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Dow Pharmaceutical Sciences, Inc.
and Valeant Pharmaceuticals North America LLC

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

DOW PHARMACEUTICAL SCIENCES, INC.
and VALEANT PHARMACEUTICALS
NORTH AMERICA LLC,

Plaintiffs,

v.

ACTAVIS LABORATORIES UT, INC.,
ACTAVIS INC., and ALLERGAN PLC
formerly known as ACTAVIS PLC,

Defendants.

Civil Action No.: _____

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Dow Pharmaceutical Sciences, Inc. (“Dow”) and Valeant Pharmaceuticals North America LLC (“Valeant”) (collectively, “Plaintiffs”) by way of Complaint against Defendants Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.) (“Actavis UT”), Actavis Inc., and Allergan plc (f/k/a Actavis plc) (collectively, “Actavis” or “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Dow is a corporation organized and existing under the laws of California having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

2. Plaintiff Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

3. Upon information and belief, Actavis UT is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 577 Chipeta Way, Salt Lake City, Utah and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. Upon information and belief, Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. Upon information and belief, Allergan plc (f/k/a Actavis plc) is a publicly-traded company organized and existing under the laws of Ireland, having its corporate headquarters at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland, and U.S. administrative headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. Upon information and belief, Actavis UT is a wholly owned by Actavis, Inc. Upon information and belief, Allergan plc is the global parent of, *inter alia*, Actavis UT and Actavis, Inc.

NATURE OF THE ACTION

7. This is an action for infringement of United States Patent No. 8,288,434 (“the

'434 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Actavis's filing of an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic benzoyl peroxide and clindamycin phosphate topical gel (3.75%/1.2%) ("Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel").

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, this court has jurisdiction over Actavis UT. Upon information and belief, Actavis UT is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis UT directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Actavis UT purposefully has conducted and continues to conduct business in this judicial district. According to Actavis UT's Annual Report filed March 10, 2015, with the State of Utah, Department of Commerce, Division of Corporations & Commercial Code, registered principles of Actavis UT provide addresses at 400 Interpace Parkway, Parsippany, NJ 07054.

10. Upon information and belief, this court has jurisdiction over Actavis, Inc. Upon information and belief, Actavis, Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis, Inc. directly, or indirectly, manufactures, markets, and sells generic drug

products, including generic products manufactured by Actavis UT, throughout the United States and this judicial district, and this judicial district is a likely destination for Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Actavis, Inc.'s principle place of business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Upon information and belief, Actavis, Inc. is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this court has jurisdiction over Allergan plc. Upon information and belief, Allergan plc is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Allergan plc directly, or indirectly through its wholly owned subsidiaries, manufactures, markets, and sells generic drug products, including generic drug products manufactured by Actavis UT, throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel. According to Allergan plc's Form 10-Q, filed November 6, 2015, "Allergan plc is a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of brand name [], medical aesthetics, generic, branded generic, biosimilar and over-the-counter [] pharmaceutical products." Upon information and belief, Allergan plc purposefully has conducted and continues to conduct business in this judicial district.

12. Upon information and belief, Actavis UT, Actavis, Inc., and Allergan plc operate as a single integrated business. Upon information and belief, Allergan plc's Form 10-Q, filed November 6, 2015, and Form 10-K, filed February 18, 2015, indicate that it files a single financial report to the SEC for itself and its subsidiaries. Upon information and belief, Allergan

plc, Actavis UT, and Actavis, Inc. share at least one corporate officer.

13. Actavis knows or should know that Onexton® is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that information is included in Onexton®'s label and prescribing information.

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENT IN SUIT

15. The U.S. Patent and Trademark Office (“PTO”) issued the ’434 patent on October 16, 2012. The ’434 patent claims, *inter alia*, formulations of benzoyl peroxide, including formulations of benzoyl peroxide and clindamycin, and methods of treating acne with such formulations. Plaintiffs hold all substantial rights in the ’434 patent and have the right to sue for infringement thereof. A copy of the ’434 patent is attached hereto as Exhibit A.

16. Dow is the holder of New Drug Application (“NDA”) No. 050819 for Onexton®, which the FDA approved on November 24, 2014. In conjunction with NDA No. 050819, the ’434 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

17. Benzyl peroxide and clindamycin phosphate topical gel (3.75%/1.2%) is sold in the United States under the trademark Onexton®.

ACTAVIS’S INFRINGING ANDA SUBMISSION

18. Upon information and belief, Actavis filed or caused to be filed with the FDA ANDA No. 208757, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

19. Upon information and belief, Actavis’s ANDA No. 208757 seeks FDA approval to sell in the United States Actavis’s generic benzoyl peroxide and clindamycin phosphate

topical gel, intended to be a generic version of Onexton[®].

20. Dow received a letter from Actavis UT dated January 15, 2016, purporting to be a Notice of Certification for ANDA No. 208757 (“Actavis’s notice letter”) under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

21. Actavis’s notice letter alleges that Actavis has submitted to the FDA ANDA No. 208757 seeking FDA approval to sell Actavis’s generic benzoyl peroxide and clindamycin phosphate topical gel, intended to be a generic version of Onexton[®].

22. Actavis’s notice letter provides that any request for confidential access to Actavis’s ANDA No. 208757 should be made to Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

23. Actavis’s notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of valid claims 1, 4-9, 11, 13-19, 22-27, 29, 31-36, 41, 44-49, 51, and 53-58 of the ’434 patent.

24. Upon information and belief, ANDA No. 208757 seeks approval of Actavis’s generic benzoyl peroxide and clindamycin phosphate topical gel that is the same, or substantially the same, as Onexton[®].

25. Upon information and belief, Actavis UT’s actions relating to ANDA No. 208757 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Actavis, Inc. and Allergan plc.

COUNT I AGAINST ACTAVIS

Infringement of the ’434 Patent under § 271(e)(2)

26. Paragraphs 1-25 are incorporated herein as set forth above.

27. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '434 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208757 seeking approval for the commercial marketing of Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '434 patent.

28. Upon information and belief, Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel will, if approved and marketed, infringe at least one claim of the '434 patent.

29. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '434 patent.

COUNT II AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '434 Patent

30. Paragraphs 1-29 are incorporated herein as set forth above.

31. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

32. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

33. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '434 patent, including Actavis's filing of ANDA No. 208757.

34. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '434 patent.

35. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel will constitute infringement of at least one claim of the '434 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Actavis on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '434 patent by submitting or causing to be submitted ANDA No. 208757 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration of the '434 patent;
2. order that that the effective date of any approval by the FDA of Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel be a date that is not earlier than the expiration of the '434 patent, or such later date as the Court may determine;
3. enjoin Actavis from the commercial manufacture, use, import, offer for sale, and/or sale of Actavis's generic benzoyl peroxide and clindamycin phosphate topical gel until expiration of the '434 patent, or such later date as the Court may determine;

4. enjoin Actavis and all persons acting in concert with Actavis from seeking, obtaining, or maintaining approval of Actavis's ANDA No. 208757 until expiration of the '434 patent;

5. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: February 26, 2016

Respectfully submitted,

s/Melissa A. Chuderewicz
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CERTIFICATION OF NON-ARBITRABILITY
PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

s/Melissa A. Chuderewicz

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Dated: February 26, 2016