176108, at *6 (E.D. Va. Nov. 12, 2015) (internal quotations omitted). *Accord, e.g., Richards v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977).

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." *Id.* col. 76, ll. 41-46.

In addition to being the exclusive licensee of the '447 patent, plaintiff also manufactures the Zilver PTX, which performs both physical and biological stenting of blood vessels. Specifically, the Zilver PTX is a self-expanding nitinol[6] stent coated with the drug paclitaxel; the physical aspect of the stent imparts outward force on the vascular wall and supports the paclitaxel coating, maintaining the drug in direct contact with the vascular wall. This physical support allows the administration of the paclitaxel, which inhibits the contraction or migration of smooth muscle cells in the vascular wall and prevents restenosis, the narrowing of arteries over time.

In June 2010, plaintiff applied for FDA approval to market the Zilver PTX commercially. The Zilver PTX is a combination product in that it comprises device and drug components, and the FDA determined that its primary mode of action is that of a device. Accordingly, the FDA agency center charged with premarket review of devices had primary jurisdiction to review the Zilver PTX. *See* 21 U.S.C. § 353(g)(1)(B). The FDA granted the premarket approval application for the Zilver PTX on November 14, 2012.

On December 7, 2012, shortly after FDA approval of the Zilver PTX, plaintiff filed with the PTO an application for a patent term extension for the '447 patent.[7] This application sought a

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[6] Nitinol is a metal alloy of nickel and titanium. *See* A587.

[7] Plaintiff applied for the patent term extension on behalf of (*i.e.*, as an agent of) Boston Scientific Scimed, Inc., the owner of the '447 patent. *See* A868. As such, the application was proper pursuant to § 156(d)(1), which allows "the owner of record of the patent or its agent" to

five-year term extension, the maximum amount allowed by statute,[8] on the basis that the '447 patent claims a method of using the Zilver PTX. Thereafter, in March 2015, the PTO issued plaintiff a Requirement for Information directing plaintiff to provide additional information necessary to the PTO's determination of the '447 patent's eligibility for a patent term extension.[9] Specifically, the PTO sought to discover from plaintiff how the '447 patent "claims...a method of using" the Zilver PTX consistent with the Hatch-Waxman Act. 35 U.S.C. § 156(a). In June 2015, plaintiff responded to the PTO's request by identifying claim 12 of the '447 patent as claiming a method of using the Zilver PTX. As noted, 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." Col. 76, ll. 41-46.

In October 2015, the PTO issued an initial decision denying plaintiff's application for a patent term extension. Thereafter, plaintiff unsuccessfully sought reconsideration of the initial decision, and the PTO issued its final decision denying plaintiff's application on December 11, 2015. The PTO's final decision explained that the Zilver PTX was reviewed and approved by the FDA as a medical device, and hence, in the PTO's view, in order for a patent to claim a method

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submit an application for a patent term extension. The PTO does not contest plaintiff's standing or statutory authorization to seek a patent term extension for the '447 patent, given plaintiff's status as a licensee and agent. *See* Transcript of Motions Hearing (Friday, June 3, 2016) at 4:15-23.

[8] *See* 35 U.S.C. § 156(g)(6)(A) ("If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.").

[9] *See* 37 C.F.R. § 1.750 ("The Director or other appropriate officials may require from applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension.").

of using the medical device, the patent must recite one or more structural elements of the device. The PTO reached this conclusion by referencing the definition of "device" in the FDCA, which focuses on structural features to the exclusion of chemical features.[10] Because claim 12 focuses on biological rather than physical stenting, it does not recite the structural elements of the Zilver PTX as required under the PTO's interpretation of § 156(a), and accordingly the PTO concluded that claim 12 of the '447 patent does not claim a method of using the Zilver PTX.

On December 21, 2015, plaintiff filed the instant action seeking judicial review of the PTO's final decision denying the application for a patent term extension.

II.

As this case involves a federal agency's interpretation of a federal statute, an important threshold consideration is whether the PTO's interpretation of the Hatch-Waxman Act, which in relevant part amended the Patent Act, is entitled to any deference. Judicial deference to administrative interpretations of federal law manifests in two separate doctrines, namely *Skidmore* deference[11] and *Chevron* deference.[12] The older of these doctrines, *Skidmore* deference, emerged over seventy years ago and instructs that the appropriate level of deference to an agency's statutory interpretation depends on the interpretation's "power to persuade,"

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[10] *See* 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, including any component, part, or accessory, which...does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.").

[11] *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) ("[T]he rulings, interpretations and opinions" of an agency may constitute "a body of experience and informed judgment to which courts and litigants may properly resort for guidance.").

[12] *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984) ("[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.").

which in turn depends on, *inter alia*, "the thoroughness evident in its consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements." *Skidmore*, 323 U.S. at 140. Forty years after the birth of *Skidmore*, the Supreme Court established a stronger form of deference, *Chevron* deference, under which "administrative implementation of a particular statutory provision qualifies for...deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001).

The PTO correctly does not request *Chevron* deference for the statutory interpretation advanced in the final decision denying plaintiff's patent term extension application. Indeed, "*Chevron* deference is generally reserved for agency interpretations set forth after notice-and-comment rulemaking or a formal adjudication," and patent term extension decisions are mere "informal adjudications." *Meds. Co. v. Kappos*, 731 F. Supp. 2d 470, 475 (E.D. Va. 2010) (applying, *inter alia*, *Mead Corp.*, 533 U.S. at 231-34, and concluding that patent term extension decisions are not entitled to *Chevron* deference). The informal nature of the PTO's patent term extension decisions is sufficient, standing alone, to preclude *Chevron* deference. *See id.* But on an even broader level, "[b]ecause Congress has not vested the [PTO] with any general substantive rulemaking power...the rule of controlling deference set forth in *Chevron* does not apply." *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

Yet, the PTO argues that its interpretation is entitled to the weaker form of deference under *Skidmore*. This argument must be welcome news for *Skidmore*, which has had a rough go of it ever since the birth of *Chevron*. Like the figurative older child neglected in the wake of a new sibling's arrival, in 1984 *Skidmore* was relegated to the status of an administrative law

sideshow while the federal courts fawned over *Chevron*. Indeed, by the age of just three and a half years, courts had cited *Chevron* over six hundred times,[13] and by the time *Chevron* turned sixteen, some were ready to declare *Skidmore* dead altogether.[14] To be sure, *Skidmore* gets a little attention from time to time, in essence just enough tips of the hat from the Supreme Court to assure us that *Skidmore* is still breathing. *See, e.g., Mead Corp.*, 533 U.S. at 234-39; *Met. Stevedore Co. v. Rambo*, 521 U.S. 121, 136 (1997). Still, the fact remains that *Skidmore* is in large part an afterthought, shunted into *Chevron*'s shadow, invoked only after *Chevron* has been deemed inapplicable in a given case, and afforded perhaps a day's worth of lecture time in administrative law courses.

But *Skidmore* still has at least one friend—the Federal Circuit—where "*Skidmore* deference carries more force than in other circuits." *Exelixis, Inc. v. Kappos*, 906 F. Supp. 2d

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[13] Antonin Scalia, Judicial Deference to Administrative Interpretations of Law, 1989 Duke L.J. 511, 512 (1989) (citing Clark Byse, Judicial Review of Administrative Interpretation of Statutes: An Analysis of *Chevron*'s Step Two, 2 Admin. L.J. 255, 255 (1988)). Justice Scalia's 1989 defense of judicial deference to administrative interpretations of law is highly instructive in that Justice Scalia's defense was a matter of practical judgment rather than abstract principle. *See id.* at 515-17 (rejecting the position that constitutional separation of powers requires deference and instead defending deference as a rational response to the realities of the administrative state as it existed at the time). In other words, judicial deference to agency interpretations of law is context-sensitive. Indeed, as the scope of the administrative state changed between 1989 and 2015, so too did Justice Scalia's views about the ability of deferential doctrines to strike an appropriate balance between the rule of law and the will of the people. *See Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1211 (2015) (Scalia, J., concurring in the judgment) (criticizing the Supreme Court's "elaborate law of deference to agencies' interpretation of statutes and regulations" as "[h]eedless of the original design of the APA"). As Justice Scalia recognized, deferential doctrines are not interpretative norms to be applied reflexively, but must be administered with care to ensure that the application of each doctrine in context serves to give effect to the doctrine's underlying purpose.

[14] *See Christensen v. Harris Cnty.*, 529 U.S. 576, 589 (2000) (Scalia, J., concurring in part and concurring in the judgment) (calling *Skidmore* "an anachronism, dating from an era in which [courts] declined to give agency interpretations...authoritative effect," an era that "came to an end with...[*Chevron*]").

474, 483 n.21 (E.D. Va. 2012), *vacated and remanded on other grounds sub nom.*, *Exelixis, Inc. v. Lee*, 550 F. App'x 894 (Fed. Cir. 2014). Indeed, although the Supreme Court has not provided much guidance on the application of *Skidmore* other than to suggest that "some deference" or "respect" is due to any reasonable agency interpretation of a statute the agency administers,[15] the Federal Circuit has made the effort to put some meat on the bones of the Supreme Court's "general statements" about *Skidmore* deference by articulating three criteria that, if present, require deference.[16] *See Cathedral Candle*, 400 F.3d at 1366. Specifically, (i) the agency must have "conducted a careful analysis of the statutory issue," (ii) the agency's position must be "consistent" with past practice and "reflect[] agency-wide policy," and (iii) the agency's position must be "a reasonable conclusion as to the proper construction of the statute." *Id.*

Yet, even under the Federal Circuit's approach to *Skidmore* deference, the PTO's interpretation of the Hatch-Waxman Act here is entitled to no deference for at least two reasons. First, the PTO's interpretation of § 156(a) in this case does not qualify for *Skidmore* deference under the Federal Circuit's *Cathedral Candle* decision. To begin with, on this record it is unclear that the PTO's position represents an "agency-wide policy" rather than a determination limited to this case. *Cf. Meds. Co.*, 731 F. Supp. 2d at 477 (observing that patent term extension decisions

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[15] *See Christensen*, 529 U.S. at 587; *Met. Stevedore Co.*, 521 U.S. at 136.

[16] The discussion of *Skidmore* presented here assumes, as the Federal Circuit assumes, that the Supreme Court did not mean for *Skidmore* "to reduce to the proposition that 'we defer if we agree,'" in which case "*Skidmore* deference would entail no deference at all." *Cathedral Candle Co. v. U.S. Int'l Trade Comm'n*, 400 F.3d 1352, 1366 (Fed. Cir. 2005). Rather, as the Federal Circuit understands *Skidmore*, the Supreme Court "intends" for courts to defer to agency interpretations of statutes when certain criteria are present in the agency's reasoning. *See id.* Of course, if this view of *Skidmore* is incorrect and *Skidmore* means nothing more than that courts should adopt an agency's interpretation only if it is the most persuasive, then *Skidmore* is just a common sense truism instead of a doctrine of administrative law, in which case the analysis of *Skidmore*'s application to the PTO is beside the point.

are non-precedential). Without such an assurance, *Skidmore* deference is inappropriate under *Cathedral Candle*, 400 F.3d at 1366. Moreover, the PTO's statutory interpretation here cannot fairly be characterized as "careful," which the Federal Circuit also requires before *Skidmore* deference is appropriate. *Id.* The PTO's analysis of § 156 makes at least two critical assumptions, namely (i) that the FDA's determination of a product's primary mode of action is relevant to whether a product is a drug or a device for purposes of § 156 and (ii) that the FDCA's definition of "device" applies to § 156. Regardless whether these assumptions are right or wrong—and as Part III, *infra*, shows, they are mistaken—the PTO's analysis is not "careful" because the PTO never sought to *justify* these critical assumptions. *See id.* Rather, the PTO's final decision merely asserts the assumptions as foregone conclusions. *See* A872 ("Because the review of the [Zilver PTX] was under section 515 of the [FDCA] and not section 505 of the [FDCA], the method of using the approved product (medical device) must be a method of using [a device as defined in the FDCA]."). Thus, no *Skidmore* deference is due under *Cathedral Candle*.

But more fundamentally, even assuming that the PTO's interpretation satisfied *Cathedral Candle*, it is doubtful that the PTO should be afforded *Skidmore* deference for an interpretation of a substantive provision of the Patent Act, such as § 156. Indeed, the Federal Circuit in *Cathedral Candle* discussed deference to the U.S. International Trade Commission's interpretation of a statute, not the PTO's interpretation of the Patent Act. *Id.* at 1366-67. To be sure, there are cases in which courts have suggested that *Skidmore* deference may apply to PTO interpretations of the Patent Act in some instances,[17] but courts would be prudent to treat the

[17] *See, e.g., Wyeth v. Kappos*, 591 F.3d 1364, 1372 (Fed. Cir. 2010) (considering the PTO's claim of deference but concluding that unambiguous statutory language controlled); *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338, 349-50 (E.D. Va. 2009) (affording no deference because the

PTO's requests for *Skidmore* deference with skepticism.[18] Put simply, the logic of deference to agency interpretations of statutes is rooted in the broader logic of the administrative state, namely that agencies possess expertise that warrants respect as to interpretations of statutes that the agency administers.[19] The nation's patent law regime, however, is not a creature of the modern administrative state, and there is good reason therefore to reject the reflexive application of administrative law doctrines in the patent law context.[20]

PTO's interpretation failed to persuade), *aff'd sub nom., PhotoCure ASA v. Kappos*, 603 F.3d 1372, 1376 (Fed. Cir. 2010) (same); *Merck & Co., Inc.*, 80 F.3d at 1550.

[18] This skepticism is properly limited to claims of deference for interpretations of substantive provisions of the Patent Act, as it is well settled and less controversial that the PTO receives *Skidmore* deference for interpretations of its implementing regulations. *See, e.g., Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1381 (Fed. Cir. 2002) (collecting authority for the proposition that *Skidmore* deference is appropriate for the PTO's interpretations of its implementing regulations).

[19] *See* 1 Richard J. Pierce, Jr., Administrative Law Treatise § 3.3 (4th ed. 2002) (describing the conceptual foundation of *Chevron*), § 6.4 at 334 (explaining that *Skidmore* deference is rooted in the idea that "there are reasons to believe that agency positions are often wise and correct"); Scalia, *supra* note 13, at 516 (arguing that "the theoretical justification for those pre-*Chevron* cases that sometimes deferred to agency legal determinations" was "no different from" the theoretical justification for *Chevron*, namely that an agency deserves respect where Congress "meant to leave [an ambiguity's] resolution to the agency").

[20] For a more thorough discussion of the principles discussed here, *see generally* Orin S. Kerr, Rethinking Patent Law in the Administrative State, 42 Wm. & Mary L. Rev. 127 (2000) (challenging the application of administrative law doctrines to the patent system). Particularly relevant for purposes of the discussion here, Professor Kerr persuasively argues that the Patent Act is not a regulatory statute administered by a regulatory agency; no one administers the Patent Act. *See id.* at 167 n.169. Kerr's private law theory of the patent system builds on the earlier work of Professor Edmund Kitch. *See generally* Edmund Kitch, The Nature and Function of the Patent System, 20 J.L. & Econ. 265 (1977). Although not universally accepted, Kerr's insightful conceptualization is certainly not without its supporters. *See, e.g.,* Joseph Scott Miller, Substance, Procedure, and the Divided Patent Power, 63 Admin. L. Rev. 31, 36 n.25 (2011) ("Kerr's contract analogy captures the [PTO]'s role."); John R. Thomas, Liberty and Property in Patent Law, 39 Hous. L. Rev. 569, 614-16 (2002) (citing Kerr's work to illustrate the PTO's limited functions).

To elucidate this point, although the Supreme Court has acknowledged that *Skidmore* may well apply "where statutory circumstances indicate no intent to delegate general authority to make rules with force of law, or where such authority was not invoked," this observation was made in the context of an agency's administration of a "regulatory scheme" characteristic of the administrative state. *See Mead Corp.*, 533 U.S. at 235, 237. Yet, the nation's patent law regime is not a regulatory scheme in the typical administrative law sense; rather, the Patent Act operates much more like a traditional common law unilateral contract offer by Congress. Specifically, Congress has offered that if an inventor makes a discovery meeting certain criteria, then the United States will grant the inventor an intangible property right in that discovery. *See* 35 U.S.C. §§ 101-03 (criteria for patentability). Importantly, it is Congress that has stated the terms of the offer, and the PTO's job is merely to determine whether any given inventor purporting to have accepted the offer has, in fact, done so. In this respect, the PTO is not engaged in a regulatory function, but instead serves as Congress's agent in what functionally amounts to a contract negotiation. Indeed, if an inventor and the PTO disagree about the terms of Congress's offer or about any other provision of the "contract" embodied in the Patent Act, the dispute is resolved the same as any common law contract dispute, namely by invoking a neutral third party to determine the objective meaning of the disputed term and to enforce the contract according to that meaning. *See* 35 U.S.C. §§ 141, 145 (providing for judicial review). And § 156 is surely part of Congress's offer and the terms of the Patent Act's contract, insofar as § 156(a) represents a mandatory benefit to which certain inventors who accept Congress's offer are entitled.

In light of the foregoing, when the PTO litigates a dispute under the Patent Act like the instant case, the PTO essentially stands as an offeror's agent in a contract dispute. In the law of unilateral contracts, which provides a conceptually helpful analogy, there is no background rule

that an offeror (or an offeror's agent) receives a thumb on scale on interpretative matters merely by advancing a "careful," "consistent," and "reasonable" argument about the contract's meaning. *See Cathedral Candle*, 400 F.3d at 1366 (interpreting *Skidmore* as requiring deference where these criteria are present). Nor is there a background presumption that a party to a contract is more likely to understand the contract's terms by virtue of having been a party to many similar contracts in the past. In short, *Skidmore* deference—or something akin to such deference—is never due to an offeror in a contract dispute merely by virtue of his status as offeror or as a repeat player with a certain type of contract. And there is no compelling, rational reason to conclude that the PTO should be treated any differently from an ordinary contract litigant merely by virtue of the fact that the PTO is an agency. In other words, what should matter for purposes of judicial deference under *Skidmore* is the substance of what an agency does. Where, as here, the agency is more fairly viewed as a contracting party's agent than a regulator, this must surely be a relevant "factor" bearing on the PTO's "power to persuade." *Skidmore*, 323 U.S. at 140. To conclude otherwise would be to accept a form of categorical administrative agency exceptionalism in which anything reasonable that an agency says about a statute relevant to its work is entitled to some respect simply because the agency says it. At bare minimum, such respect should be limited to agencies functioning in a regulatory capacity, as the status as regulator is at least arguably reflective of the agency's specialized expertise.

Nothing stated here should be understood as an attack on the authority of *Chevron* or *Skidmore* when applied in the proper circumstances. To the contrary, the purpose of this discussion has been to suggest that federal courts should not decouple deferential doctrines from the justifications for those doctrines. There is no dispute that *Chevron* and *Skidmore* are limited to "an agency's construction of a statute it is charged with administering." *Cathedral Candle*,

400 F.3d at 1365. The conclusion here is simply that, properly understood, the PTO is not "charged with administering" the Patent Act in a regulatory sense. *Id.* Thus, the logic of *Skidmore* does not fit comfortably with the functions of the PTO. Specifically, because the PTO's functions, as relevant here, are more analogous to those of an agent engaged in the ordinary private law task of complying with contract-like agreements affecting the disposition of property rather than those of a public law entity engaged in regulation, the indicia of expertise that warrant *Skidmore* deference are not present here. Put more simply, given the PTO's function in this context, there is no compelling reason to believe that the PTO's positions on the meaning of the Patent Act are "wise and correct" in a manner that justifies deference under an administrative law doctrine like *Skidmore*. *See* Pierce, *supra* note 19, § 6.4 at 334. Like any party attempting to enforce the terms of a contract, the PTO is entitled to no special deference in assessing the meaning of the terms.

In sum, (i) because the PTO's interpretation of § 156 here is neither carefully reasoned nor constitutes agency-wide policy and (ii) because the logic of *Skidmore* does not apply to PTO interpretations of substantive provisions of the Patent Act like § 156, no deference is due here to the PTO's interpretation of § 156 as reflected in the final decision denying plaintiff's application.

III.

Analysis now turns to the merits of the precise question presented. Although the parties disagree with one another on multiple issues, the dispute between the parties boils down to a single question: Does the '447 patent "claim[]...a method of using" a "medical device" as those terms are used in the Hatch-Waxman Act? *See* 35 U.S.C. § 156(a), § 156(f)(1)(B). In essence, plaintiff's position is that claim 12 of the '447 patent is an open method of biologically stenting a mammalian artery, and therefore the method may well include the use of the Zilver PTX. The

PTO, in opposition, stands by its administrative determination that because the FDA reviewed the Zilver PTX as a device, the Zilver PTX is also a device for purposes of § 156, and in light of the definition of "device" in the FDCA, the '447 patent can claim a method of using the Zilver PTX only if the patent recites one or more structural elements of the product.

The task here is to determine the correct interpretation of § 156. If the PTO denied plaintiff's application "based on an erroneous interpretation of law," then the PTO committed an abuse of discretion under the APA. *See Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004). At the same time, if the PTO's erroneous interpretation resulted in no "prejudicial error," then affirmance of the PTO's decision may still be appropriate. *See* 5 U.S.C. § 706; *Shinseki v. Sanders*, 556 U.S. 396, 406 (2009) ("[T]he APA's reference to prejudicial error is intended to sum up in succinct fashion the harmless error rule applied by the courts in the review of lower court decisions as well as of administrative bodies.") (internal quotations and alterations omitted).

A.

As a preliminary matter, the PTO argues that certain of plaintiff's statutory arguments have been waived and cannot be considered. These arguments fail.

As the Federal Circuit has observed, "a party generally may not challenge an agency decision on a basis that was not presented to the agency." *In re DBC*, 545 F.3d 1373, 1378 (Fed. Cir. 2008). This rule finds its roots in "considerations of practical justice," which include (i) allowing an agency to correct its own mistakes and (ii) promoting judicial efficiency by keeping out of court claims that could be quickly and economically resolved before the agency. *See id.* at 1378-79 (internal quotations omitted). These principles point conclusively to the absence of a waiver on this record.

Plaintiff's position throughout the patent term extension application process has been that the PTO is misreading the Hatch-Waxman Act by imposing as a limitation on patent term extension eligibility the requirement that a patent claiming a method of using a device recite structural elements of the device.[21] Thus, there is no doubt that the essence and the premise of plaintiff's argument was presented to the PTO, and this is sufficient to preclude waiver. As the Fourth Circuit once instructively explained, even though every nuance of an argument is not presented to an agency "as ardently and cogently" as to a court, waiver does not occur if the agency clearly rejected the premise of the claim. *See Lane Hollow Coal Co. v. Dir., Office of Workers' Comp. Programs*, 137 F.3d 799, 806 (4th Cir. 1998).

Precisely this occurred here. Every statutory argument plaintiff advances in this lawsuit, although perhaps not "ardently and cogently" presented to the PTO, relates directly to plaintiff's fundamental premise as that premise was presented to the PTO during the administrative process. *Id.* The PTO's position, in effect, is that plaintiff can argue in federal court only the precise statutory arguments presented to the PTO. Yet, to accept the PTO's position would be to run roughshod over the purposes of the waiver doctrine. Plaintiff's statutory arguments about the meaning of the Hatch-Waxman Act gave the PTO ample opportunity to adopt an interpretation that would satisfy plaintiff. An agency is not entitled, as a matter of course, to pre-screen any and all arguments that might support a proposition; rather, the agency is entitled only to the reasonable opportunity to address the proposition itself. *See In re DBC*, 545 F.3d at 1378 (noting that a purpose of the waiver doctrine is to discourage disregard of agency procedures by giving the agency an opportunity to correct its own mistakes). There can be no doubt that the PTO had

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[21] *See, e.g.,* Request for Reconsideration of Denial (A851-64), at 7-8 ("[C]laim 12 of the '447 patent is 'a method of using a product' under 35 U.S.C. § 156, the product being the ZILVER controlled-delivery system.").

sufficient opportunity to—and did in fact—confront plaintiff's fundamental statutory argument that § 156 encompasses claim 12 of the '447 patent.

Accordingly, plaintiff has not waived any of the arguments presented in this litigation, as every statutory argument relates to the single question of statutory interpretation at the heart of the dispute: For purposes of the Hatch-Waxman Act, what does it mean for a patent to "claim[]...a method of using" a "medical device"? Analysis therefore proceeds to answer this question.

B.

When resolving the meaning of a statute, "the starting point...is the language of the statute itself." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980). Indeed, it is axiomatic that "[i]f the statutory language is plain," a court "must enforce it according to its terms." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015). Moreover, it is "fundamental" that "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning." *Perrin v. United States*, 444 U.S. 37, 42 (1979). Only in "rare and exceptional circumstances" will unambiguous statutory language not end the analysis. *See Wyeth*, 591 F.3d at 1369. Of course, some ambiguities are evident only when the words are viewed "in their context and with a view to their place in the overall statutory scheme." *King*, 135 S. Ct. at 2489 (internal quotations omitted). Thus, although the analysis properly focuses on the text, the analysis is not necessarily limited to the text.

The key provision in the instant action is § 156(a), which 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 from the original expiration date of the patent" if certain conditions

are met.[22] A "product" for purposes of § 156(a) means, as relevant here, "[a]ny medical device...subject to regulation under the [FDCA]." 35 U.S.C. § 156(f)(1)(B).[23] Thus, the '447 patent is eligible for a patent term extension if (i) the '447 patent claims a method of using a medical device subject to regulation under the FDCA and (ii) the statutory criteria under § 156(a)(1)-(5) are all met.

The parties do not dispute that the Zilver PTX is a qualifying "medical device" under § 156(f)(1)(B). They hardly could. As generally understood, a "device" is a contraption, contrivance, or similar physical article. *See, e.g.,* Webster's Third New International Dictionary 618 (1993) (a "device" is a "contrivance").[24] And a device is "medical" in nature if its purpose relates to the diagnosis, treatment, or prevention of disease. *See, e.g., id.* at 1402 (defining "medical" as "of, relating to, or concerned with...the practice of medicine," and defining "medicine" as "the science and art dealing with...the prevention, alleviation, or cure of

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[22] The statutory criteria for a patent term extension in § 156(a)(1)-(5) are not in issue in this lawsuit, as the PTO did not base its denial of plaintiff's application on a failure to satisfy any of these criteria. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("[A] reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency.").

[23] Because § 156(f)(1) provides a statutory definition of "product," that definition controls over any contrary ordinary meaning. *See Perrin*, 444 U.S. at 42 (acknowledging that the "ordinary, contemporary, common meaning" controls "unless otherwise defined"); Caleb Nelson, Statutory Interpretation 84 (2011) ("Of course, when a statute specifically defines one of the terms that it uses, courts apply the stated definition in preference to the ordinary meaning of that term.").

[24] *Accord, e.g.,* The American Heritage College Dictionary 380 (3d ed. 1993) (defining "device" as "[a] contrivance or an invention serving a particular purpose"); Webster's II New Riverside University Dictionary 370 (1984) (similar); Black's Law Dictionary 407 (5th ed. 1979) (similar). To be sure, dictionary definitions are not necessarily dispositive of a word's ordinary meaning, but they are valuable tools in approximating the sense in which linguistic communities use and understand words, and therefore can confirm that an understanding of a word is ordinary rather than idiosyncratic. *See Struniak v. Lynch*, --- F. Supp. 3d ---, 2016 WL 393953, at *6 n.11 (E.D. Va. Jan. 29, 2016) (citing Nelson, *supra* note 23, at 126).

disease").[25] Because the Zilver PTX is a contrivance that stents arteries and prevents restenosis, and therefore serves a purpose related to the treatment and prevention of disease, the Zilver PTX is undoubtedly a "medical device" in the ordinary sense of the term. Moreover, it is undisputed that the Zilver PTX is regulated under the FDCA.

The dispositive question then becomes whether the '447 patent claims a method of using the Zilver PTX, a question the PTO answered in the negative. The PTO's reasoning in this regard begins with the uncontested (and correct) premise that the FDA reviewed the Zilver PTX as though it were purely a medical device. The FDA did so because the Zilver PTX is a combination product with the primary mode of action of a device, a conclusion plaintiff does not dispute. *See* 21 U.S.C. § 353(g)(1) (regulating combination products on the basis of their primary modes of action). Accordingly, the PTO treated the Zilver PTX as a medical device for purposes of reviewing plaintiff's patent term extension application. The PTO then imported the definition of "device" from the FDCA to determine that a patent claims a method of using a medical device only if the patent recites one or more structural elements of the device. *See* 21 U.S.C. § 321(h) (defining "device"). Specifically, the FDCA's definition of "device" excludes contrivances that "achieve [their] primary intended purposes through chemical action." *Id.* As such, the PTO characterized § 321(h) as focusing on structural features to the exclusion of chemical features. And because the '447 patent does not recite any structural elements of the Zilver PTX, the PTO determined that the '447 patent does not claim a method of using a product for purposes of § 156(a).

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[25] *Accord, e.g.,* The American Heritage College Dictionary 846 (3d ed. 1993) (defining "medical" as "[o]f or relating to the study or practice of medicine"; defining "medicine" as "[t]he science of diagnosing, treating, or preventing disease and injury to the body or mind"); Webster's II New Riverside University Dictionary 738 (1984) (similar); Black's Law Dictionary 885-86 (5th ed. 1979) (similar).

Plaintiff's objections to the PTO's reasoning may be succinctly summarized: How the FDA reviews a product under § 353(g) and how § 321(h) defines a "device" for purposes of the FDCA are irrelevant to whether a patent "claims...a method of using" a "medical device," an inquiry that should focus exclusively on the text of § 156. Plaintiff's objection is well taken; the PTO improperly wandered afield from the text of § 156. Yet, the PTO's foray into the FDCA was a harmless detour, as the PTO ultimately arrived at the correct destination, albeit in a roundabout way.

As previously noted, it is "fundamental" that "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning." *Perrin*, 444 U.S. at 42. Thus, the baseline presumption is that "medical device" as used in § 156(f)(1)(B) refers to any contraption, contrivance, or related article that serves a purpose related to the diagnosis, treatment, or prevention of disease.[26] The FDCA's definition of "device" is narrower than the ordinary meaning of "medical device," in that § 321(h) excludes from its coverage any contraption, contrivance, or related article that "achieve[s] its primary intended purposes through chemical action," a limitation that does not exist in the ordinary sense of the term. Importantly, the narrower statutory definition of "device" in § 321(h) does not by its own terms purport to apply to § 156, inasmuch as § 321 is prefaced with language limiting the application of the definitions contained therein to Chapter 9 of Title 21 of the United States Code. *See* 21 U.S.C. §

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[26] *See supra*, notes 24-25 and accompanying text (defining "device," "medical," and "medicine"). Moreover, § 156(f)(1)(B) refers to "[a]ny" medical device, which underscores the breadth of the definition, *i.e.*, that it includes even contrivances for which chemical action performs most of the therapeutic heavy lifting. *See* Webster's Third New International Dictionary 97 (1993) (defining "any" as "one indifferently out of more than two; one or some indiscriminately of whatever kind"). In other words, a contrivance with a purpose related to the diagnosis, treatment, or prevention of disease (a "medical device") may well achieve its primary therapeutic effect through chemical action.

321 ("For the purposes of this chapter--"). In this regard, importing § 321(h)'s definition of "device" into § 156 flouts § 321's express statutory limitation on the reach of the definition of "device." Simply put, § 321(h) does not "otherwise define[]" the term "medical device" as used in § 156, and so the "ordinary, contemporary, common meaning" of the term controls. *Perrin*, 444 U.S. at 42.

The PTO nonetheless argues that the definition from § 321(h) applies to § 156 because § 156(f)(1)(B) refers to medical devices "subject to regulation under the [FDCA]." Yet, this language does not warrant or invite an importation of § 321(h)'s definition of "device" into § 156; rather, it merely narrows the scope of the ordinary meaning of "medical device," such that the only contraptions, contrivances, and related articles with purposes relating to the diagnosis, treatment, and prevention of disease that are covered are those that the FDCA regulates. Thus, a physical contraption with a drug component that achieves its primary therapeutic effect through chemical action is still a medical device for purposes of § 156 as long as the contraption is subject to FDCA regulation *in some respect*. And this is so whether the FDA regulates the product as a device, as a drug, or as a biological product.

Context further supports this conclusion, insofar as where Congress intended to color the meaning of terms under § 156(f) according to the definitional provisions of the FDCA, it did so unambiguously. Thus, § 156(f)(5) gives the term "informal hearing" "the meaning prescribed for such term by section 201(y) of the [FDCA]," which is codified at § 321. *See also* H.R. Rep. No. 98-857(II), 1984 U.S.C.C.A.N. 2686, 2709 (1984). In fact, the House Report on the Hatch-Waxman Act cites § 321 several times, but never in connection to what constitutes a "device" for purposes of § 156(f)(1)(B). *See id.* at 2694, 2696, 2698, 2709. That there is no unambiguous link between § 156(f)(1)(B) and § 321(h) in either the text or the legislative history of the Hatch-

Waxman Act—despite the fact that such links exist with regard to other terms in §§ 156 and 321—points all the more persuasively to the conclusion that a "medical device" for purposes of § 156(f)(1)(B) should not be construed to have the same meaning as "device" under § 321(h), but should instead take its ordinary meaning.[27]

The fact that the FDA reviewed the Zilver PTX as a medical device does nothing to change this analysis. When the FDA determines a combination product's primary mode of action for purposes of FDCA review, the FDA is not identifying the nature of the product itself. Rather, the FDA's determination of a primary mode of action is merely an identification of the predominate means by which the product achieves its therapeutic effect. *See* 21 C.F.R. § 3.2(k) (defining "mode of action"), § 3.2(m) (defining "primary mode of action"). For purposes of classifying a product under the Hatch-Waxman Act, it makes no difference whether the FDA reviews a product as a device, as a drug, as a biological product, or as a unicorn—if the product is a contraption, contrivance, or related article with a purpose related to the diagnosis, treatment, or prevention of disease, then it is a medical device under § 156(f)(1)(B).

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[27] Of course, if the ordinary, contemporary, and common meaning of "medical device" happened to accord with what is codified at § 321(h), then it would be fully appropriate to read "device" in § 156(f)(1)(B) and § 321(h) as sharing the same meaning. The point here is simply that where Congress borrows an older statute's definitions as a source of meaning for certain provisions of a new statute, but not others, courts should not deviate from the ordinary, contemporary, and common meaning of the new statute's terms that do *not* explicitly borrow from the older statute simply for the sake of creating statutory harmony. To do so would be to fall victim to the "original sin" of "assum[ing] that a word which appears in two or more legal rules, and so in connection with more than one purpose, has and should have precisely the same scope in all of them," a folly against which the Supreme Court has repeatedly cautioned. *See Wachovia Bank v. Schmidt*, 546 U.S. 303, 319 (2006) (internal quotations omitted). *See also General Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 595 n.8 (2004); *United States v. Cleveland Indians Baseball Co.*, 532 U.S. 200, 213 (2001); *NationsBank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 262 (1995); *Civil Aeronautics Bd. v. Delta Air Lines, Inc.*, 367 U.S. 316, 328 (1961).

In short, the PTO's statutory analysis of § 156 is flawed. Section 156's language is adequate (i) to classify the Zilver PTX as a drug or as a medical device for purposes of the Hatch-Waxman Act and (ii) to analyze the '447 patent's eligibility for a patent term extension. There is no need or warrant to refer to the FDCA or the actions of the FDA to reach these conclusions. Yet, it does not necessarily follow that the PTO's ultimate conclusion must be set aside. As the analysis that follows demonstrates, the PTO's interpretative error was ultimately harmless.

C.

Distilled to its essence, the PTO's justification for denying plaintiff's patent term extension was that the '447 patent does not recite any structural elements of the Zilver PTX. In plaintiff's view, the PTO's structural element requirement is atextual and amounts to the administrative addition of a patent term extension eligibility criterion. This characterization is not accurate, however, as the PTO's requirement that the '447 patent must recite a structural element of the Zilver PTX derives from two statutory sources, namely (i) the definition of "device" in § 321(h) and (ii) the meaning of "claims" in § 156(a), as the Federal Circuit interpreted that term in *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997). As already discussed, the PTO's reliance on § 321(h) rather than on the ordinary, contemporary, and common meaning of "medical device" was in error. But if the same outcome obtains by synthesizing the ordinary, contemporary, and common meaning of "medical device" together with the holding of *Hoechst-Roussel*, then the PTO's error is harmless. It remains, therefore, to apply § 156(a) to claim 12 of the '447 patent in light of the ordinary, contemporary, and common meaning of "medical device" and the requirements of *Hoechst-Roussel*.

In *Hoechst-Roussel*, 109 F.3d at 757, the Federal Circuit affirmed the PTO's denial of a patent term extension for U.S. Patent No. 4,631,286 ("the '286 patent"). The '286 patent made two relevant claims, (i) the compound 1-hydroxy-tacrine and (ii) a method of treating a patient in need of memory enhancement by administering an effective amount of 1-hydroxy-tacrine. *See id.* In 1990, approximately four years after the '286 patent issued, a company that was neither the owner nor licensee of the '286 patent submitted for FDA approval a new drug, the active ingredient of which was tacrine hydrochloride. *See id.* Upon ingestion, tacrine hydrochloride metabolizes into, *inter alia*, 1-hydroxy-tacrine, which then performs the function of memory enhancement in patients with Alzheimer's disease, the target population of the tacrine hydrochloride drug. *See id.* Thus, the administration of the tacrine hydrochloride drug allegedly infringed the '286 patent in that "when administered, tacrine hydrochloride metabolizes into another product, 1-hydroxy-tacrine, which [the '286 patent] has claimed." *Id.* at 759. Because the administration of the tacrine hydrochloride drug would infringe the '286 patent's claimed method of administering 1-hydroxy-tacrine, the plaintiff in *Hoechst-Roussel* argued that the '286 patent claimed a method of using the tacrine hydrochloride drug and therefore qualified for a patent term extension. *See id.* at 758. The Federal Circuit rejected this argument, reasoning that "the concept of a 'claim' is different from the concept of infringement, and, as a result, the plain meaning of 'claims' is not the same as the plain meaning of infringement." *Id.* at 759.

Importantly, *Hoechst-Roussel* stands for the proposition that for purposes of § 156(a), a patent does not claim all products that directly infringe the patent claims.[28] In this respect,

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[28] Although this proposition is arguably not pellucid on the face of the *Hoechst-Roussel* opinion, the conclusion is at least properly inferred from Judge Newman's concurrence in the judgment. As Judge Newman explained, she agreed that there is a distinction "between what is claimed and what is infringed…in the circumstance of infringement by equivalents," but not where, as in

"claim" in § 156(a) is not used in the patent law term of art sense, but "the ordinary meaning of that term" applies instead. *Id.*; *see also id.* at 764 (Newman, J., concurring in the judgment) (characterizing the majority's interpretation as "a new, vague, and unnecessary distinction between what is claimed and what is infringed, unique to [§ 156] of Title 35."). Importantly, the Federal Circuit did not identify precisely what is meant by "the ordinary meaning" of "claims" in § 156(a). But helpfully, the Federal Circuit clarified that "[w]ith respect to direct infringement," the "claims define the patent owner's property rights whereas infringement is the act of trespassing upon those rights." *Id.* at 759. Thus, having the exclusive right to make, use, and sell a particular innovation is insufficient to "claim" the innovation for purposes of § 156. *See id.*; 35 U.S.C. § 271 (defining infringement). Rather, the Federal Circuit held in *Hoechst-Roussel* that for a patent to qualify for a patent term extension, the patent must claim the particular product that underwent FDA review. *See Hoechst-Roussel*, 109 F.3d at 761 (affirming denial of a patent term extension because the "'286 patent neither claims tacrine hydrochloride nor a method of using that product"). In this respect, the "ordinary meaning" of "claim" that the Federal Circuit applied resembles the meaning of the term as used in the world of tangible property—the ordinary world in which most people operate—in which to "claim" property is to assert title over a particular and clearly defined tract of land. *See* Webster's Third New International Dictionary 414 (1993).

Hoechst-Roussel, the patent's claims "are literally and directly infringed" by the product subject to FDCA regulation. *See Hoechst-Roussel*, 109 F.3d at 764 n.2 (Newman, J., concurring in the judgment). Thus, if the *Hoechst-Roussel* panel majority meant something short of saying that a directly infringing product may not be claimed for purposes of § 156(a), then presumably there would not have been a disagreement between the majority and Judge Newman warranting Part II of Judge Newman's opinion concurring in the judgment.

Understanding *Hoechst-Roussel* as requiring the analysis to focus sharply on the particular product allegedly claimed also finds support in the text of § 156(a), which repeatedly employs the language "a product." In this context, the indefinite article "a" serves its usual and expected purpose "as a function word before most singular nouns...when the individual in question is undetermined, unidentified, or unspecified." Webster's Third New International Dictionary 1 (1993). In this respect, the reference to "a product" indicates that an eligible patent must claim *one* product, or at least a *particular* product, from among the entire set of drug products and medical devices that qualify under § 156(f)(1).[29]

Hoechst-Roussel's particularity requirement also accords with the fundamental purpose of Title II of the Hatch-Waxman Act. As the Federal Circuit has explained, the Hatch-Waxman Act "encourage[s] new drug research by restoring some of the patent term lost while drug products undergo testing and await FDA pre-market approval." *See Glaxo Operations UK Ltd.*, 894 F.2d at 396. Put differently, the whole point of Title II of the Hatch-Waxman Act is to protect the profitability of medical innovations by ensuring that inventors of FDCA-regulated drugs and medical devices do not forego several years of their patent's term without the ability to make money with the invention. If a patent owner could claim a patent term extension merely because a directly infringing product underwent FDA review *even though* the patent owner was

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[29] Plaintiff advances an alternative argument about the significance of the word "a" in § 156(a), arguing that "a method" can mean *any* method. This argument is undoubtedly correct. *See* Webster's Third New International Dictionary 1 (1993) (where the indefinite article "a" is "used with a following restrictive modifier," such as "of using a product," the indefinite article means "any"). At the same time, this argument misses the point that a qualifying method—of which there may be many—must relate to a particular product because the patent must claim "*a* method of using *a* product." 35 U.S.C. § 156(a) (emphasis added). *Cf.* William S. Stevens, The Common Law Origins of the Infield Fly Rule, 123 U. Pa. L. Rev. 1474, 1474 (1975) (mocking the pedantry and citation requirements of law review articles by providing a citation to the definition of the article's opening word—"[t]he").

otherwise able to put his patent to productive and profitable use during the review period, then the Hatch-Waxman Act would be handing out windfalls rather than compensating for losses.

Hoechst-Roussel well illustrates this point. The applicant there had a method claim that gave it the right to exclude others from administering 1-hydroxy-tacrine as a treatment for memory deficiencies. *See* 109 F.3d at 759. That right to exclude encompassed any number of means or methods of administering 1-hydroxy-tacrine and was not limited to the administration of the specific tacrine hydrochloride drug that underwent FDA approval and prompted the patent term extension application. Thus, the '286 patent's claims were profitable even in the absence of FDA approval of the tacrine hydrochloride drug because the '286 patent allowed the patent owner to exclude other directly infringing products from the outset of the patent term. Indeed, in *Hoechst-Roussel* the product that served as the alleged basis for the patent term extension was not even submitted for FDA review until almost four years after the '286 patent issued. *See id.* at 757. In the approximately four preceding years, the owner of the '286 patent was presumably able to profit from the ability to exclude others, absent payment of a royalty, from administering 1-hydroxy-tacrine as a treatment for memory deficiencies. Thus, the '286 patent was not the type of patent about which Congress was concerned when it enacted Title II of the Hatch-Waxman Act to ensure that medical innovators were sufficiently incentivized to continue investing in medical innovations, in that the '286 patent never sacrificed a period of profitability to the regulatory process.

The instant case is analogous to *Hoechst-Roussel* in at least two crucial respects. Like the '286 patent, claim 12 of the '447 patent does not claim a method of using the particular product that underwent FDA review. To the contrary, claim 12 of the '447 patent claims a method that can be performed by a number of products, of which the Zilver PTX is but one. *Cf. Hoechst-*

Roussel, 109 F.3d at 759 n.4 (concluding that a qualifying method claim must claim the precise product undergoing FDA review). Indeed, the fact that claim 12 of the '447 patent does not recite structural features of the Zilver PTX, a deficiency that the PTO treated as dispositive, is certainly evidence that claim 12 does not claim a method of using the particular product. Moreover, under the ordinary, contemporary, and common meaning of "medical device," as used in § 156(f)(1)(B), a qualifying "product" will necessarily be physical and contain structural features.[30] The absence of a recitation of *any* structural features suggests not only that claim 12 does not claim a method of using the Zilver PTX specifically, but that claim 12 does not claim a method of using *any* particular device at all.[31]

Further, the '447 patent is similar to the '286 patent in that both patents could have been profitably exploited well before the products allegedly triggering term extension eligibility underwent FDA review. Indeed, the Zilver PTX was not submitted for FDA review until June 2010, nearly *twelve years* after the '447 patent issued. In this respect, the '447 patent, like the '286 patent in *Hoechst-Roussel*, falls beyond the reach of the policy problem that Title II of the Hatch-Waxman Act was designed to address. Specifically, the profitability of claim 12 of the

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[30] *See supra*, note 24 and accompanying text.

[31] To be perfectly clear, claim 12's reference to "biologically stenting" is not a recitation of any structure. As the specification teaches, "biological stenting" occurs where "the vascular smooth muscle cells synthesize protein required to repair minor cell trauma and secrete interstitial matrix, thereby facilitating the fixation of the vascular lumen in a dilated state near its maximal systolic diameter." Col. 5, ll. 45-49. And it is well settled that "the specification is always highly relevant to"—and often dispositive of—"the meaning of a disputed term" in a claim. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Quite apart from the specification, it does not necessarily follow that because a "stent" is physical, "stenting" involves the use of structure. For one, "biologically," which modifies "stenting" in claim 12, implies a non-structural process. Moreover, to suggest that "stenting" cannot be performed without physical structure simply because a "stent" is physical would be like saying that "filing" cannot occur without physical files, even though modern technology renders electronic filing a possibility.

'447 patent does not turn on the ability to use the Zilver PTX, in that claim 12 sweeps broadly enough that the use of any number of products could infringe the claim.[32] Yet, as *Hoechst-Roussel* teaches, simply that a product or method of using a product directly infringes a claim does not mean that the patent claims that product for purposes of § 156(a). *See* 109 F.3d at 759.

Plaintiff's objection to what it views as an atextual eligibility requirement—that the '447 patent must recite some structure to claim the Zilver PTX—is understandable. Yet, as the foregoing analysis illustrates, this requirement is not in fact atextual, but follows from the Federal Circuit's interpretation of the term "claims" in § 156(a) and that section's reference to "a product." Specifically, in order for a method claim to qualify for a patent term extension under § 156(a), the method must claim the use of the particular product that underwent FDA review. Where the product in issue is a "medical device," it follows from the ordinary meaning of that term that the claimed product will be physical in nature and have some structure. Claim 12 of the '447 patent recites no structure and does not expressly contemplate the use of any structure, and it therefore cannot be said that the patent claims a method of using *any* particular product, much less the Zilver PTX. Thus, although the PTO erred in concluding that § 321(h) requires that a

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[32] Indeed, claim 12 is actually broader than the claims in issue in *Hoechst-Roussel*, in that claim 12 employs the word "comprises," which "creates a presumption that the body of the claim is open." *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1350 (Fed. Cir. 2001). In plaintiff's view, this language indicates that additional steps—including physical stenting generally and the use of the Zilver PTX specifically—may be included in the claimed method. But the presumption of openness raised by the term "comprises" merely means "that an infringing process could practice other steps in addition to the ones mentioned." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007). As *Hoechst-Roussel* makes clear, that the use of a physical stent generally or the Zilver PTX specifically as part of a process may infringe the claimed method is insufficient to establish that claim 12 claims a method of using the Zilver PTX. *See* 109 F.3d at 759. It also bears mentioning briefly that nothing in this decision should be understood as passing on the validity of claim 12 under 35 U.S.C. § 101, so any suggestion of infringement is simply that—a suggestion. *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2357 (2014) (a patent claim is invalid if it is directed to an abstract idea without an inventive concept that transforms the abstract idea into a patent-eligible application).

patent claiming a method of using a medical device recite some structure in order to qualify for a term extension under § 156(a), the PTO's ultimate conclusion was not in error. That the '447 patent's failure to recite structure demonstrates that claim 12 does not claim a method of using the Zilver PTX finds firm support (i) in the ordinary meaning of "a product" in § 156(a), (ii) in the ordinary meaning of "medical device" in § 156(f)(1)(B), and (iii) in the meaning of "claims" in § 156(a), as interpreted by the Federal Circuit. In this regard, even though the PTO denied plaintiff's application based on an erroneous interpretation of law, the error was harmless and the PTO's denial need not be set aside as arbitrary and capricious. *See* 5 U.S.C. § 706.

IV.

For the foregoing reasons, the PTO's final decision denying plaintiff's application for a patent term extension for the '447 patent was not arbitrary, capricious, an abuse of discretion, or otherwise contrary to law in a manner that warrants setting the denial aside. Accordingly, plaintiff's motion for summary judgment must be denied, and the PTO's motion for summary judgment must be granted.

An appropriate order will issue.

Alexandria, Virginia
June 8, 2016

/s/
T. S. Ellis, III
United States District Judge