IN THE 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 and Director of the United States Patent and Trademark Office,
and JOHN J. DOLL, Commissioner for Patents,

Defendants.

Civil Action No. 1:08CV718-LO/JFA

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

Plaintiff, for its complaint herein, alleges:

NATURE OF THE ACTION

1. This is an action for a declaratory judgment that defendants' decision denying plaintiff's application for extension of a patent term under 35 U.S.C. § 156 is contrary to law, and for injunctive and other relief.

2. Plaintiff seeks review of defendants' denial of plaintiff's application for extension of a patent term under 35 U.S.C. § 156. The decision ("Final Decision") of the Commissioner for Patents, the United States Patent and Trademark Office ("PTO"), dated May 13, 2008, denying plaintiff's application with respect to U.S. Patent No. 6,034,267 (the "'267 patent"), is attached hereto as Exhibit A. A copy of the '267 patent is attached as Exhibit B. A copy of the

defendant Commissioner's initial decision ("Notice of Final Determination"), dated April 11, 2007, is attached as Exhibit C.

3. This Action arises under 35 U.S.C. § 156 (added by the Drug Price Competition and Patent Term Restoration Act), and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

JURISDICTION AND VENUE

4. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361, 2201-2202, and 5 U.S.C. §§ 701-706. There exists between the parties an actual controversy, justiciable in character, in respect of which plaintiff requires a declaration of its rights by the Court.

5. Venue is proper in this district by virtue of 28 U.S.C. § 1391(e).

THE PARTIES

6. Plaintiff Photocure ASA ("Photocure") is a Norwegian public limited company having a place of business at Hoffsveien 48, NO-0377 Oslo, Norway. Plaintiff is the current owner of the '267 patent.

7. Defendant Jon W. Dudas is named in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, Patent and Trademark Office, United States Department of Commerce. The Director is the head of the PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official with responsibility for decisions to grant extension of patent terms under 35 U.S.C. § 156, which

was added by the Drug Price Competition and Patent Term Restoration Act of 1984. *See* 35 U.S.C. §§ 3(a), 156(d) and (e).

8. Defendant John J. Doll is named in his official capacity as Commissioner for Patents, Patent and Trademark Office, United States Department of Commerce. The Commissioner for Patents is the chief operating officer for the operation of the PTO relating to patents and is responsible for the management and direction of all aspects of the activities of the PTO that affect the administration of patent operations. *See* 35 U.S.C. § 3(b)(2)(A). The Final Decision, dated May 13, 2008, denying plaintiff's application for patent term extension for Metvixia™ was issued in the name of the Commissioner for Patents.

THE '267 PATENT AND THE METVIXIA™ DRUG PRODUCT

9. The '267 patent was issued by the United States Patent and Trademark Office on March 7, 2000, naming as inventors Karl E. Gierskcky, Johan Moan, Qian Peng, Harald Steen, Trond Warloe, and Alf Bjorseth. The '267 patent concerns treatment of actinic keratoses, among other disorders, by the technique known as photodynamic therapy ("PDT," also known as "photochemotherapy"). PDT is a medical treatment for eliminating unwanted cells, such as those of a tumor or other growth. PDT entails causing a light-sensitive molecule (a "photosensitizer") to accumulate in the unwanted cells, and then shining light of an appropriate wavelength on the cells, thereby activating the photosensitizer, which sets off a chain of events that culminates in the death of the cells. It is desirable that the photosensitizer accumulate primarily in the unwanted cells and to a lesser extent or not at all in neighboring, normal cells. Actinic keratosis is a premalignant warty lesion that occurs on the sun-exposed skin, *e.g.*, face,

scalp, or hands, of aged light-skinned people. It may develop into squamous cell carcinoma of low-grade malignancy or into basal cell carcinoma.

10. The inventors discovered, among other things, a method of PDT treatment that entails administering methylaminolevulinate hydrochloride to a tissue to be treated, thereby inducing the accumulation of the photosensitizer protoporphyrin IX in the cells to be eliminated. This method affords substantial advantages over the use in PDT of aminolevulinic acid hydrochloride. *See* '267 patent at col. 1, ll. 9-20, col. 3, ll. 19-23, col. 5, ll. 25-32, col. 4, l. 57-col. 5, l. 9. Both methylaminolevulinate and aminolevulinic acid are converted by cells into protoporphyrin IX. The advantages that methylaminolevulinate affords over aminolevulinic acid include superior selectivity of uptake by target lesions, superior penetration of target lesions, reduced (unwanted) systemic distribution of the active ingredient, and reduced pain resulting from PDT. *See id.* at col. 4, l. 57-col. 5, l. 9. In the '267 patent, the inventors were granted claims both to pharmaceutical compositions comprising methylaminolevulinate hydrochloride and to methods of photochemotherapeutic treatment comprising administering such compositions.

11. The commercial embodiment of the '267 patent is Metvixia™, which contains methylaminolevulinate hydrochloride, along with inactive ingredients. While aminolevulinic acid hydrochloride had previously been marketed in the United States in other drug products, Metvixia™ was the first commercial drug product to contain methylaminolevulinate hydrochloride (an ester of aminolevulinic acid hydrochloride). Metvixia™ was a new drug as defined under Section 201(p) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and accordingly a New Drug Application ("NDA") approved by Food and Drug Administration

("FDA") pursuant to section 505(b) of the Act, was required before the drug product could be commercially marketed.

12. Photocure undertook the development of the product to establish, by adequate and well-controlled clinical trials, the product's safety and efficacy as a drug for treatment of actinic keratosis. Clinical studies on Metvixia™ (originally called "Metvix") began in 1997 outside the U.S. On February 24, 2000, Photocure filed an Investigational New Drug Application ("IND") with FDA for the Metvixia™ drug product.

13. On September 26, 2001, Photocure submitted an NDA for the product. FDA approved the NDA on July 27, 2004, permitting the commercial marketing of Metvixia™. The labeling approved by FDA describes Metvixia™ as an oil in water emulsion containing methylaminolevulinate hydrochloride at a concentration equivalent to 168 mg/g methylaminolevulinate. In combination with red light from a CureLight BroadBand Model CureLight 01 lamp, Metvixia™ is approved for use in treating non-hyperkeratotic actinic keratoses. On June 26, 2008, the FDA approved Metvixia™ in combination with red light from Aktilite® CL128, an LED-based narrow band lamp, for use in treating non-hyperkeratotic actinic keratoses.

14. The approved Metvixia™ drug product falls within claims 8 and 9 of the '267 patent and its approved use falls within claims 1 and 3-7 of the '267 patent.

THE AGENCY DECISION UNDER REVIEW

15. Section 156 of 35 U.S.C., added by the Drug Price Competition and Patent Term Restoration Act of 1984, permits the term of certain patents claiming approved drug products (or

their use or method of manufacture) to be extended to compensate for the length of time involved in obtaining regulatory review of the drug product. 35 U.S.C. § 156(a) provides that the term of a patent "shall be extended" if the following requirements 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 paragraphs (1) through (4) of subsection (d);
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use;
>
> (5)(A) * * * 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).

Plaintiff's '267 patent satisfies each of these requirements. Defendants were therefore under a mandatory duty to extend the term of this patent in accordance with the provisions of 35 U.S.C. § 156.

16. On September 20, 2004, plaintiff timely filed an application in the PTO for a section 156 patent term extension for the '267 patent, which had issued on March 7, 2000 and is set to expire on March 8, 2016. The PTO issued its Notice of Final Determination denying plaintiff's application on April 11, 2007. Plaintiff timely filed a Request for Reconsideration of the PTO's decision on November 9, 2007. The PTO issued its Final Decision denying plaintiff's application on May 13, 2008. The PTO's denial of plaintiff's application constitutes final agency action on the application. *See* 37 C.F.R. § 1.750.

17. The PTO denied the application for a patent term extension for the '267 patent on the ground that it failed to satisfy the first commercial marketing requirement of 35 U.S.C.

§ 156(a)(5)(A). Even though Metvixia™ represents the first permitted commercial marketing or use of a drug containing methylaminolevulinate hydrochloride or a salt or ester of methylaminolevulinate hydrochloride as the active ingredient, the PTO reasoned that Metvixia™'s approval did not satisfy 35 U.S.C. § 156(a)(5)(A) because the term "product," as used in 35 U.S.C. § 156(a)(5)(A) and defined in 35 U.S.C. § 156(f), is properly construed, according to the PTO, to mean the "underlying molecule" exclusive of the "appended portions" that make the molecule an ester or salt. Final Decision at 5. Thus, the active ingredient of Metvixia™, according to the PTO, is aminolevulinic acid, and, since aminolevulinic acid hydrochloride previously was approved for commercial marketing, the approval of Metvixia™ did not represent the first permitted commercial marketing required by the statute.

COUNT I

18. Plaintiff repeats and incorporates by reference the allegations set forth in Paragraphs 1 through 17.

19. Defendants acted in a manner contrary to law in denying plaintiff's application for a patent term extension for the '267 patent in violation of 35 U.S.C. § 156, including 35 U.S.C. § 156(a)(5)(A).

20. The PTO's construction is contrary to law and will frustrate the overriding purpose of title II of the Drug Price Competition and Patent Term Restoration Act, which is to encourage research and innovation, including the development of new active ingredients.

COUNT II

21. Plaintiff repeats and incorporates by reference the allegations set forth in Paragraphs 1 through 20.

22. Defendants' denial of plaintiff's application for a patent term extension for the '267 patent is arbitrary and capricious and not in accordance with law, and therefore should be set aside under the Administrative Procedure Act, 5 U.S.C. §§ 701-706, including 5 U.S.C. § 706(2).

RELIEF REQUESTED

WHEREFORE, Plaintiff prays that the Court:

23. Issue a declaratory judgment that defendants acted unlawfully in denying plaintiff's application for patent term extension;

24. Issue a declaratory judgment that plaintiff's application for patent term extension satisfies each of the requirements set forth in 35 U.S.C. § 156;

25. Issue an order setting aside the defendant Commissioner's denial of plaintiff Photocure's application for patent term extension;

26. Issue an order compelling defendant Commissioner to comply with the requirements of 35 U.S.C. § 156(d)(2)(A) and, after compliance with those requirements, to take action to extend the term of U.S. Patent No.6,034,267 in accordance with the provisions of 35 U.S.C. § 156;

27. Award plaintiff its cost and reasonable attorneys' fees; and

28. Grant other or further relief as may be appropriate.

Respectfully submitted,

Date: July 11, 2008

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