

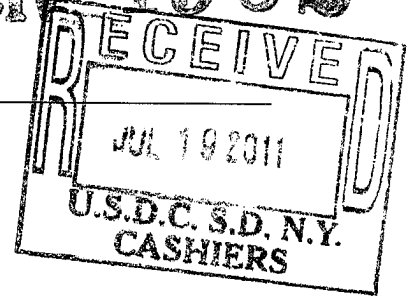
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JUDGE SWAN
THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MEDICIS PHARMACEUTICAL)
CORPORATION,)
)
Plaintiff,)
)
v.)
)
NYCOMED U.S., INC.)
)
Defendant.)

11 CIV 4962

C.A. No.



COMPLAINT

Plaintiff Medicis Pharmaceutical Corporation (“Medicis”), for its complaint against Defendant Nycomed U.S., Inc. (“Nycomed U.S.”), alleges as follows:

THE PARTIES

1. Medicis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256. Medicis is a leading independent specialty pharmaceutical company in the United States, focusing primarily on the treatment of dermatological and aesthetics conditions. Since its inception in 1988, Medicis has developed and commercialized numerous brand-name prescription medications in the therapeutic categories Medicis serves. Because of their clinical effectiveness and high quality, Medicis’ products have earned wide acceptance by both physicians and patients.

2. Upon information and belief, Nycomed U.S. is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 60 Baylis Road, Melville, New York 11747.

JURISDICTION AND VENUE

3. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 101, *et seq.*

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)–(c) and 1400(b).

6. This Court has personal jurisdiction over Nycomed U.S. by virtue of, virtue of its incorporation and place of business in New York. This Court also has jurisdiction over Nycomed U.S. by virtue of, *inter alia*, its transaction of business and derivation of substantial revenue from services or things used or consumed in this judicial district, its substantial and continuous contacts with this judicial district, and its purposeful availment of the rights and benefits of New York law. Upon information and belief, Nycomed U.S. engages in the manufacture, sale, and distribution of pharmaceutical products within the United States generally and the state of New York specifically.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 7,981,909

7. Medicis incorporates by reference the averments set forth in paragraphs 1–6 as if fully set forth herein.

8. United States Patent No. 7,981,909 (“the ‘909 patent”), entitled “Use of 1-Hydroxy-2-Pyridones for the Treatment of Seborrheic Dermatitis,” was duly and lawfully issued on July 19, 2011. A true and correct copy of the ‘909 patent is attached to this Complaint as Exhibit 1.

9. The ‘909 patent resulted from Application No. 13/018,417, filed on Jan. 31, 2011.

10. Medicis is the owner of all rights, title, and interest in the '909 patent, including the right to sue and recover for infringement thereof.

11. The '909 patent recites four (4) claims directed to a "method of treating seborrheic dermatitis." For example, Claim 1 of the '909 patent recites:

A method of treating seborrheic dermatitis of the scalp comprising administering to the scalp of a human seborrheic dermatitis patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising only one active ingredient, the active ingredient consisting of ciclopirox, and at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; wherein the composition has a pH ranging from about 4.5 to about 6.5; and wherein the composition is a single composition and is a shampoo.

12. Medicis is the holder of New Drug Application No. 21-159 approved by the United States Food and Drug Administration for Loprox® Shampoo (ciclopirox) 1%. Loprox® Shampoo is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults.

13. On or about May 25, 2010, Nycomed U.S. received FDA approval for a generic ciclopirox 1% shampoo.

14. Upon information and belief, Nycomed U.S.'s generic ciclopirox 1% shampoo is indicated for treating seborrheic dermatitis of the scalp.

15. Pursuant to federal regulation, including, without limitation, 21 C.F.R. Sections 314.94(a)(4) and (a)(8), Nycomed U.S.'s ANDA seeking approval of its generic ciclopirox 1% shampoo was required to contain a statement that the conditions of use prescribed, recommended, or suggested in the labeling proposed for its generic product had been previously approved for the reference listed drug, Loprox® Shampoo, and that its labeling is the same as the labeling of Loprox® Shampoo, except for certain differences not relevant here.

16. Because Loprox® Shampoo is only indicated for the topical treatment of seborrheic dermatitis of the scalp in adults, upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), the label for Defendant Nycomed U.S.'s generic ciclopirox 1% shampoo contains the same indication and instructions for use as the label for Loprox® Shampoo.

17. Upon information and belief, subject to Rule 11(b)(3), Nycomed U.S.'s generic ciclopirox 1% shampoo comprises the active ingredient ciclopirox and at least one surfactant and has a pH in the range of about 4.5 to about 6.5.

18. The package insert for Nycomed U.S.'s generic ciclopirox 1% shampoo includes instructions for dosage and administration of the shampoo.

19. Upon information and belief, Nycomed U.S. has infringed, and is still infringing, the '909 patent, either directly and/or indirectly, literally or under the doctrine of equivalents, by its activities, including making, using, offering for sale, selling in the United States or importing, without authority, ciclopirox 1% shampoo.

20. Nycomed U.S.'s infringing activities have caused and will continue to cause Medicis irreparable harm, for which it has no adequate remedy at law, unless Nycomed U.S.'s activities are enjoined.

21. Medicis has been and continues to be damaged by Nycomed U.S.'s infringement of the '909 patent in an amount to be determined at trial.

22. On or about June 4, 2011, Medicis notified Nycomed U.S. of the application that resulted in the '909 patent and provided a copy of the published application to Nycomed U.S.

23. Upon information and belief, Nycomed U.S.'s infringement of the '909 patent is willful and deliberate, and justifies an increase in damages of up to three times in accordance with 35 U.S.C. § 284.

24. Upon information and belief, Nycomed U.S.'s infringement of the '909 patent is exceptional and entitles Medicis to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

25. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Medicis demands a trial by jury of this action of all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, Medicis respectfully requests that:

- (a) Judgment be entered that Nycomed U.S. has infringed one or more claims of the Asserted Patent;
- (b) Judgment be entered permanently enjoining Nycomed U.S., its directors, officers, agents, servants and employees, and those acting in privity or in concert with them, and its subsidiaries, divisions, successors and assigns, from further acts of infringement of the Asserted Patent;
- (c) Judgment be entered awarding Medicis all damages adequate to compensate it for Nycomed U.S.'s infringement of the Asserted Patent including all pre-judgment and post-judgment interests in the maximum rate permitted by law;
- (d) Judgment be entered that Nycomed U.S.'s infringement of the Asserted Patent is willful and deliberate, and therefore, that Medicis is entitled to treble damages as provided by 35 U.S.C. § 284;
- (e) Judgment be entered that Nycomed U.S.'s infringement of the Asserted Patent is willful and deliberate, and, therefore, that this is an exceptional case entitling Medicis to an


award of its attorneys' fees for bringing and prosecuting this action, together with interest, and costs of the action, pursuant to 35 U.S.C. § 285; and

(f) Judgment be entered awarding Medicis such other and further relief as this Court may deem just and proper.

Dated: July 19, 2011

Respectfully submitted,

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