IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION,

Plaintiff,

v.

ACTAVIS MID ATLANTIC LLC,

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis"), for its Complaint against Defendant Actavis Mid Atlantic LLC ("Actavis"), hereby alleges as follows:

THE PARTIES

1. Medicis is a Delaware corporation with its 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 podiatric conditions and aesthetics medicine. Because of their clinical effectiveness and high quality, Medicis's products have earned wide acceptance by both physicians and patients.

2. Upon information and belief, Defendant 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.

NATURE OF THE ACTION

3. This is a civil action concerning the infringement of United States Patent No. 8,236,816 ("the '816 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

JURISDICTION AND VENUE

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

5. This Court has personal jurisdiction over Actavis because Actavis is organized and exists under the laws of the State of Delaware. Upon information and belief, Actavis also manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district. Moreover, Actavis has previously consented to personal jurisdiction in this Court, including in *Medicis Pharmaceutical Corp., et. al. v. Actavis Mid Atlantic LLC*, C.A. No. 11-0409 (D. Del.).

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

BACKGROUND

7. Medicis is the lawful owner of the '816 patent, titled "2x2x2 Week Dosing Regimen for Treating Actinic Keratosis with Pharmaceutical Compositions Formulated with 3.75% Imiquimod," which was duly and legally issued by the United States Patent and Trademark Office on August 7, 2012. A copy of the '816 patent is attached as Exhibit A.

8. Medicis holds New Drug Application No. 22-483 for, *inter alia*, the topical treatment of clinically typical, visible, or palpable actinic keratoses ("AK") of the full face or balding scalp in immunocompetent adults using 3.75% imiquimod cream. Medicis

markets and sells this cream in the United States under the brand name "Zyclara® Cream (3.75%)."

9. Medicis's Zyclara® Cream (3.75%) is extremely successful and widely used throughout the world to treat diseases of the skin, including AK. Currently, there is no generic version of Zyclara® Cream (3.75%) approved by the United States Food and Drug Administration ("FDA") for sale in the United States.

10. Pursuant to 21 U.S.C. § 355(b)(1), the '816 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Zyclara® Cream (3.75%).

ACTS GIVING RISE TO THIS ACTION

11. Upon information and belief, Actavis submitted Abbreviated New Drug Application ("ANDA") No. 203-792 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Actavis's ANDA No. 203-792 seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic 3.75% imiquimod cream ("the Actavis Generic Product") prior to the expiration of the '816 patent.

12. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Actavis certified in ANDA No. 203-792 that the claims of the '816 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of the Actavis Generic Product.

13. Medicis received written notification of Actavis's ANDA No. 203-792 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated August 7, 2012, and sent via UPS ("Notice Letter"). In its Notice Letter, Actavis alleged that claims 1-18 of the '816 patent would not be infringed by the commercial manufacture, use, offer for sale, or sale of the

Actavis Generic Product. Actavis further alleged that claims 1-18 of the '816 patent are invalid for obviousness.

14. Upon information and belief, the proposed label for the Actavis Generic Product includes a Full Prescribing Information section.

15. Upon information and belief, within the Full Prescribing Information section of the proposed label for the Actavis Generic Product, the Indications and Usage and Dosage and Administration subsections each contain language relating to AK.

16. Upon information and belief, the Indications and Usage subsection includes the statement that the Actavis Generic Product is indicated for the topical treatment of clinically typical, visible, or palpable AK of the full face or balding scalp in immunocompetent adults, and the Dosage and Administration subsection includes the statement that, for treatment of AK, the Actavis Generic Product should be applied once daily to the skin of the affected area (either the entire face or balding scalp) for two 2-week treatment cycles separated by a 2-week no-treatment period. The use of the Actavis Generic Product in accordance with this prescribing information is encompassed by the literal scope of at least claim 1 of the '816 patent.

17. Actavis's submission of ANDA No. 203-792 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '816 patent under 35 U.S.C. § 271(e)(2)(A).

18. Upon information or belief, Actavis has been aware of the '816 patent since at least August 7, 2012, the date of its Notice Letter. Moreover, by including within its proposed label prescribing information that is encompassed by the literal scope of at least claim 1 of the '816 patent, Actavis specifically intends to encourage infringement of that patent by use of the Actavis Generic Product according to that prescribing information.

19. Medicis is entitled to a declaration that, if Actavis commercially manufactures, uses, offers for sale, or sells the Actavis Generic Product within the United States and/or imports the Actavis Generic Product into the United States, Actavis would infringe and/or induce the infringement of the '816 patent.

20. Medicis will be irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. Plaintiff Medicis does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Medicis prays for judgment as follows:

A. That Defendant Actavis has infringed one or more claims of the '816 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Actavis's ANDA No. 203-792 shall not be a date that is earlier than the latest expiration date of the '816 patent, including any applicable exclusivities or extensions;

C. That Defendant Actavis, its officers, agents, servants, and employees, and those persons acting in concert, participation, or in privity with any of them, and their successors or assigns, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing into the United States the Actavis Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '816 patent prior to its expiration, including any exclusivities or extensions to which Plaintiff Medicis is or becomes entitled;

D. That this case be declared exceptional under 35 U.S.C. § 285, and that Plaintiff Medicis be awarded the attorney fees, costs, and expenses that it incurs in prosecuting this action; and

E. That Plaintiff Medicis be awarded such other and further relief as this Court deems just and proper.

Dated: August 31, 2012

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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