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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 LLC, TEVA PHARMACEUTICALS
USA, INC. and TEVA PHARMACEUTICAL
INDUSTRIES LTD.,

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. (“Actavis UT”), Actavis LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (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.

4. Upon information and belief, Actavis LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. Upon information and belief, Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 8 Gloria Lane Suite 10, Fairfield, New Jersey 07004.

6. Upon information and belief, Teva Pharmaceutical Industries Ltd. is a publicly-traded company organized and existing under the laws of Israel, having its corporate headquarters at 5 Basel Street P.O. Box 3190 Petach Tikva 4951033, Israel.

7. Upon information and belief, Actavis UT and Actavis LLC are wholly-owned subsidiaries by Teva Pharmaceutical USA, Inc., which is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent Nos. 9,504,704 (“the

'704 patent”) and 9,561,208 (“the ’208 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’ 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%; Eq. 1.2% Base) (“Actavis’ generic benzoyl peroxide and clindamycin phosphate topical gel”).

JURISDICTION AND VENUE

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

10. Upon information and belief, this Court has jurisdiction over Actavis UT. Upon information and belief, Actavis UT is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis UT directly, or indirectly, develops, 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’ 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. Upon information and belief, Actavis UT has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

11. Upon information and belief, this Court has jurisdiction over Actavis LLC. Upon information and belief, Actavis LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products.

Upon information and belief, Actavis LLC directly, or indirectly, develops, manufactures, markets, and sells 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' generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Actavis LLC's principal place of business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Upon information and belief, Actavis LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Upon information and belief, this court has jurisdiction over Teva Pharmaceuticals USA, Inc. Upon information and belief, Teva Pharmaceuticals USA, Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Teva Pharmaceuticals USA, Inc. directly, or indirectly, develops, manufactures, markets, and sells 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' generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Teva Pharmaceuticals USA, Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Teva Pharmaceuticals USA, Inc. operates and maintains branches in Fairfield, New Jersey and Woodcliff, New Jersey. Upon information and belief, Teva Pharmaceuticals USA, Inc. is registered in the State of New Jersey as a "wholesaler" and "manufacturer and wholesales" of drugs, with Registration Nos. 5003436 and 5000583. Upon information and belief, Teva Pharmaceuticals USA, Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting

counterclaims in other civil actions initiated in this jurisdiction.

13. Upon information and belief, this court has jurisdiction over Teva Pharmaceutical Industries Ltd. Upon information and belief, Teva Pharmaceutical Industries Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Teva Pharmaceutical Industries Ltd. directly, or indirectly, develops, manufactures, markets, and sells 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' generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Teva Pharmaceutical Industries Ltd. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Teva Pharmaceuticals Industries Ltd. purposefully has conducted and continues to conduct business in this judicial district.

14. Upon information and belief, Actavis UT, Actavis LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. operate as a single integrated business. Upon information and belief, Actavis UT, Actavis LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

15. Actavis UT 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.

16. 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

17. The PTO issued the '704 patent on November 29, 2016. The '704 patent claims, *inter alia*, formulations of benzoyl peroxide and clindamycin, and methods of treating acne with such formulations. Plaintiffs hold all substantial rights in the '704 patent and have the right to sue for infringement thereof. A copy of the '704 patent is attached hereto as Exhibit A.

18. The PTO issued the '208 patent on February 7, 2017. The '208 patent claims, *inter alia*, formulations of benzoyl peroxide and clindamycin, and methods of treating acne with such formulations. Plaintiffs hold all substantial rights in the '208 patent and have the right to sue for infringement thereof. A copy of the '208 patent is attached hereto as Exhibit B.

19. 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 '208 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

20. Benzoyl peroxide and clindamycin phosphate topical gel (3.75%; Eq. 1.2% Base) is sold in the United States under the trademark Onexton[®].

ACTAVIS' INFRINGING ANDA SUBMISSION

21. 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).

22. Upon information and belief, Actavis' ANDA No. 208757 seeks FDA approval to sell in the United States Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel, intended to be a generic version of Onexton[®].

23. Dow received a letter dated March 7, 2017, from Actavis UT, purporting to be a Notice of Certification for ANDA No. 208757 ("Actavis' 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).

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

25. Actavis' 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 claims 1-14 and 16-18 of the '704 patent and claims 1, 3-8, 10, 12-14, 16 and 17 of the '208 patent.

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

27. 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 LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd..

COUNT I AGAINST ACTAVIS

Infringement of the '704 Patent under § 271(e)(2)

28. Paragraphs 1-27 are incorporated herein as set forth above.

29. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '704 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208757 seeking approval for the commercial marketing of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '704 patent.

30. Upon information and belief, Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel will, if approved and marketed, infringe at least one claim of the '704

patent.

31. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '704 patent.

COUNT II AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '704 Patent

32. Paragraphs 1-31 are incorporated herein as set forth above.

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

34. 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.

35. 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' generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '704 patent, including Actavis' filing of ANDA No. 208757.

36. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '704 patent.

37. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' generic benzoyl peroxide

and clindamycin phosphate topical gel will constitute infringement of at least one claim of the '704 patent.

COUNT III AGAINST ACTAVIS

Infringement of the '208 Patent under § 271(e)(2)

38. Paragraphs 1-37 are incorporated herein as set forth above.

39. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '208 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208757 seeking approval for the commercial marketing of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '208 patent.

40. Upon information and belief, Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel will, if approved and marketed, infringe at least one claim of the '208 patent.

41. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '208 patent.

COUNT IV AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '208 Patent

42. Paragraphs 1-41 are incorporated herein as set forth above.

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

44. 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.

45. 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' generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '208 patent, including Actavis' filing of ANDA No. 208757.

46. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '208 patent.

47. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel will constitute infringement of at least one claim of the '208 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 '704 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' generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration of the '704 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least

one claim of the '208 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' generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration of the '208 patent;

3. order that that the effective date of any approval by the FDA of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel be a date that is not earlier than the expiration of the '704 patent and the '208 patent, or such later date as the Court may determine;

4. enjoin Actavis from the commercial manufacture, use, import, offer for sale, and/or sale of Actavis' generic benzoyl peroxide and clindamycin phosphate topical gel until expiration of the '704 patent and the '208 patent, or such later date as the Court may determine;

5. enjoin Actavis and all persons acting in concert with Actavis from seeking, obtaining, or maintaining approval of Actavis' ANDA No. 208757 until expiration of the '704 patent and the '208 patent;

6. 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;

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

Dated: March 14, 2017
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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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/ William P. Deni, Jr.
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