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

PHOTOCURE ASA,	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.: 1:08-cv-718
	)	
JON W. DUDAS, *et al.*,	)	
	)	
	)	
Defendants.	)	

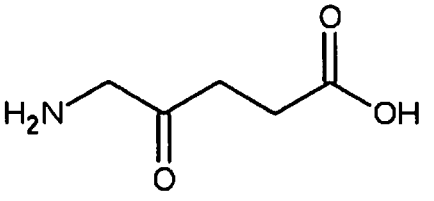
MEMORANDUM OPINION

In this action, Plaintiff PhotoCure seeks to extend the term of its drug patent, which was effectively shortened by the lengthy Food and Drug Administration ("FDA") approval process. 35 U.S.C. § 156 (2006) permits patent term extensions in such circumstances, provided that the applicant meets specific statutory elements. One such element requires that the drug be the first permitted commercial marketing or use of "the product." 35 U.S.C. § 156(a)(5)(A) (2006). On May 13, 2008, the Defendants, employees of the United States Patent and Trademark Office ("USPTO"), denied PhotoCure's application for a patent term extension under "the product" provision. PhotoCure now appeals this decision. The question presented herein is whether the patented drug supporting the term extension application at issue meets the requirement of § 156(a)(5)(A) that the use of "the product" following FDA approval constitutes the first commercial marketing or use. The Court holds that the patented drug in this case meets the above statutory requirement.

I. BACKGROUND

On March 7, 2000, the USPTO issued U.S. Patent No. 6,034,267 (the "'267 patent") entitled "Esters of 5-Aminolevulinic Acid as Photosensitizing Agents in Photochemotherapy." The patent lists Plaintiff PhotoCure as the assignee. The '267 patent claims both a pharmaceutical compound called methyl aminoevulinate hydrochloride ("MAL hydrochloride"), and a method of using that compound to treat actinic keratoses through a technique called photochemotherapy.[1] Claims 8 and 9 of the '267 patent cover the MAL hydrochloride compound itself, while claims 1 and 3-7 cover the method of using that compound in conjunction with performing photochemotherapy.

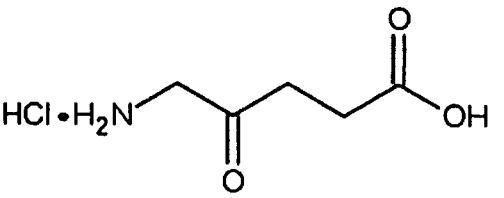
MAL hydrochloride is an "ester" of the organic acid called aminolevulinic acid ("ALA"). An organic acid is a compound consisting of either a hydrogen or organic chemical group covalently bonded to an acid group. The specific acid group found in ALA is called the carboxyl group, which is represented by the chemical formula COOH. The chemical formula for ALA as a whole is $C_5H_9NO_3$. The chemical structure is diagrammed below:



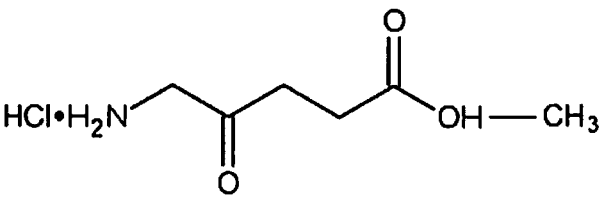
When hydrochloric acid ("HCl") is added to an organic acid, a salt of that organic acid is formed. Thus, when HCl is added to ALA, the resultant compound is a salt of ALA, called aminolevulinic acid hydrochloride (ALA hydrochloride). The chemical formula for ALA

[1] Actinic keratoses are premalignant lesions on sun-exposed skin having the ability to develop into carcinomas.

hydrochloride is $C_5H_9NO_3HCl$. A diagram showing the chemical structure for ALA hydrochloride, which reflects the addition of HCl, is shown below:



When the hydrogen atom (H) is removed from the COOH group of an organic compound and replaced with an organic chemical group, an ester of that organic compound is formed. Therefore, in the case of ALA hydrochloride, if the H from the COOH group is replaced with the organic chemical group CH_3, the resultant compound is an ester of ALA hydrochloride called MAL hydrochloride.[2] The chemical formula for MAL hydrochloride is $C_6H_{11}NO_3HCl$. The chemical structure is:



Worth noting is that ALA hydrochloride and MAL hydrochloride both have ALA as their base organic acid, or underlying molecule. In other words, ALA hydrochloride and MAL hydrochloride share the same parent acid, ALA. ALA hydrochloride and MAL hydrochloride are just two members of a large family of salts and esters that derive from the parent acid ALA.[3]

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[2] In addition to being an ester of ALA hydrochloride, MAL hydrochloride can be characterized as both an ester and a salt of the base organic acid ALA.

[3] A term used to describe the underlying molecule, or parent acid, of a large salt and ester family is "active moiety." Therefore, ALA hydrochloride and MAL hydrochloride also can be said to share the same active moiety.

The commercial embodiment of the '267 patent is the drug Metvixia™ ("Metvixia"), which contains MAL hydrochloride as its key ingredient.[4] Metvixia was the first commercial drug to contain MAL hydrochloride as its key ingredient. However, a commercial drug predating Metvixia called Levulan™ ("Levulan") implemented ALA hydrochloride as its key ingredient. As a result, the key ingredients in both Metvixia and Levulan share the same active moiety, ALA.[5]

Because Metvixia qualified as a "new drug" under § 201(p) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(p) (2006), it required approval by the FDA before it could be commercially marketed and sold. In an attempt to obtain this FDA approval, PhotoCure submitted a New Drug Application on September 26, 2001. On July 27, 2004, the Metvixia drug was approved for commercial and marketing use.

Due to the inability of PhotoCure to obtain FDA approval until more than four years after the USPTO issued the '267 patent, a significant portion of time elapsed between when PhotoCure gained patent rights and when it could profit from those patent rights by commercially marketing and selling the drug. In order to aid patent holders in PhotoCure's position, Congress passed 35 U.S.C. § 156 (2006), commonly referred to as the Hatch-Waxman Act, which permits patent term extensions for patent holders who have their terms reduced by the FDA regulatory process.

Not every patent having its term shortened by the FDA regulatory process, however, qualifies for an extension. Extensions are only appropriate if the statutory requirements of §

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[4] Metvixia also contains other chemical compounds that serve as inactive ingredients.

[5] Despite sharing the same active moiety, PhotoCure asserts that substantial differences exist in the effects that MAL hydrochloride and ALA hydrochloride have on the human body. In support of this assertion, PhotoCure points to data and expert opinion suggesting that these differences are as follows: selectivity of uptake by target lesions; penetration of target lesions; (unwanted) systemic distribution of the active ingredient; pain resulting from use in PDT; and mechanisms by which cells take up the active ingredient. J.A. 422, 642.

156(a) are met. One such requirement provides that an extension may only be granted if the drug covered by the patent is the "first permitted commercial marketing or use of the product." 35 U.S.C. § 156(a)(5)(A) (2006).[6] Section 156(f) further defines the term "product" to mean the "active ingredient" of the drug, as well as any salt or ester of the active ingredient. 35 U.S.C. § 156(f)(2) (2006).

On September 22, 2004, PhotoCure timely filed a patent term extension application with the USPTO for the '267 patent. This application was denied. On November 13, 2007, PhotoCure filed a "Request for Reconsideration of Final Determination of Ineligibility for Patent Term Extension." The USPTO issued its final agency decision on May 13, 2008.

In this decision, the USPTO interpreted § 156(a)(5)(A) to mean that the underlying molecule, or active moiety, and all of its salts and esters qualify as the same "product." United States Patent and Trademark Office, *Final Decision Regarding Patent Term Extension Application under 35 U.S.C. § 156 for U.S. Patent No. 6,034,267*, 3 (May 13, 2008) [hereinafter "USPTO Decision"]. Because Levulan's key ingredient (ALA hydrochloride) and Metvixia's key ingredient (MAL hydrochloride) share the same active moiety (ALA), Levulan and Metvixia contain the same "product" under this interpretation, which is ALA. And because Levulan earned FDA approval before Metvixia, the USPTO held that "the [FDA] approval of METVIXIA™ (methyl aminolevulinate hydrochloride) [did] not constitute the first permitted commercial marketing or use of the 'product'" under § 156(a)(5)(A). USPTO Decision at 1. As a result, PhotoCure's request for a patent term extension was denied.

PhotoCure now appeals the USPTO's decision. In its complaint, PhotoCure alleges that the USPTO's decision was contrary to law (Count I), as well as arbitrary and capricious and not in accordance with law (Count II).

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[6] The remaining requirements are outlined in Section IV.A., infra.

II. JURISDICTION AND VENUE

Subject matter jurisdiction exists pursuant to 28 U.S.C. § 1331 (2006) because this action arises under federal law; 28 U.S.C. § 1338(a) (2006) because this action arises under an "Act of Congress relating to patents"; and 28 U.S.C. § 1361 (2006), which provides district court jurisdiction over a "mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff."

The relief requested is authorized by 28 U.S.C. §§ 2201-2202 (2006), which permit declaratory judgment when an actual controversy exists. The parties do not dispute that an actual controversy exists. The relief requested is also authorized by 5 U.S.C. §§ 701-705 (2006), which outline a framework for judicial review of agency decisions.

Finally, venue is proper under 28 U.S.C. § 1391(e) (2006).

III. STANDARD OF REVIEW

Because this case involves judicial review of a final agency decision, the Administrative Procedure Act ("APA") provides the applicable standard of review. *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 395 n.4 (Fed. Cir. 1990). Under the APA, agency action may be set aside if the court finds that the agency action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In making this determination, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973).

Here, the parties agree that no factual disputes exist and that the undisputed facts of the case are contained in the administrative record. Accordingly, PhotoCure moved for summary judgment on October 14, 2008, and Defendants Jon Dudas and John Doll of the USPTO moved

for summary judgment on November 4, 2008. Because this action presents no disputed issues of material fact, the Court will resolve it at the summary judgment stage under Fed. R. Civ. P. 56. The Court, using the facts found in the administrative record, will base its decision on whether the USPTO's action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

IV. ANALYSIS

A. Statutory Framework

A patent can only qualify for a term extension under § 156 if the following five conditions are met:

> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;
> (2) the term of the patent has never been extended under subsection (e)(1) of this section;
> (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements . . . of subsection (d);
> (4) the product has been subject to a regulatory review period before its commercial marketing or use;
> (5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the *product* after such regulatory review period 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) (2006) (emphasis added).

Defendants do not dispute that Plaintiff's '267 patent meets the first four conditions of § 156(a). The lone contested issue is whether the fifth condition, § 156(a)(5)(A), is met. Resolution of this issue requires the court to decide which compound of the drug being used to support the patent term extension request qualifies as the "the product." Congress, in the statute, supplied further definition for "the product" term. Section 156(f)(1)(A) defines "product" as "a drug product," which, in turn, is defined as "the *active ingredient* of . . . 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) (2006) (emphasis added). Therefore, identifying which compound in the drug qualifies as "the product" for § 156(a)(5)(A) purposes requires the court to determine the drug's "active ingredient." That active ingredient, along with the entire group of salts and esters that derive from it, constitute "the product."

The court then must determine whether the active ingredient, or any of its salts or esters, (i.e. "the product") were previously approved by the FDA. If so, the relevant patent term extension application must be denied. Applying this statutory framework to the facts of the present case, if the active ingredient of Metvixia, or any one of its salts or esters, were previously approved by the FDA for commercial marketing or use, then the '267 patent cannot be granted a term extension.

PhotoCure argues that the active ingredient in Metvixia is MAL hydrochloride, since that is the critical compound in Metvixia that enables the drug to work effectively. If PhotoCure's view is accepted, MAL hydrochloride and all of the salts and esters that derive from it would qualify as "the product." ALA and ALA hydrochloride would not qualify as "the product" under this approach, because neither are salts or esters of MAL hydrochloride. This would mean that Levulan, whose key ingredient is ALA hydrochloride, also would not be covered by "the product" language and could not bar the '267 patent from an extension. Instead, under the PhotoCure interpretation, the '267 patent would satisfy § 156(a)(5)(A) because Metvixia would be the first permitted commercial marketing or use of a drug containing "the product" MAL hydrochloride.[7]

[7] The USPTO acknowledged that that neither MAL hydrochloride nor any of its salts or esters have been previously approved by the FDA for commercial marketing or use. USPTO Decision at 7.

On the other hand, the USPTO argues that the active ingredient must always be the underlying molecule of the salt and ester family in its non-esterified and non-salified form (i.e., the active moiety approach). Adopting the active moiety approach in this case would lead to ALA qualifying as the "active ingredient" of Metvixia. As a result, ALA, and all of its salts and esters, including ALA hydrochloride and MAL hydrochloride, would qualify as "the product." Under this reasoning, ALA, and all of its salts and esters, would also qualify as "the product" of Levulan. Thus, under the active moiety approach, Levulan and Metvixia would be viewed as containing the same product. Because Levulan would earn FDA approval before Metvixia under the active moiety approach, Metvixia, would not qualify as the first permitted commercial marketing or use of a drug containing "the product" ALA, which means that the patent covering Metvixia would not qualify for a term extension. In short, the outcome of this case turns on whether the active moiety approach or the PhotoCure approach is adopted.

B. Case Law

i. Glaxo I & II

This Court previously addressed the issue of how to interpret §§ 156(a)(5)(A) and 156(f)(2) in *Glaxo Operations UK Ltd. v. Quigg*, 706 F.Supp. 1224 (E.D. Va. 1989) ("*Glaxo I*"). The facts of *Glaxo I* are nearly identical to those of this case. The patent holder in *Glaxo I* sought a term extension for its patent covering cefuroxime axetil, an orally administered antibiotic compound commercially marketed as Ceftin Tablets. *Glaxo I*, 706 F.Supp. at 1225. Cefuroxime axetil is an ester of cefuroxime, its parent organic acid and active moiety. *Id.* at 1225. But because two salts of cefuroxime had been the active ingredients of drugs earning FDA approval before the Ceftin Tablets, the USPTO denied the application for a term extension. *Id.* at 1225-26. Specifically, the USPTO applied the active moiety approach and explained:

> [F]or the purpose of eligibility for patent term extension, an active ingredient in the acid, salt or ester form is treated as the same drug product . . . [I]t must be concluded that the active ingredient in CEFTIN is an ester of cefuroxime. A sodium salt of cefuroxime has been approved for commercial marketing or use by the FDA prior to the approval of CEFTIN. Accordingly, the permission for commercial marketing or use of the product (i.e., the active ingredient cefuroxime axetil) after the regulatory review period was not the first permitted commercial marketing or use of the product (cefuroxime as a salt or ester) . . . .

Id. at 1226 (citing *In re Glaxo Operations UK Ltd.*, Request for Patent Term Extension under 35 U.S.C. § 156 for U.S. Patent No. 4,267,320 at 3-4 (Sept. 9, 1988)).

Judge Ellis, however, reversed the USPTO's decision, explaining that the Office's interpretation of § 156 ignored the plain meaning of the statute by permitting a compound to qualify as the "active ingredient" when that compound was not physically present in the drug. *Id.* at 1227. Specifically, Judge Ellis reasoned that:

> Cefuroxime itself is not present at all in Ceftin Tablets; it is therefore not an "ingredient." This conclusion is inescapable given the plain and unambiguous language of the statute. An ingredient is a "constituent element of a mixture or compounds." *Webster's Second University Dictionary* (1984). It must be something found in the mixture or compound, not just something that can be derived from it or from which the mixture or compound can be derived. Simply because the ester cefuroxime axetil may be derived from the acid cefuroxime through esterification is no basis for concluding that cefuroxime is some how an "ingredient." One might as well say that a caterpillar is an ingredient of a butterfly. This is palpably not so. To be sure, a butterfly comes from, or derives from, a caterpillar in metamorphosis as does the ester from the acid in esterification.

Id. at 1227-28.

Judge Ellis also found significance in the fact that the statute used the term "ingredient" instead of "moiety":

> [N]either this Court, nor the Commissioner is at liberty to ignore . . . the fact that the statute uses "ingredient," not "moiety." Equating "active moiety" with "active ingredient" . . . results in reading out of the statute the plain meaning of the phrase Congress chose. This is unwarranted for "'[a] fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.'" *Ethicon, Inc. v. Quigg*, 849

> F.2d 1422, 1426 (Fed.Cir.1988) (quoting *Perrin v. United States,* 444 U.S. 37, 42 (1979)).

Id. at 1228.

Finally, after an extensive review of the legislative history, Judge Ellis noted that nothing in the legislative history discusses the terms "active ingredient" or "active moiety." *Id.* at 1228. As a result, he concluded that the legislative history provides no basis for reading the term "active ingredient" contrary to its plain meaning to include ingredients not physically present in the drug.

On appeal of *Glaxo I*, the Federal Circuit affirmed Judge Ellis's ruling, stating that "the district court correctly construed and properly applied the operative terms of § 156(a)." *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 393 (Fed. Cir. 1990) (*Glaxo II*). The court in *Glaxo II*, similar to Judge Ellis's approach, extensively analyzed the legislative history of § 156 to determine whether it clearly expressed an intention that the statute be construed contrary to its plain meaning. *Glaxo II*, 894 F.2d at 395-96. The USPTO had cited specific House Report language and floor statements in *Glaxo II* in hopes of persuading the court that the legislative history should be construed contrary to its plain meaning and that the active moiety approach was what Congress intended. *Id.* at 397-98. But the court rejected these arguments, explaining that none of the legislative history spoke directly to the term "the product." *Id.* at 398.

As a result, the court concluded that the terms of the statute should be interpreted according to their plain meaning. *Id.* at 395. In reaching this conclusion, the court reasoned that "the terms 'active ingredient,' 'salt,' and 'ester' had well-defined, ordinary, common meanings when Congress enacted the Act" and merit legal consequence. *Id.* at 395. The court refrained from deciding whether its plain meaning approach, or the USPTO active moiety approach, was

better from a policy standpoint, explaining that "[s]triking balances in legislative language is Congress' job." *Id.* at 399.

ii. Pfizer I & II

The Federal Circuit addressed the issue of how to interpret §§ 156(a) and (f) again in *Pfizer, Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004) (*Pfizer II*). In that case, Pfizer owned a patent covering the base molecule amlodipine and two of its salts, amlodipine besylate and amlodipine maleate. *Pfizer II*, 359 F.3d at 1363. Pfizer obtained FDA marketing approval for a drug called Norvasc, which contained amlodipine besylate as its key ingredient. *Id.* at 1364-65; *see also Pfizer, Inc. v. Dr. Reddy's Labs., Ltd.* 2002 WL 31833744, at *1 (D. N.J. 2002) (*Pfizer I*). After obtaining approval, Pfizer applied for and was granted a term extension for the patent covering the Norvasc drug. *Id.* at 1364.

Also after Pfizer's FDA approval, Dr. Reddy's applied for its own FDA approval of a drug containing amlodipine maleate as its key ingredient. *Pfizer II*, 359 F.3d at 1364. Attempting to convince the court that its drug was not covered by Pfizer's patent term extension, Dr. Reddy's argued that the "active ingredient" of Pfizer's Norvasc drug was amlodipine besylate and not the underlying parent molecule amlodipine. *Id.* at 1364. Pfizer, on the other hand, asserted the "active moiety" argument, which would result in amlodipine qualifying as the "active ingredient" of Norvasc. *Id.* 1365. Under the active moiety interpretation, Pfizer's patent term extension would cover both amlodipine besylate and amlodipine maleate because both compounds are salts of the "active ingredient" amlodipine.

The court, reversing the district court which had applied *Glaxo II*, applied the active moiety approach and held that amlodipine was the § 156 "active ingredient" of Norvasc. Under this statutory construction, Pfizer's patent term extension covered amlodipine, amlodipine

besylate, and amlodipine maleate. *Pfizer II*, 359 F.3d at 1367. The court explained why it adopted the active moiety approach:

> The statute foresaw variation in the salt or ester of an active ingredient, and guarded against [this] loophole . . . . [T]he Hatch-Waxman Act established a balance whereby the patent term extension is offset by facilitating generic entry when the extended term expires, yet preserving the innovation incentive. Whether or not this bargain achieved "perfect symmetry"—Dr. Reddy's argues that it was not intended to do so, but was designed to favor the generics—the text of the statute shows that it was not intended to be defeated by simply changing the salt.

Id. at 1366 (internal citations omitted).

iii. The Glaxo II/Pfizer II Conflict

Interestingly, the Federal Circuit in *Pfizer II* did not cite *Glaxo II* or *Glaxo I*, even though *Pfizer II* and those cases are clearly in conflict. *Glaxo I* and *II* stand for the proposition that a compound can only qualify as the "active ingredient" of a drug if that compound itself is present in the drug.[8] *See Glaxo II*, 894 F.2d at 393; *Glaxo I*, 706 F.Supp. at 1227-28. *Pfizer II*, in contrast, supports the active moiety approach, which results in automatically naming the base molecule the "active ingredient" in any instance where a salt or ester of that base molecule is the key ingredient in the drug. *Pfizer II*, 359 F.3d at 1367. The active moiety approach does not require that the active ingredient be a compound physically present in the drug.

The Court must determine whether it is required to follow *Glaxo II* or *Pfizer II*. Importantly, *Pfizer II* postdated *Glaxo II* and was a panel decision that the Federal Circuit declined to hear *en banc*. "[The Federal Circuit] has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *in banc*. Where there is a direct conflict, the precedential decision is the first." *Newell Companies,*

[8] *Glaxo II* does not expressly state that the compound must be present in the drug in order to qualify as the "active ingredient." However, the *Glaxo II* court's interpretation of § 156, in combination with its affirmance of *Glaxo I* persuades this Court that *Glaxo II* must be read to incorporate this concept.

Inc. v. Kenney Manufacturing Co., 864 F.2d 757, 765 (Fed. Cir. 1988) (internal citations omitted); *see Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1371 (Fed. Cir. 2008). Therefore, this court is bound by *Glaxo II*.[9]

C. Application

Applying *Glaxo II* to the facts of this case, the active ingredient in Metvixia is MAL hydrochloride and not the active moiety ALA, because MAL hydrochloride is the ingredient physically present in Metvixia that permits the drug to work effectively. ALA does not exist in Metvixia in any capacity besides its esterified form of MAL hydrochloride. Therefore, MAL hydrochloride, and any salt or ester deriving from it, constitute "the product" under § 156. ALA and ALA hydrochloride, on the other hand, are not covered by "the product" language.

As a result, Levulan, whose key ingredient is ALA hydrochloride, does not contain the same "product" as Metvixia. It necessarily follows that Levulan cannot qualify as the first permitted use of a drug containing "the product" at issue in this case. Instead, Metvixia is the first permitted commercial marketing or use of a drug containing "the product" MAL hydrochloride. *See* 35 U.S.C. § 156(a)(5)(A) (2006). Therefore, this Court holds that the '267 patent covering Metvixia satisfies § 156(a)(5)(A), and that the USPTO's decision to apply the active moiety interpretation and deny PhotoCure a patent term extension under this provision was contrary to the plain meaning of the statute and thus not in accordance with law. *See* 5 U.S.C. § 706(2)(A).

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[9] The Court is aware of the *Tunik v. Merit Systems Protection Board* case where the Federal Circuit stated the following: "where an earlier panel decision on statutory construction was based on deference to an agency interpretation, a later panel of this court is free to consider whether a new agency interpretation is reasonable without en banc reconsideration of the earlier panel decision." 407 F.3d 1326, 1338 (Fed. Cir. 2005). This rule does not apply to the present case, however, because the USPTO interpretation in *Glaxo II* (i.e. the "earlier panel decision") was accorded no deference, and because, as explained below in Section IV.D, the USPTO interpretation in this case merits no deference, as well.

Even though this holding is compelled by *Glaxo II*, the Court would reach the same result had the issue been one of first impression. The primary definition of the term "ingredient" requires that the ingredient actually be contained in the compound. *See* 7 Oxford English Dictionary 963-64 (2d ed.1989) (an "ingredient" is "[s]omething that enters into the formation of a compound or mixture; a component part, constituent or element."). Therefore, the Court believes that a plain meaning interpretation of the § 156(f)(2) "active ingredient" term requires the actual presence of a compound qualifying as the "active ingredient" in the drug.

To adopt the active moiety approach would entail construing the term "active ingredient" in such a manner that permits compounds to qualify as ingredients of drugs even when those compounds are not actually present in the drug. To adopt such a construction would be permissible, in this Court's view, only if there was support in the legislative history. But the Court could find no legitimate support for the active moiety approach in the § 156 legislative history. Therefore, the Court will not construe the "active ingredient" term against its plain meaning by adopting a construction that permits compounds not present in the drug to qualify as the "active ingredient."

Also worth emphasizing is that the term "active moiety" was indisputably well-known at the time Congress drafted the statute. If Congress desired to infuse the "active moiety" concept into §§ 156(a) and (f), it could have done so easily by including the term somewhere in either of those two provisions.

D. Agency Deference

The USPTO argues that its active moiety interpretation of § 156 is entitled to *Chevron* and *Skidmore* deference. *Chevron* established a two-step test for determining the amount of

deference accorded to agency actions having the force of law.[10] *See Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *Citizens Exposing Truth about Casinos v. Kempthorne*, 492 F.3d 460, 466 (D.C. Cir. 2007). Under the first step, the court must determine "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. If so, then "that is the end of the matter; for the court, as well as the agency must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43. However, if the statute is silent (i.e., "left a gap") or ambiguous with respect to a specific issue, then the analysis proceeds to "Step Two." *Chevron*, 467 U.S. at 842-44. Under Step Two, the court must give the agency's interpretation deference unless it is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 843.

The controlling statutory terms in this case are "product," "drug product," and "active ingredient." As explained above, the terms "product" and "drug product" are further defined by the "active ingredient" language of § 156(f)(2). Congress, however, did not supply a statutory definition for the "active ingredient" term. Therefore, if *Chevron* deference is appropriate in this case, it would apply most directly to the USPTO's interpretation of the undefined "active ingredient" term and not the further defined "product" and "drug product" terms.

The *Glaxo II* court addressed the issue of whether Congress "left a gap" in or ambiguously drafted the terms in § 156(f)(2). Specifically, the court stated that "section 156(f)(2)'s operative terms, individually and as combined in the full definition, have a common and unambiguous meaning, which leaves no gap to be filled in by the administering agency. Accordingly, we need not defer to any reasonable interpretation of the Commissioner." *Id.* at 398. In other words, because the statutory terms in § 156(f)(2) (e.g., "active ingredient") are

[10] The USPTO interpreted § 156(f)(2) in its formal adjudication of the '267 patent term extension case. Because this interpretation came through formal adjudication, it clearly has the force of law and is ripe for a *Chevron* analysis.

unambiguous, the *Chevron* analysis ends at Step One and the Court must give effect to the intent of Congress. Following the *Glaxo II* reasoning, this Court concludes that the USPTO's formal active moiety interpretation of the § 156(f)(2) "active ingredient" term merits no *Chevron* deference.

The USPTO also argues that it is entitled to *Skidmore* deference, a lesser and different form of deference than that of *Chevron*. *See Skidmore v. Swift & Co.*, 323 U.S. 134 (1944); *United States v. Mead Corp.*, 533 U.S. 218, 227-28 (2001). Unlike *Chevron* deference, *Skidmore* deference can apply to agency interpretations not having the force of law, such as those contained in opinion letters, policy statements, agency manuals, and enforcement guidelines. *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (internal citations omitted). Such agency interpretations are "'entitled to respect' . . . but only to the extent that those interpretations have the 'power to persuade.'" *Id.* (internal citations omitted).

The amount of deference that an agency interpretation of a statute warrants under *Skidmore* varies with the circumstances. *Mead*, 533 U.S. at 228; *Cathedral Candle Co. v. United States Int'l Trade Comm'n*, 400 F.3d 1352, 1365-66 (Fed. Cir. 2005). One factor courts consider in determining how much deference to award is "the writer's thoroughness, logic, and expertise." *Cathedral Candle*, 400 F.3d at 1366 (citing *Mead*, 533 U.S. at 235.). Additionally, the Federal Circuit has explained:

> [W]e believe the Supreme Court intends for us to defer to an agency interpretation of the statute that it administers if the agency has conducted a careful analysis of the statutory issue, if the agency's position has been consistent and reflects agency-wide policy, and if the agency's position constitutes a reasonable conclusion as to the proper construction of the statute, even if we might not have adopted that construction without the benefit of the agency's analysis.

Cathedral Candle Co., 400 F.3d at 1366.

The USPTO first argues that it warrants *Skidmore* deference because it has consistently applied the same principles to patent term extension applications. The Court disagrees. For example, the USPTO clearly applied the active moiety approach at the formal agency adjudication stage of this case. Yet at the time the agency decision issued on May 13, 2008, § 2751 of the Manual of Patent Examining Procedures (MPEP), one of the most prominent documents published by the USPTO, stated the following: "The ester form is a different active ingredient from the salt form. Both the ester and the salt active ingredient may each support an extension of patent term of different patents provided the acid itself has not previously been approved." Even more, this language was contained under the USPTO's definition of "drug product" and cited both *Glaxo I* and *Glaxo II*. *See* MPEP § 2751. This MPEP language does not comport with the "active moiety" approach. The USPTO stated as much in its brief, writing that "the guidance in MPEP § 2751 about the patent term extension eligibility for salts and esters is admittedly incorrect, and the agency is revising it." Reply Brief for Defendants at 8-9, *PhotoCure v. Dudas, et al.*, 1:08-cv-718 (E.D. Va. 2008).

Because of the conflict between the interpretation advised in MPEP § 2751 and the "active moiety" approach used in the formal adjudication, the Court is not persuaded that the USPTO should merit any deference under *Skidmore* for being "consistent" in constructing and "careful" in analyzing §§ 156(a) and (f). *See Cathedral Candle Co.*, 400 F.3d at 1366.

Furthermore, the USPTO does not merit deference for its active moiety construction of §§ 156(a) and (f) being a "reasonable conclusion as to the proper construction of the statute." *See id.* Once more, the USPTO's interpretation of "active ingredient" in this case runs afoul of the plain meaning of the statute and finds no legitimate support in the legislative history. Such an interpretation, in the Court's view, is not reasonable.

Finally, the USPTO asserts that its expertise in understanding the chemistry of drug products calls for a high level of *Skidmore* deference. Any amount of deference earned as a result of such expertise, however, would be insufficient to convince the Court to follow the USPTO in adopting an inconsistent and unreasonable statutory construction contrary to plain meaning. *See Garcia v. U.S.*, 469 U.S. 70, 75 (1984) (quoting *TVA v. Hill*, 437 U.S. 153, 187 n.33 (1978)) ("[w]hen we find the terms of a statute unambiguous, judicial inquiry is complete, except in rare and exceptional circumstances") (internal quotations omitted). For these reasons, the Court will not defer to the USPTO's interpretation of § 156(a). Instead, the Court's holding in Section IV.C stands.

V. CONCLUSION

For the foregoing reasons, the Court shall grant Plaintiff's Motion for Summary Judgment on Counts I and II. Accordingly, the Court shall deny Defendants' Motion for Summary Judgment on those same counts.

Entered this 31st day of March, 2009.

Alexandria, Virginia

/s/
Liam O'Grady
United States District Judge