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

PHOTOCURE ASA, Plaintiff, v. JON W. DUDAS, Under Secretary of Commerce for Intellectual Property & Director of the United States Patent and Trademark Office, *et al.*, Defendants.	)	Civil Action No. 1:08cv718

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

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INTRODUCTION

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act and codified in part in 35 U.S.C. § 156, to give patent owners the right to extend the term of a patent covering a drug product to make up partially for the patent term lost during regulatory review by the Food and Drug Administration ("FDA"). *See* H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 14-15, *reprinted in* 1984 U.S. Code Cong. & Admin. News. 2647, 2647-48; *see also Unimed, Inc. v. Quigg*, 888 F.2d 826, 829 (Fed. Cir. 1989) (explaining that § 156 of the Hatch-Waxman Act "ameliorate[s] the loss incurred when patent terms tick away while the patented product is awaiting [FDA] regulatory approval for marketing."). Congress, however, carefully restricted the extension provisions in the Hatch-Waxman Act to pioneering new drugs, as opposed to the follow-on inventions that typically occur after a pioneering new drug is patented; *e.g.*, a different use, dose, or formulation. *See Fisons plc v. Quigg*, 1988 WL 150851, *7 (D.D.C. 1988) ("*Fisons I*"). The patent term extension provisions in the Hatch-Waxman Act represent a careful balance that Congress achieved only after much negotiation and controversy between brand pharmaceutical companies and generic manufacturers. *See id.* at *7-9. The compromise nature of the Act explains why Congress limited the types of inventions eligible for patent term extension while simultaneously providing incentive for beneficial new drug research and development. *See id.* at *10.

In administrative proceedings before the United States Patent and Trademark Office ("USPTO"), Photocure sought to upset Congress's carefully crafted balance by securing a patent term extension for its U.S. Patent No. 6,034,267 ("the '267 patent"). Photocure's petition was based upon the FDA regulatory review of its drug Metvixia®, which is protected by the '267

patent. But Metvixia® is not a pioneering new drug; instead, it is a "follow-on" drug – a different formulation of an earlier-FDA approved drug called Levulan®. Drugs are formulated in certain ways, for example as a salt or ester, to help stabilize the drug, improve its solubility, and increase its bioavailability. Metvixia® is formulated as the salt and ester of aminolevulinic acid. Levulan® is formulated as a salt of aminolevulinic acid.

This case is about whether the earlier commercial marketing of Levulan® extinguishes Photocure's ability to secure a patent term extension for the patent protecting Metvixia® under § 156. Through an interpretation of the pertinent statutory language, the USPTO concluded that both Metvixia® and Levulan® contained the same "active ingredient," and as such, denied Photocure's patent term extension application. Photocure now seeks judicial review of that decision pursuant to the Administrative Procedure Act ("APA"). The USPTO's denial was not arbitrary, capricious, or an abuse of discretion, and was otherwise in accordance with law, especially given the deference due USPTO's statutory interpretation, and the narrow judicial review available to Photocure under the APA. The denial flows from the statutory language of § 156, effects the intent of Congress, is consistent with case law, and maintains the compromise embodied in the Hatch-Waxman Act. Accordingly, this Court should affirm USPTO's denial of Photocure's application, and enter summary judgment in its favor.

UNDISPUTED MATERIAL FACTS

Photocure correctly concedes, *Pl. Mem.* (Dkt. No. 13), at 5, 7-8, that it seeks judicial review of the USPTO's decision to deny its administrative petition pursuant to the limited waiver of sovereign immunity found in the APA. The APA confines review of Executive Branch action by the Article III judiciary to the administrative record of proceedings before the pertinent agency.

See 5 U.S.C. § 706; *Camp v. Pitts*, 411 U.S. 138, 142 (1973). And as such, "there can be no genuine issue of material fact" in an APA action, *R.R. Donnelly & Sons v. Dickinson*, 123 F. Supp. 2d 456, 458 (N.D. Ill. 2000). For this reason, the parties concluded (Dkt. No. 7) that the action presented legal questions that could be resolved on joint motions for summary judgment:

> [I]t is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did."

Am. Forest Res. Coun. v. Hall, 533 F. Supp. 2d 84, 89 (D.D.C. 2008) (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)).

Because the Local Rules of this Court require such a statement, see LOC. CIV. R. 56(B), however, USPTO provides that it is in agreement with Photocure's list of undisputed material facts with certain minimal exceptions. Each of these exceptions (paragraphs 8, 10, and 11) relates to certain differences (both perceived and actual) between USPTO's initial and final administrative decisions in this action. At the outset, none of these purported "facts" is at all material because this Court – pursuant to the provisions of the "APA" – only possesses jurisdiction to review the agency's "final agency action," 5 U.S.C. § 704; accordingly, the particularities of the USPTO's initial decision have no bearing on this Court's adjudication of the parties' cross-motions for summary judgment. *See, e.g.*, *Fireman's Fund Ins. Co. v. Murchison*, 937 F.2d 204, 207 (5th Cir. 1991). With this said, USPTO notes the following disputes:

8. Whether USPTO changed the basis for its decision is a legal conclusion; it is not a question of fact.

10. In its Initial Decision, USPTO stated that the active ingredient in Levulan® is

aminolevulinic acid hydrochloride ("ALA HCl"). In its Final Decision, however, USPTO corrected itself that the active ingredient in Levulan® is aminolevulinic acid ("ALA"). *See* A637, A639.

11. In its Initial Decision, USPTO stated that the active ingredient in Metvixia® is methylaminolevulinate hydrochloride ("MAL HCl"). In its Final Decision, however, USPTO corrected itself that the active ingredient in Metvixia® is aminolevulinic acid (ALA). *See* A637, A639.

USPTO also adds the following undisputed material facts, beginning the numerical sequence where Photocure's list ended:

21. Methylaminolevulinate hydrochloride (MAL HCl) is both an ester and salt of aminolevulinic acid (ALA), specifically the methyl ester and the hydrochloride salt. A417

22. Aminolevulinic acid hydrochloride (ALA HCl) is a salt of aminolevulinic acid (ALA). A417.

23. The FDA granted data exclusivity to Photocure for Metvixia® as a new ester or salt of an active ingredient. *See* Ex. A (FDA Exclusivity Data for Metvixia®).

STATUTORY BACKGROUND & ADMINISTRATIVE PROCEEDINGS

As the Federal Circuit has identified, through the Hatch-Waxman Act, Congress sought to "ameliorate the loss" a patent owner "incur[s] when patent terms tick away while the patented product is awaiting [FDA] regulatory approval for marketing." *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829 (Fed. Cir. 1989). Congress attempted to obviate this "loss" through what is now codified at 35 U.S.C. § 156, which authorizes USPTO – with the assistance of the Food and Drug Administration ("FDA") to extend the original patent term on certain – but not all – drugs.

Section 156(a) sets forth several eligibility requirements for a patent term extension, the vast majority of which Photocure satisfies. As such, this discussion will focus on the sole eligibility requirement that is in dispute – whether FDA's approval of Metvixia® is "the first permitted commercial marketing or use of the *product* under the provision of law under which such regulatory review period occurred." 35 U.S.C. § 156(a)(5)(A) (emphasis added). The issue here therefore is whether the approval of Metvixia® is the first permitted commercial marketing or use of the "product" under the provision of law under which the regulatory review period occurred.

The statute generally provides as follows with respect to the terms at issue here:

> (f)(1) The term "product" means:
>
> (A) A drug product.
>
> . . . .
>
> (2) The term "drug product" means the *active ingredient* of –
>
> (A) a new drug, antibiotic drug, or human biological product . . .
>
> . . . .
>
> including any salt or ester of the *active ingredient*, as a single entity or in combination with another *active ingredient*.

35 U.S.C. § 156(f)(2) (emphasis added). Of premier importance, Congress did not specifically define "active ingredient." Both USPTO and FDA have defined the phrase – in the context in which it is used in § 156(f) (*i.e.*, "active ingredient including any salt or ester of the active ingredient") – broadly to mean "active moiety." A639-40; Ex. B; *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,358 (Oct. 3, 1994). And in turn, FDA has defined "active moiety" as "the molecule or ion . . . responsible for

the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.108(a); *see also* 21 C.F.R. § 60.3(b)(2) (defining "active ingredient" to include "any component that is intended to furnish pharmacological activity . . . includ[ing] those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect"). As such, the FDA definition is congruent to the USPTO definition at issue here. The question in the instant action – as it was before the USPTO – is given this language, whether the same "active ingredient" is found in both Levulan® and Metvixia®; if so, Photocure is not entitled to a patent term extension.

Photocure filed its initial application for a patent term extension with USPTO in September 2004. A353-62. The FDA thereafter informed USPTO of its view that Levulan® and Metvixia® contained the same "product" as the term is defined in § 156(f). A409-10. And on April 11, 2007, USPTO issued its initial denial of Photocure's application, although it expressly invited Photocure to seek reconsideration of the decision. A412-14. Photocure availed itself of that suggestion – and sought reconsideration – on November 13, 2007. A415-20.

USPTO conclusively denied Photocure's application through a detailed, nine-page final decision – the sole decision at issue in this Court – issued on May 13, 2008. A635-43. In that decision, USPTO recognized that Photocure itself conceded that aminolevulinic acid ("ALA") was "present in both Metvixia® and Levulan® as the underlying molecule," and that the difference between the two drugs was "ALA merely formulated differently in each product." A637. USPTO concluded as follows:

> ALA simply is formulated differently in the two different drugs: as a hydrochloride salt of its methyl ester in Metvixia®, and as a hydrochloride salt in Levulan®. However, the difference in formulation does not matter for purposes of defining a product in section

> 156. The statutory definition of "product" *includes the underlying molecule as well as any salt or ester of the underlying molecule.*

A639 (emphasis added). USPTO arrived at this definition through an analysis of, *inter alia,* the plain statutory language, as well as the manner by which FDA had – via formal regulation – defined "active ingredient." A638-40. As such, because the same "underlying molecule" constituted the "active ingredient" in both drugs, USPTO held that Photocure was not entitled to a patent term extension.

ARGUMENT

I. STANDARDS OF REVIEW

A. Summary Judgment

Summary judgment should be granted if "there is no genuine issue as to any material fact and [] the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). Because this action arises under the APA, "the focal point of summary judgment review is 'the administrative record already in existence, not some new record made initially in the reviewing court.'" *Tafas v. Dudas*, 541 F. Supp. 2d 805, 810 (E.D. Va. 2008) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). The parties have already agreed that there are no genuine issues as to any material fact, *see* Order (9/18/08), at 1 (Dkt. No. 11); *Pl. Mem.,* at 8; as such, this case is ripe for summary judgment. The sole question therefore presented in the instant action is whether Photocure has borne its burden to demonstrate that USPTO's refusal to grant it a patent term extension under § 156 was "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A).

B. ADMINISTRATIVE PROCEDURES ACT REVIEW

This Court does not conduct a *de novo* review of the USPTO's ultimate conclusion that plaintiff failed to demonstrate that it was entitled to a patent term extension. Much to the contrary, this Court's review standard is rather circumscribed, *see Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983), and USPTO's decision can only be overturned if it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In undertaking this review, this Court "perform[s] 'only the limited, albeit important, task of reviewing agency action to determine whether the agency conformed with controlling statutes,' and whether the agency has committed 'a clear error of judgment.'" *Holly Hill Farm v. United States*, 447 F.3d 258, 263 (4th Cir. 2006). The standard of review is "narrow," and does not authorize a district court "to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). In the end, a reviewing court pursuant to the APA "must give deference . . . to the agency's decision if supported by rational basis in the record." *Fort Mill Telephone Co. v. FCC*, 719 F.2d 89, 91 (4th Cir. 1983); *see also MMTC, Inc v. Rogan*, 369 F. Supp. 2d 675, 678 (E.D. Va. 2004).

II. USPTO's Denial of Photocure's Application for a Patent Term Extension Does Not Represent a "Clear Error in Judgment"

A. USPTO's Interpretation of the Term "Active Ingredient" Is Entitled to *Chevron* Deference

In *Chevron USA, Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984), the Supreme Court established a framework for giving substantial deference to an agency's interpretation of a statute it is charged with administering. The Supreme Court explained that if Congress "has directly spoken to the precise question at issue" and its intent is clear, then "the court, as well as the agency, must give

effect to [that] unambiguously expressed intent." *Id.* at 842-43. If, however, "the statute is silent or ambiguous with respect to the specific issue," the Supreme Court explained that the court must defer to the agency's interpretation as long as it is "based on a permissible construction of the statute." *Id*. at 843. "*Chevron*'s premise is that it is for agencies, not courts, to fill statutory gaps." *National Cable & Telecommunications Ass'n v. Brand X Internet Services*, 545 U.S. 967, 982 (2005). This is because such gap-filling "involves difficult policy choices that agencies are better equipped to make than courts," *id.* at 981, especially in "technical and complex" fields, *Chevron*, 467 U.S. at 865.

As a threshold matter, the USPTO is entitled to *Chevron* deference in its interpretation of the definition of the term "active ingredient" as used in § 156 because that statutory provision gives the Director of the USPTO authority to issue patent term extensions. *See, e.g.*, 35 U.S.C. § 156(d)(5)(B) (stating that "[i]f the Director determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Director shall publish in the Federal Register a notice of such determination"); 35 U.S.C. § 156(e)(1) (stating "[i]f the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of term of the patent a certificate of extension"). It has been "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *United States v. Mead*, 533 U.S. 218, 227-28 (2001) (quoting *Chevron*, 467 U.S. at 844)); *see also Lacavera v. Dudas*, 441 F.3d 1380, 1383 (Fed. Cir. 2006) ("Because the PTO is specifically charged with administering this statute, we analyze a

challenge to the statutory authority of its regulations under the *Chevron* framework."), cert. denied, 127 S. Ct. 1246 (2007).

The facts here are analogous to those in *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330 (Fed. Cir. 2008), through which litigants challenged USPTO's interpretation of the statutory term "original application" as used in connection with *inter partes* reexamination. *See id.* at 1331. In *Cooper Technologies*, the Federal Circuit gave *Chevron* deference to the USPTO's interpretation, explaining that the USPTO had authority to interpret the *inter partes* reexamination statute because its interpretation governed the conduct of proceedings in the Office, activities that the agency is expressly charged with undertaking under 35 U.S.C. § 2. *See id.* at 1336. In the instant action, Photocure challenges the USPTO's interpretation of the phrase "active ingredient" in § 156(f). It therefore follows that the *Chevron* framework should apply because § 156 expressly gives the USPTO the authority to administer the patent term extension scheme.

In the event this Court declines to accord *Chevron* deference to USPTO's interpretative effort, the agency is at least entitled to deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *See Cathedral Candle Co. v. United States Int'l Trade Comm'n*, 400 F.3d 1352, 1365 (Fed. Cir. 2005) ("Even if *Chevron* deference does not apply, an agency's construction of a statute that it is charged with administering is still subject to some deference under the standard set forth by the Supreme Court in *Skidmore* . . . ."). The level of *Skidmore* deference depends on the circumstances, such as "the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position" as well as "the writer's thoroughness, logic, and expertise, its fit with prior interpretations, and any other source of weight." *Id.* (quoting *Mead*, 533 U.S. at 228, 235).

USPTO's interpretation of "active ingredient" merits a high level of *Skidmore* deference because the agency has extensive expertise in executing the provisions of § 156, having applied that provision more than 800 times since its enactment in 1984. Moreover, USPTO has elaborate expertise in understanding the chemistry of drug products, having vast experience examining and issuing drug patents.

And there can be little doubt that the agency has given thorough consideration to the scope of § 156 and formulated its construction of "active ingredient" after careful consideration of the express language of § 156, its entire legislative history, the public policy notions undergirding the provision of patent term extensions, and the prevailing decisional authority. In this regard, it is readily apparent that the interpretation of "active ingredient" offered in the instant administrative decision "reflects the agency's fair and considered judgment on the matter in question." *Auer v. Robbins*, 519 U.S. 452, 462 (1997). Contrary to Photocure's contentions, USPTO has repeatedly interpreted "active ingredient" for purposes of § 156(f) in the exact manner reflected in its final decision here. *See Ex. B*. And given the USPTO's consistent application of its definition of "active ingredient," any change now would call into question the USPTO's previous eligibility decisions involving different formulations.

B. *CHEVRON* STEP ONE: SECTION 156 CONTAINS AMBIGUITY IN THE DEFINITION OF "DRUG PRODUCT" AND IN TURN "PRODUCT"

The initial step of the *Chevron* analysis inquires, as stated earlier, into whether the statute is "silent or ambiguous with respect to the *specific issue*" raised by the agency's regulatory construction. *Chevron*, 467 U.S. at 843 (emphasis added); *Wheatland Tube Co. v. United States*, 495 F.3d 1355, 1359 (Fed. Cir. 2007). Although § 156 expressly defined "product" to mean "drug

product," and further defined "drug product" to mean "active ingredient of a new drug . . . including any salt or ester of the active ingredient," 35 U.S.C. § 156, Congress did not provide any specific definition for the term "active ingredient." As the Federal Circuit has held, this lacuna alone demonstrates that the statute is at the least ambiguous (for *Chevron* purposes) with respect to the specific issue raised here. *See, e.g., Wheatland Tube*, 495 F.3d at 1359-60; *Motorola, Inc. v. United States*, 436 F.3d 1357, 1365 (Fed. Cir. 2006). Nor did Congress reveal anything about its intended meaning for the term in the legislative history of § 156. Because Congress has not addressed the meaning of the word "active ingredient," an "interpretational gap exists regarding a statutory provision." *Suramerica de Aleciones Laminadas, C.A. v. United States*, 966 F.2d 660, 665 (Fed. Cir. 1992). This Court therefore should move to *Chevron*'s second step and examine the reasonableness of the agency's gap-filling.

The Federal Circuit's decision in *Glaxo Operations UK Ltd v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990) ("*Glaxo II*"), is not to the contrary. In that case, the Federal Circuit opined that the USPTO is not entitled to *Chevron* deference in its interpretation of the term "*product*" in § 156 as meaning "new chemical entity." *See Glaxo II*, 894 F.2d at 398. But the Federal Circuit declined *Chevron* deference in *Glaxo II* because the term "product" – which was at issue in that case – did not involve silent or ambiguous statutory language. *See id.* at 394-97. As such, Congress left no statutory gap for USPTO to fill. In particular, as the USPTO's final denial explained, "[t]he Federal Circuit did not discuss the definition of the term 'active ingredient' because, unlike here, the determination of the active ingredient was not in dispute in *Glaxo*." A640. The *Glaxo II* panel specifically provided that the parties – unlike those in the instant action – agreed on the

identification of the "active ingredient" at issue. *Glaxo II*, 894 F.2d at 394 ("It is undisputed that cefuroxime axetil is the active ingredient of CEFTIN tablets.").

And as such, any assistance Photocure seeks to glean in *Glaxo II* regarding the definition to be accorded the term "active ingredient" in § 156(f), *Pl. Mem.*, at 12, 16, is nothing more than mere *dicta*. *See Invitrogen Corp. v. Biocrest Mfg.*, 424 F.3d 1374, 1381 n.* (Fed. Cir. 2005); *see also Boesing v. Spiess*, 540 F.3d 886, 892 n.5 (8th Cir. 2008) (recognizing statement in previous as *dicta* because it was necessary to the court's holding). Accordingly, despite Photocure's pleas to the contrary, *Pl. Mem.*, at 12, 16, any putative commentary in *Glaxo II* regarding Congress' use of "active ingredient" in § 156(f) is not binding on this Court. *See, e.g.*, *Scott v. Taylor*, 470 F.3d 1014, 1017 n.3 (11th Cir. 2006) (holding that *dicta* is not binding on future courts). This is especially true given the Federal Circuit's explicit reversal of Photocure's exact reading of *Glaxo II* in *Pfizer v. Dr. Reddy's Labs., Inc.*, 359 F.3d 1361 (Fed. Cir. 2004). *See infra* Part II.C.2.

C. *CHEVRON* STEP TWO: THE USPTO'S CONSTRUCTION OF "ACTIVE INGREDIENT" IS REASONABLE AND ENTITLED TO DEFERENCE

1. The Language of Section 156 Supports the USPTO's Construction of "Active Ingredient" as Referring to the Underlying Molecule (Excluding Those Appended Portions Cause the Molecule to be a Salt or Ester) Responsible for the Physiological or Pharmacological Action of the Drug

The construction USPTO has given to the phrase "active ingredient" – both in the administrative decision at issue in the instant action and previous decisions – is consistent with the language of § 156. Section 156 specifies that the term "product" as used in § 156(a)(5)(A) means "drug product," 35 U.S.C. § 156(f)(1), and specifies that the term "drug product" means "the *active ingredient* of [a] new drug . . . including any salt or ester of the active ingredient, as a

single entity or in combination with another active ingredient." *Id.* § 156(f)(2) (emphasis added). As a result, making all the links, and separating the superfluous statutory language, the definition for "product" can be expressed as follows:

> Product = drug product = the active ingredient of [a] new drug . . . including any salt or ester of the active ingredient.

In distinguishing "active ingredient" from a "salt or ester of the active ingredient," the language of the statute therefore suggests that the "active ingredient" cannot itself be a salt or an ester. It follows that the "active ingredient" must be a distinct molecule or ion from either a salt or an ester – an underlying molecule or ion (excluding those appended portions of the molecule that cause it to be a salt or ester) responsible for the physiological or pharmacological action of the drug.

The language of the statute also provides that a "drug product" may exist as an active ingredient ***or*** as a salt or ester of an active ingredient. Taking these possibilities into account, as the USPTO's final decision maintained, A637, § 156(f)(2) permits a "product" to include: (i) the non-salified and non-esterified form of the active ingredient (*i.e.*, the underlying molecule or ion responsible for the physiological or pharmacological action of the drug substance); (ii) salts of the underlying molecule or ion; and (iii) esters of the underlying molecule or ion. Because the term "product" covers these three different chemical compositions, a salt of a molecule is statutorily the same "product" under § 156 as an ester of the molecule, and as the underlying molecule itself. The same is true for an ester of a molecule as well as the underlying molecule itself. For purposes of its patent term extension provisions, § 156 does not differentiate between an underlying molecule, a salt of the underlying molecule, or an ester of the underlying molecule. Rather, the statute treats all three forms as a "product." As such, if any one of the three forms has previously

been subject to commercial marketing or use, then any subsequent form will not meet the eligibility requirements in § 156(a)(5)(A); it will not be first.

2. The USPTO's Construction of "Active Ingredient" Is Consistent with Judicial Precedent

The Federal Circuit has construed the term "active ingredient" as used in § 156 in accord with the definition provided in the instant USPTO decision. First, in *Fisons I*, the district court addressed the meaning of the phrase "the first permitted commercial marketing or use of the product," which appears in § 156(a)(5)(A), in connection with Fisons' patent term extension application. *Fisons I*, 1988 WL 150851, at *3. Fisons argued that "product" should not be interpreted to mean "active ingredient," but instead referred to the "particular drug product that the FDA approved." *Id.* After considering the plain language of the statute and its legislative history, the district court disagreed, finding that the term "'product' as used in Subsection (5)(A) refers only to the patented drug's active ingredient." *Id.* at *5. The Federal Circuit affirmed, "hold[ing] that the district court correctly applied the definition given in 35 U.S.C. § 156(f) to the term 'product' used in section 156(a)(5)(A)." *Fisons v. Quigg*, 876 F.2d 99, 102 (Fed. Cir. 1989) ("*Fisons II*").

In *Pfizer v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004), the Federal Circuit built upon *Fisons II,* and specifically addressed the meaning of the statutory phrase "active ingredient." On this score, the *Pfizer* court accepted the FDA's definition of the term "active ingredient" as meaning "active moiety," which is the exact definition USPTO gave to the term here. *Id.* at 1366 (citing *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,358 (Oct. 3, 1994)); A639-40. The court in turn observed

that "active moiety" means "the molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or pharmacological action of the drug substance," *id.* (quoting 21 C.F.R. § 314.108(a))(omission in original). Taking *Fisons II* together with *Pfizer*, the Federal Circuit has interpreted the term "product" in § 156(a)(5)(A) to mean "active ingredient;" interpreted the phrase "active ingredient" to mean "active moiety;" and interpreted the phrase "active moiety" to mean "the molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or pharmacological action of the drug substance." Accordingly, USPTO's interpretation of § 156 is consistent with Federal Circuit precedent in construing the term "active ingredient" as referring to an underlying molecule or ion (excluding those appended portions of the molecule that cause it to be a salt or ester) responsible for the physiological or pharmacological action of the drug.

Photocure attacks *Fisons II* and *Pfizer*, contending that both cases are factually distinguishable. *Pl. Mem.*, at 16-20. Photocure's argument misses the mark, because the correct interpretation of the statutory phrase "active ingredient" does not turn on the particular facts presented to the Federal Circuit in either *Fisons II* or *Pfizer*. To the contrary, as explained earlier, USPTO relied on those cases to show how the Federal Circuit has interpreted specific terms in § 156 that are vital to resolution of this case; specifically, the terms "product" and "active ingredient." To that end, Photocure even acknowledges that the district court in *Fisons I* held that the term "product" means "active ingredient" and that the Federal Circuit affirmed that construction, exactly as the USPTO argues. *See id.* at 17.

Photocure also attempts to establish the ultimate straw man argument through its complaint that *Fisons II* does not suggest or state that "active ingredient" should be construed to mean "new chemical entity" or "active moiety." *See id.* at 17-18. USPTO agrees, having never taken the position that *Fisons II* goes that far. To the contrary, USPTO has consistently recognized that *Fisons II* provides only that "product" means "active ingredient." As explained earlier, *Pfizer* picks up where *Fisons II* left off, construing "active ingredient" to ultimately mean the "molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or pharmacological action of the drug substance." *Pfizer*, 359 F.3d at 1366.

Photocure attempts to avoid *Pfizer* by characterizing that case as inextricably tied to its facts – merely defining the rights of a patentee during the period that a patent is extended under § 156(b). *Pl. Mem.*, at 19-20. Photocure's restrictive reading of *Pfizer* lacks merit, as the Federal Circuit never articulates that its statutory analysis has no application outside of the specific facts there presented. Indeed, *Pfizer* is applicable to whether a patent should be extended under § 156(a) as well as to whether an extended patent covers an accused infringing product under § 156(b). And in this regard, *Pfizer* addresses not only the exact statutory provision in dispute here – § 156 – but also the exact subparagraph in dispute – § 156(f)(2). Moreover, § 156(f) makes clear that the definition of "product" contained therein is to be applied throughout the various provisions of § 156. *See* 35 U.S.C. § 156(f) (providing that the definition applies "for purposes of this *section*" (emphasis added)).

Finally, Photocure tries to dismiss *Pfizer* as inconsistent with *Glaxo II*, and therefore not controlling because *Glaxo II* was decided fourteen years before *Pfizer*. *Pl. Mem.*, at 20-21. *Pfizer*

is not inconsistent with *Glaxo II*; the two cases work in tandem to develop the body of Federal Circuit precedent for § 156. In *Glaxo II*, the Federal Circuit addressed the USPTO's argument that the term "product" means "any 'new chemical entity,' *i.e.*, 'new active moiety.'" *Glaxo II,* 894 F.2d at 394. The Federal Circuit disagreed, explaining that (i) Congress expressly provided an express definition of "product" in § 156(f)(2); and (ii) Congress "selected terms with narrow meanings that it chose from among many alternatives" for that definition. *Id.* at 399 (footnoting as examples of other possible words "new molecular entity," "active moiety," and "new chemical entity").

Contrary to Photocure's characterization of the issue in *Glaxo II*, *Pl. Mem.*, at 11, 18, 21-22, the Federal Circuit did not set forth a definition of "active ingredient" for purposes of § 156(f)(2) because, unlike here, the active ingredient in the FDA approved drug underlying *Glaxo II was not in dispute*. As the panel explained: "It is undisputed that cefuroxime axetil is the active ingredient of CEFTIN tablets." *Glaxo II*, 894 F.2d at 394. Accordingly, the *Glaxo II* panel had no occasion to define the parameters of the statutory phrase "active ingredient," as stated earlier, any language that Photocure may procure from *Glaxo II* on this subject is nothing more than non-binding *dicta*.

Indeed, Photocure recognizes the problem with its attempt to reconcile *Pfizer* with *Glaxo II* on the specific question raised here. In its opening memorandum, Photocure concedes that the district court in *Pfizer* "rel[ied] heavily on *Glaxo II*" in deriving its judgment, but nonetheless was reversed by the Federal Circuit in a decision that Photocure characterizes as "not entirely clear." *Pl. Mem.*, at 19. In fact, the *Pfizer* district court's position on this score is *identical* to the interpretative analysis that Photocure attempts to hoist upon this Court. But if the Federal Circuit

reversed a district court decision that characterized *Glaxo II* as "explicitly reject[ing] the argument . . . that active ingredient of a drug product . . . was synonymous with active moiety," *Pfizer, Inc. v. Dr. Reddy's Labs., Ltd.*, 2002 WL 31833744, at *7 (D.N.J. Dec. 17, 2002), and adopted that very definition *despite Glaxo II*, *see Pfizer*, 359 F.3d at 1366, it is hard to imagine how Photocure can maintain the argument that the *Glaxo II* panel at all conclusively determined (in precedential fashion) the definition of "active ingredient." And because the *Pfizer* district court's interpretation of the pertinent § 156(f) language is identical to Photocure's position here, it is equally hard to imagine how the Federal Circuit's reversal of that holding does not serve to require rejection of Photocure's position.

For this reason, the most that can be said about *Glaxo II* is that the Federal Circuit acknowledged that Congress did not *expressly* define the term "product" to mean "active moiety" insofar as that those words do not appear in § 156(f)(2). If *Glaxo II* had rejected such a definition for "active ingredient," then it is hard to imagine that *Pfizer* would have wholesale ignored Federal Circuit binding precedent to adopt it.[1]

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[1] Photocure erroneously asserts that the USPTO "thinks that *Pfizer* [] overruled *Glaxo II*," and as a result, that the USPTO must "believe that [*Pfizer* [] and *Glaxo II*] address the same issue." *Pl. Mem.* at 22 (citing *In re Patent Term Extension Application for U.S. Patent No. 6,143,771*, 2005 Commr. Pat. LEXIS 15 (July 15, 2005)). USPTO has never made any such statement in this case. And although USPTO did state that *Pfizer* overruled *Glaxo II* in an initial decision for another drug product, the agency recognized and admitted its mistake in the final agency decision for that other product. *Decision Denying Application for Patent Term Extension for U.S. Patent No. 6,143,771* (Sept. 12, 2007), at 6 (attached at Ex. B) ("*Glaxo* remains binding precedent and the USPTO erred in stating otherwise."). Furthermore, Photocure's argument as to what this Court should read into the USPTO's mistake, *i.e.*, that the USPTO "must believe that [*Pfizer II* and *Glaxo II*] address the same issue" is nothing more than a distraction. Reasonably, there is nothing to be drawn from the USPTO's mistake; all it shows is that the agency made an error, which it subsequently took steps to remedy.

3. Public Policy Supports the USPTO's Construction of "Active Ingredient"

In *Fisons I*, the district court discussed the legislative history of § 156 in detail, recognizing as follows:

> Congress did not intend that every patented drug that experienced lengthy or delayed regulatory review receive the benefits of patent restoration. Under Section 156(a)(5)(A), only new, pioneer chemical entities were to have their effective lives legislatively restored.

Fisons I, 1988 WL 150851 at *9. In making this finding, the *Fisons I* court walked through the various criticisms of § 156(a)(5)(A), noting that many commentators, particularly the pharmaceutical industry, attacked § 156(a)(5) for not applying to "new uses for the drug, new dosage forms or innovative formulations, all of which require full new drug applications." *Id.* at *7. The *Fisons I* court found that Congress did not yield to the pressure: "By enacting and not amending Section 156 in this regard, Congress implicitly, but clearly, rejected industry's plea, like that articulated by Stafford, for loosened eligibility requirements." *Id.* at *8. Additionally, the *Fisons I* court observed that the House rejected a proposed amendment supported by thirteen Representatives that sought to make patent term extension available for patents protecting aspects beyond just the pioneer chemical entity like use, dosage, and formulation. *Id.*

Here, Photocure is attempting to secure an extension for a new formulation, specifically, the ester and salt formulation of aminolevulinic acid in Metvixia® when the salt formulation of aminolevulinic acid (*i.e.*, Levulan®) has already obtained FDA approval. Such a second extension is outside the scope of what Congress intended to cover in § 156 as revealed by the legislative history of that provision. Congress intended to limit patent term extensions to the initial FDA approval for each novel chemical entity, here, that extension could have been a patent

protecting Levulan®. It did not intend to provide extensions for follow-on patents protecting different formulations, here, the patent protecting Metvixia®. Accordingly, in denying Photocure's patent term extension application, the USPTO is fulfilling Congress's intent "to restore patent life only to new chemical entities." *Id.* at *7.

In sum, the USPTO's construction of the term "active ingredient" is not just reasonable; it is also in accordance with the language of § 156, its legislative history, case law precedent, and public policy. The USPTO's definition is thus entitled to deference under *Chevron*. Applying the USPTO's definition of "active ingredient" to the facts of this case is straightforward.

D. THE APPROVAL OF METVIXIA® IS NOT THE FIRST COMMERCIAL MARKETING OR USE OF THE "PRODUCT" AS REQUIRED BY § 156(A)(5)(A)

Metvixia® is the brand name for methylaminolevulinate hydrochloride. Metvixia® also is, in Photocure's own words, "an ester of aminolevulinic acid hydrochloride." *Pl. Mem.,* at 6, ¶12. Said differently, Metvixia® is aminolevulinic acid formulated as both a salt and an ester; in particular a hydrochloride salt and a methyl ester.

Before the FDA approved Metvixia®, it approved Levulan®. Levulan® is the brand name for aminolevulinic acid hydrochloride, which in Photocure's own words, is another name for the "hydrochloride salt of aminolevulinic acid." *Id.* at 7, ¶ 20. In other words, Levulan® is aminolevulinic acid formulated as a salt; in particular, a hydrochloride salt. The following chart summarizes the various nomenclatures for the drugs at issue here:

Brand Name	Chemical Name	Formulation Type	Underlying Molecule
Metvixia®	methyl aminolevulinate hydrochloride	ester and salt of aminolevulinic acid	aminolevulinic acid
Levulan®	aminolevulinic acid hydrochloride	salt of aminolevulinic acid	aminolevulinic acid

As explained earlier, given both the language of § 156(f), and the USPTO's construction of the same, the term "product" includes: (i) the non-salified and non-esterified form of the active ingredient (*i.e.*, the underlying molecule or ion responsible for the physiological or pharmacological action of the drug substance); (ii) salts of the underlying molecule or ion; and (iii) esters of the underlying molecule or ion. As such, under the statutory definition of "product," Metvixia® is the same product as Levulan®: both are formulations of the same underlying molecule – aminolevulinic acid. Metvixia® is a salt and ester formulation of aminolevulinic acid, while Levulan® is a salt formulation of aminolevulinic acid.

Compounds are formulated in certain ways, for example as salts and esters, for purposes of stability, administration, and bioavailability. For instance, formulating a compound as a salt may help to enhance solubility of the drug and formulating a compound as an ester may make a compound more lipophilic, *e.g.,* helping it to cross a cell membrane into a cell. Because Levulan® was approved and commercially marketed before Metvixia® and because Levulan® is considered to be the same product as Metvixia® under § 156, the approval of Metvixia® is not the first commercial marketing or use of the product under the provision of law under which the regulatory review period occurred. USPTO explained exactly that in its Final Decision:

> [T]he approved 'product' is the same for both Metvixia® and Levulan® under section 156, *i.e.*, ALA merely formulated differently in each product.

A637.

Photocure repeatedly – albeit mistakenly – argues that the active ingredient in Metvixia® is MAL HCl. *Pl. Mem.,* at 12-14. In making such an argument, Photocure deletes the language "salt or ester of the active ingredient" from § 156, which embodies the congressional mandate to put all underlying molecules together with all salts and esters thereof in one "pot" for purposes of determining patent term extension eligibility. As explained earlier, the "active ingredient" as that term is used in § 156 must mean the underlying molecule, excluding that portion that cause the underlying molecule to be a salt or ester. *See Pfizer*, 359 F.3d 1361 (defining active ingredient to mean "the molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or pharmacological action of the drug substance"). Although MAL HCl is present in Metvixia®, it cannot be the "active ingredient" referenced by § 156(f) because MAL HCl is a salt and ester of the underlying molecule ALA.

This Court's acceptance of Photocure's dictionary-based definition of "active ingredient" would lead to unintended consequences. For example, for a free base molecule, there are at least 53 acid-addition salts that are FDA-approvable. *See* REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 1457 (19th ed. 1995). That means that it would be possible for a pharmaceutical company to formulate a single pioneering free base as 53 different salts and secure 53 different patent term extensions for 53 different "active ingredients" if those 53 different salt formulations were each protected by a different patent. Such a result would not encourage pharmaceutical companies to invest in research and development of new *pioneering* drugs, but instead would

cause them to invest in becoming "formulation masters" – accomplished at making different formulations of the same underlying drug invention. Congress could not have intended such an outcome, as the mere substitution of one salt for another (or one ester for another) would make patent term extension commonplace. *See Fisons I*, 1988 WL 150851 at *10 (explaining that the Hatch-Waxman Act was in part intended to spur innovation and the development only of new pioneering drugs).

In further support of its argument that MAL HCl is the active ingredient for Metvixia®, Photocure also points out that the FDA has identified MAL HCl as the active ingredient in Metvixia® both for drug labeling purposes and in the Electronic Orange Book.[2] *Pl. Mem.*, at 6, ¶11. At the outset, as Photocure itself maintains, *id.* at 8, this Court's review must be based solely upon the administrative record of proceedings before the agency, "'not some new record made initially in the reviewing court.'" *Tafas*, 541 F. Supp. 2d at 810. And as Photocure's need to cite in this regard to materials outside of the record demonstrates, it never presented such materials to USPTO during administrative processing; as such, it is barred from presenting the same for the first time in this Court.

But Photocure's reliance on the FDA's labeling information and Electronic Orange Book listing is also misplaced on the merits. The FDA has provided – through its formal regulations – two different definitions for the term "active ingredient," one definition for purposes of labeling and Orange Book listing and another definition for purposes of patent term extension eligibility

[2] The *FDA's* Electronic Orange Book, formally known as Approved Drug Products with Therapeutic Equivalence Evaluations, identifies and lists drug products approved by the FDA on the basis of safety and efficacy. *See Approved Drug Products* http://www.fda.gov/cder/orange/obannual.pdf (last visited Nov. 3, 2008).

under § 156. In its regulations related to labeling, the FDA defines "ingredient" to "appl[y] to any substance in the drug, whether added to the formulation as a single substance or in admixture with other substances." 21 C.F.R. § 201.10(b). The FDA's definition for the term "ingredient" is broad, encompassing anything in the drug; *e.g.*, the part of the drug responsible for the physiological or pharmacological action as well as the part responsible for formulation. This breadth explains why the FDA identified MAL HCl as the active ingredient in Metvixia® on the label and in the Electronic Orange Book.

By contrast, as USPTO identified in its final decision, A640, in its regulations related to patent term extension eligibility, the FDA defines the term "active ingredient" to mean "any component that is intended to further pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body of man or of animals." 21 C.F.R. § 60.3(b)(2). The FDA's definition of active ingredient for purposes of patent term extension eligibility is much narrower; it includes only the part of the drug responsible for the physiological or pharmacological action. The FDA uses a similar definition for purposes of data exclusivity. *See id.* § 314.108(a) (providing that "[a]ctive moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance."). The FDA's patent term extension eligibility and data exclusivity definitions therefore match exactly the definition USPTO applied for purposes of § 156, contrary to Photocure's claim that § 60.3 does not support USPTO's final decision. *Pl. Mem.*, at 21.

Notably, based upon its patent term extension eligibility and data exclusivity definitions for "active ingredient," which align with the USPTO's definition, the FDA has advised the USPTO that the approval of Metvixia® fails to meet the patent term extension eligibility requirement set forth in § 156(a)(5)(A). A411. And if this Court accepts Photocure's extra-record materials, it bears mentioning that the FDA likewise granted limited data exclusivity to Photocure for Metvixia® as a new ester or salt of an active ingredient and not as a new chemical entity. *See* Ex. B. The FDA's usage of the term in formal regulations, *see United States v. Mead*, 533 U.S. 218, 230 (2001), independently confirms that USPTO's interpretation of "active ingredient" is reasonable for purposes of *Chevron* deference; it at least evinces that USPTO's denial of Photocure's patent term extension application was not a "clear error in judgment."

E. PHOTOCURE'S REMAINING ARGUMENTS ARE MISPLACED

Photocure argues that this Court should define "active ingredient" according to dictionary definitions for the individual words "active" and "ingredient." *Pl. Mem.*, at 10, 15-16. Photocure also tries to turn this case into a repeat of *Glaxo II,* elaborating on the detailed (and different) facts of that case. *Id.* at 11-12, 14. Photocure's approach is misdirected.

First, Photocure's resort to dictionaries for plain meaning is rather premature, insofar as it fails to give any credence to the active language – and structure – of § 156 itself. Section 156(f)(2) states that "drug product" means "active ingredient" and includes "any salt or ester of the active ingredient." 35 U.S.C. § 156(f)(2). The phrase "any salt or ester of the active ingredient" informs the meaning of "active ingredient," revealing that Congress considered "active ingredient" to be an underlying molecule or ion distinct from any appended salt or ester group. *See United States v. Menashe*, 348 U.S. 528, 538-39 (1955) (stating that "[t]he cardinal

principle of statutory construction is to save and not to destroy" and that courts have a "duty to give effect, if possible, to every clause and word of a statute"). Photocure appears to resort to dictionary definitions because it seeks to avoid the "salt or ester formulation" issue that Congress unequivocally addressed with the final language found in § 156(f)(2).

Photocure's proffered definition further fails to conform to § 156's language. In this respect, Photocure argues that "ingredient" should be defined as "a constituent element of a mixture or compounds" and that an "active" ingredient "provides a therapeutic effect." *Pl. Mem.*, at 10 (citations omitted). Taken together, Photocure states that "active ingredient" "has a plain meaning, which is 'a constituent element of a mixture that provides a therapeutic effect when administered to a patient.'" *Id.* at 10. But under Photocure's definition, any salt or ester of an underlying molecule could qualify as an "active ingredient," and this directly conflicts with the language of § 156, which distinguishes between an "active ingredient" on the one hand, and a "salt or ester of the active ingredient" on the other hand. And more importantly, such a difficulty runs afoul of a well-established canon of statutory construction – this Court cannot interpret statutory language so as to render language meaningless, *see Babbitt v. Sweet Home Chapter*, 515 U.S. 687, 698 (1995), and that it is the "duty" of courts "to give effect, if possible, to every clause and word of a statute." *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883); *see also United States v. Mathias*, 482 F.3d 743, 749 (4th Cir. 2007) ("[I]t is 'a classic canon of statutory construction that courts must give effect to every provision and word in a statute and avoid any interpretation that may render statutory terms meaningless or superfluous.'"). But Photocure's position ignores this well-established jurisprudence, as its definition would require this Court to ignore Congress' choice to list "salt or ester of an active ingredient" as a *separate* definition for "drug product" for

purposes of § 156(f). Although Photocure's definition may work in some contexts (*e.g.*, FDA's definition for labeling/ Orange Book purposes), it is inconsistent with the language of § 156.

Photocure also supports its dictionary-based definition for "active ingredient" by reliance on *Glaxo I*. In that case, the district court[3] made the same mistake Photocure makes here. It focused on the word "ingredient," ignoring the statutory language "salt or ester of the active ingredient." *See Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224, 1227 (E.D. Va. 1989) ("Cefuroxime itself is not present at all in Ceftin Tablets; it is therefore not an "ingredient." . . . An ingredient is a 'constituent element of a mixture or compounds.'"). Additionally, the district court's butterfly-caterpillar analogy falls apart when the "salt or ester of the active ingredient" language in § 156 is taken into consideration.

Significantly, on appeal, the Federal Circuit did not adopt the district court's definition of "active ingredient." It affirmed, but did so on the ground that the term "product" does not mean "new chemical entity" as argued by the USPTO. *See Glaxo II*, 894 F.2d at 399. Moreover, as stated earlier, the Federal Circuit started from the premise that the ester cefuroxime axetil was active ingredient. *See id.* at 394 ("It is undisputed that cefuroxime axetil is the active ingredient of CEFTIN tablets."). Any potential guidance that panel provided on the question of how "active ingredient" was to be defined is nothing more than non-binding *dicta*.

Finally, the district court's decision in *Glaxo I* does not bind this Court. Only the Federal Circuit's decision in *Glaxo II* serves as precedent. *See Burandt v. Dudas*, 528 F.3d 1329, 1334 (Fed. Cir. 2008) (explaining that Federal Circuit decisions are binding precedent, while district

[3]Contrary to Photocure's incessant use of the phrase, *this* Court did not decide *Glaxo I*; to the contrary, the opinion was issued by one of this Court's Eastern District brethren. There can be little doubt that, in any event, it is not binding on this Court.

court decisions are not). For the reasons stated, that latter decision establishes only that term "product" has the meaning Congress gave to it in § 156(f)(2), *i.e.*, "the active ingredient of [a] new drug . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." *Glaxo II*, 894 F.2d at 395. This Court therefore is free to adopt the USPTO's construction of the term "active ingredient" pursuant to the *Chevron* deference analysis required here. And nothing Photocure has argued shows why the USPTO's interpretation is not reasonable.

III. THIS COURT ONLY POSSESSES JURISDICTION TO REVIEW USPTO'S FINAL DECISION

Photocure's opening memorandum offers arguments against the rationale USPTO offered in its initial decision of April 2007. *Pl. Mem.*, at 20 n.12, 22-25.[4] But the APA only waives the United States' sovereign immunity for, and therefore authorizes judicial review of, "final agency action." *See* 5 U.S.C. § 704. Congress instituted this requirement for a specific reason – it wanted to prevent the judiciary from interfering with the administrative process until its terminus so that the agency is given "an opportunity to correct its own mistakes and to apply its expertise." *FTC v. Standard Oil Co.*, 449 U.S. 232, 242 (1980); *see also In re SEC*, 374 F.3d 184, 190 (2d Cir. 2004). And here, as stated earlier, USPTO applied its expertise – in light of the specific arguments Photocure advanced on reconsideration – to craft its definitive position as reflected in the final application decision. It is therefore only USPTO's *final* decision, and the rationales offered in that decision, that are at issue in this APA action. Photocure's arguments against the

[4]To be sure, Photocure does so tepidly, stating that "[i]t is not clear whether the PTO continues to adhere to this initial position." *Pl. Mem.*, at 22. For the reasons that follow, USPTO only persists in advancing those rationales offered in its *final* decision.

position USPTO took in its initial application decision are therefore immaterial, and beyond the limited jurisdiction this Court enjoys under the APA.

IV. SECTION 156 DOES NOT CONSTITUTE A WAIVER OF SOVEREIGN IMMUNITY

In its opening brief, Photocure concedes that its sole remedy in this action falls under the auspices of the APA. *Pl. Mem.*, at 7-8. But in its complaint, Photocure proffers – in addition to its cause of action pursuant to the APA, *Complaint*, ¶22 – a separate and independent claim purporting to seek relief under § 156 itself. *Id.* ¶19. Given the lack of any mention of such an independent claim in their opening brief, it appears that Photocure has conceded that they cannot seek relief in this Court directly under § 156.

And this conclusion is certainly correct. As this Court is well aware, the United States and its agencies enjoy sovereign immunity from suit unless Congress has explicitly abrogated such immunity. *See FDIC v. Meyer*, 510 U.S. 471, 475 (1994). Indeed, "the limitations and conditions upon which the Government consents to be sued must be strictly construed and exceptions thereto are not be waived." *Martinez v. United States*, 333 F.3d 1295, 1306 (Fed. Cir. 2003) (en banc) (citations omitted). Nowhere within the provisions of § 156 is there *any* indication that Congress sought to waive the United States' sovereign immunity and allow its agency to be sued directly under its terms. As such, defendants are entitled to the entry of summary judgment on Photocure's separate claim under § 156.[5]

[5]This conclusion is certainly an academic point, as USPTO concedes – as it must – that the APA serves as a general waiver of the United States' sovereign immunity for equitable relief, *see United Tribe v. United States*, 253 F.3d 543, 548 (10th Cir. 2001), and that in performing the limited judicial review function authorized by the APA, this Court must determine whether the USPTO's decision "was not in accordance with law," 5 U.S.C. § 706(2)(A), including § 156.

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CERTIFICATE OF SERVICE

I hereby certify that on this date, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing ("NEF") to the following:

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