IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION, DOW PHARMACEUTICAL SCIENCES, INC., and ALYZAN, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACTAVIS MID ATLANTIC LLC,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Medicis Pharmaceutical Corporation ("Medicis"), Dow Pharmaceutical Sciences, Inc. ("Dow"), and Alyzan, Inc. ("Alyzan") (collectively, "Plaintiffs") allege as follows:

THE PARTIES

1. Medicis is a Delaware corporation with its principal place of business in Scottsdale, Arizona. Medicis is a leading independent specialty pharmaceutical company in the United States, focusing primarily on the treatment of dermatological and podiatric conditions and aesthetics medicine. Medicis has developed and commercialized leading branded prescription products in a number of therapeutic categories. Because of their clinical effectiveness and high quality, Medicis's products have earned wide acceptance by both physicians and patients.

2. Dow is a California corporation with its principal place of business in Petaluma, California.

3. Alyzan is a corporation organized under the laws of the State of Louisiana.

4. On information and belief, Defendant Actavis Mid Atlantic LLC ("Actavis") is a limited liability company organized and existing under the laws of the State of

Delaware with its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

JURISDICTION AND VENUE

5. This is an action of patent infringement under 35 U.S.C. § 271. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6. Venue is proper in this Court for this action under, at least, 28 U.S.C. § 1391(b) and (c), and 1400(b).

7. This Court has personal jurisdiction over Actavis because Actavis is organized and exists under the laws of the State of Delaware. On information and belief, Actavis also manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

THE PATENTS-IN-SUIT

8. On May 14, 2002, United States Letters Patent No. 6,387,383 (the "'383 patent"), entitled TOPICAL LOW-VISCOSITY GEL COMPOSITION, was duly and legally issued. The '383 patent is currently scheduled to expire on August 3, 2020. The '383 patent discloses and claims novel pharmaceutical compositions for treating skin disorders, as well as novel methods for treating skin disorders. A copy of the '383 patent is attached as Exhibit 1.

9. Dow is the owner through assignment of the '383 patent. Medicis is the exclusive licensee of the '383 patent.

10. On February 16, 2010, United States Reissued Patent No. US RE41,134 (the "'134 patent"), entitled SLOW RELEASE VEHICLES FOR MINIMIZING SKIN IRRITANCY OF TOPICAL COMPOSITIONS, was duly and legally issued to Dr. Gail S.

Bazzano. The '134 patent is currently scheduled to expire on February 24, 2015. The '134 patent discloses and claims novel pharmaceutical compositions of tretinoin for application to the skin, as well as novel methods for treating a skin condition with tretinoin. A copy of the '134 patent is attached as Exhibit 2.

11. Alyzan is the owner through assignment of the '134 patent. Medicis is the exclusive licensee of the '134 patent.

12. Collectively, Plaintiffs have all rights to sue and recover for the infringement of the '383 patent and the '134 patent, which will be referred to as the "patents-in-suit."

BACKGROUND

13. Medicis is the owner of approved New Drug Application No. 050802 for clindamycin phosphate 1.2% and tretinoin 0.025% gel, which is sold under the trademark Ziana.® Medicis's Ziana® gel is extremely successful and is widely used throughout the world to treat diseases of the skin, including acne vulgaris. Currently, there is no generic version of Ziana® approved by the United States Food and Drug Administration ("FDA") for sale in the United States.

14. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Medicis has listed the '383 patent and the '134 patent in the Orange Book as covering its Ziana® gel.

15. On information and belief, Actavis has submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 202-564 under 21 U.S.C. § 355(j) seeking the FDA's approval to manufacture commercially and sell its proposed product, a generic version of Ziana®,

Clindamycin Phosphate/Tretinoin Topical Gel ("Proposed Product"), containing the active ingredients clindamycin phosphate and tretinoin, before the expiration of the patents-in-suit.

16. On March 29, 2011 Actavis sent a "Notification pursuant to §505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act for U.S. Patent Nos. RE41,134 and 6,387,383," to Plaintiffs. Actavis stated in that letter that it intends to market its Proposed Product before the expiration of the patents-in-suit.

17. On information and belief, Actavis's Proposed Product is a composition that would infringe the patents-in-suit.

COUNT I

18. Each of the preceding paragraphs 1–17 is incorporated as if fully set forth herein.

19. On information and belief, Actavis submitted ANDA No. 202-564 to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '383 patent, before the expiration of the '383 patent. On information and belief, Actavis has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

20. The commercial manufacture, use or sale of Actavis's Proposed Product would infringe the '383 patent.

21. On information and belief, when Actavis filed ANDA No. 202-564 seeking approval to market a generic version of Ziana® before the expiration of the '383 patent, Actavis was aware of the existence of the '383 patent and that filing the ANDA constituted an act of infringement of the '383 patent.

COUNT II

22. Each of the preceding paragraphs 1–17 is incorporated as if fully set forth herein.

23. On information and belief, Actavis submitted ANDA No. 202-564 to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '134 patent, before the expiration of the '134 patent. On information and belief, Actavis has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

24. The commercial manufacture, use or sale of Actavis's Proposed Product would infringe the '134 patent.

25. On information and belief, when Actavis filed ANDA No. 202-564 seeking approval to market a generic version of Ziana® before the expiration of the '134 patent, Actavis was aware of the existence of the '134 patent and that filing the ANDA constituted an act of infringement of the '134 patent.

REQUESTED RELIEF

Plaintiffs respectfully seek the following relief:

(a) That judgment be entered that Actavis has infringed the '383 patent by submitting to the FDA ANDA No. 202-564;

(b) That judgment be entered that Actavis has infringed the '134 patent by submitting to the FDA ANDA No. 202-564;

(c) That a permanent injunction be issued enjoining Actavis, its officers, agents or attorneys or employees, and those acting in active concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation

into the United States, of any chemical entity, therapeutic composition, or method of use claimed by the '383 patent or '134 patent for the full terms thereof, and from inducing or contributing to such activities;

(d) That an order be issued, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 202-564 be a date that is not earlier than the date of expiration of the '383 patent or '134 patent;

(e) Awarding Plaintiffs such other and further relief as this Court may deem just and proper under the circumstances.

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