

**PEPPER HAMILTON, LLP**

301 Carnegie Center

Suite 400

Princeton, NJ 08543-5276

(609) 452-0808

*Attorneys for Plaintiffs*

*DOW PHARMACEUTICAL SCIENCES, INC. and*

*VALEANT PHARMACEUTICALS NORTH AMERICA LLC*

**IN THE UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF NEW JERSEY**

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

Plaintiffs, )

v. )

ACTAVIS, INC., WATSON )  
LABORATORIES, INC., ANDRX CORP. and )  
WATSON PHARMA, INC. )

Defendants.

Civil Action No.:

**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, Inc. (“Actavis”) (formerly Watson Pharmaceuticals, Inc.), Watson Laboratories, Inc. (“Watson Labs.”), Andrx Corporation (“Andrx”) (a wholly-owned subsidiary of Actavis), and Watson Pharma, Inc. (“Watson Pharma”) (collectively “Watson”) allege as follows:

### **THE PARTIES**

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

2. Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 700 Route 202/206 N, Bridgewater, NJ 08807.

3. Upon information and belief, Actavis is a corporation organized and existing under the laws of Nevada, and has a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis resulted from Watson Pharmaceuticals, Inc.'s acquisition of the Swiss-based Actavis Group.

4. Upon information and belief, Watson Labs. is a corporation organized and existing under the laws of the state of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, CA 92880. Upon information and belief, Watson Labs. is a wholly-owned subsidiary of Actavis.

5. Upon information and belief, Andrx is a Delaware corporation. Upon information and belief, Andrx is a wholly-owned subsidiary of Actavis.

6. Upon information and belief, Watson Pharma is a corporation organized and existing under the laws of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Actavis.

### **NATURE OF THE ACTION**

7. This is an action for infringement of United States Patent No. 8,663,699 ("the '699 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 Watson Labs.' 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 generic clindamycin phosphate and benzoyl peroxide gel, 1.2%/2.5%, for topical use (“Watson’s generic clindamycin phosphate and benzoyl peroxide 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. Upon information and belief, Actavis is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Actavis directly 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 Watson’s generic clindamycin phosphate and benzoyl peroxide gel. Upon information and belief, Actavis purposefully has conducted and continues to conduct business in this judicial district.

10. Upon information and belief, this court has jurisdiction over Watson Labs. Upon information and belief, Watson Labs. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Actavis, Watson Pharma and/or Andrx Corp., throughout the United States and in this judicial district. Upon information and belief, Watson Labs. purposefully has conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this Court has jurisdiction over Andrx. Upon information and belief, Andrx directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Actavis, Watson Labs., and/or Watson Pharma, throughout the United States and in this judicial district. Upon information and

belief, Andrx purposefully has conducted and continues to conduct business in this judicial district.

12. Upon information and belief, this Court has jurisdiction over Watson Pharma. Upon information and belief, Watson Pharma directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Actavis, Watson Labs., and/or Andrx Corp., throughout the United States and in this judicial district. Upon information and belief, Watson Pharma purposefully has conducted and continues to conduct business in this judicial district.

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

#### **COUNT FOR PATENT INFRINGEMENT**

14. The U.S. Patent and Trademark Office (“PTO”) issued the ’699 patent on March 4, 2014, and the ’699 patent expires on June 3, 2029. The ’699 patent claims, inter alia, methods of treating acne by topically applying formulations of benzoyl peroxide and clindamycin phosphate. Plaintiffs hold all substantial rights in the ’699 patent and have the right to sue for infringement thereof. A copy of the ’699 patent is attached hereto as Exhibit A.

15. Dow is the holder of New Drug Application (“NDA”) No. 050819 for Acanya<sup>®</sup>, which the FDA approved on October 23, 2008. In conjunction with NDA No. 050819, the ’699 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

16. Clindamycin phosphate and benzoyl peroxide gel, 1.2%/2.5%, is sold in the United States under the trademark Acanya<sup>®</sup>.

17. Upon information and belief, Watson Labs. filed with the FDA ANDA No. 205128, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

18. Upon information and belief, Watson Labs.' ANDA No. 205128 seeks FDA approval to sell in the United States Watson's generic clindamycin phosphate and benzoyl peroxide gel, intended to be a generic version of Acanya<sup>®</sup>.

19. Dow received a letter from Watson Labs. dated March 14, 2014, purporting to be a Notice of Certification for ANDA No. 205128 ("Watson'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).

20. Watson's notice letter alleges that Watson Labs. has submitted to the FDA ANDA No. 205128 seeking FDA approval to sell generic clindamycin phosphate and benzoyl peroxide gel, intended to be a generic version of Acanya<sup>®</sup>.

21. Upon information and belief, ANDA No. 205128 seeks approval of Watson's generic clindamycin phosphate and benzoyl peroxide gel that is the same, or substantially the same, as Acanya<sup>®</sup>.

22. Under 35 U.S.C. § 271(e)(2), Watson Labs. has infringed at least one claim of the '699 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205128 seeking approval for the commercial marketing of Watson's generic clindamycin phosphate and benzoyl peroxide gel before the expiration date of the '699 patent.

23. Upon information and belief, Watson's generic clindamycin phosphate and benzoyl peroxide gel will, if approved and marketed, infringe at least one claim of the '699 patent.

24. Upon information and belief, Watson Labs. will, through the manufacture, use import, offer for sale and/or sale of Watson's generic clindamycin phosphate and benzoyl peroxide gel, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '699 patent.

25. Upon information and belief, Watson Labs.' actions relating to ANDA No. 205128 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Watson Pharmaceuticals, Inc. (now Actavis), Andrx, and Watson Pharma.

**WHEREFORE**, Plaintiffs Dow and Valeant respectfully request that the Court enter judgment in their favor and against Defendants on the patent infringement claim set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Watson has infringed at least one claim of the '699 patent through Watson's submission of ANDA No. 205128 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Watson's generic clindamycin phosphate and benzoyl peroxide gel before the expiration of the '699 patent;
2. order that the effective date of any approval by the FDA of Watson's generic clindamycin phosphate and benzoyl peroxide gel be a date that is not earlier than the expiration of the '699 patent, or such later date as the Court may determine;
3. enjoin Watson from the commercial manufacture, use, import, offer for sale and/or sale of Watson's generic clindamycin phosphate and benzoyl peroxide gel until expiration of the '699 patent, or such later date as the Court may determine;
4. enjoin Watson and all persons acting in concert with Watson from seeking, obtaining or maintaining approval of Watson's ANDA No. 205128 until expiration of the '699 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 attorneys fees;

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

Dated: April 25, 2014

Respectfully submitted,

s/ John F. Brenner  
By: John F. Brenner, Esq.  
**PEPPER HAMILTON LLP**  
Suite 400, 301 Carnegie Center  
Princeton, NJ 08543  
609-951-4193  
brennerj@pepperlaw.com

*Attorneys for Plaintiffs  
Dow Pharmaceutical Sciences, Inc. And Valeant  
Pharmaceuticals North America LLC.*

**Of Counsel:**  
Bryan C. Diner  
Justin J. Hasford  
FINNEGAN, HENDERSON,  
FARABOW, GARRETT & DUNNER, LLP  
901 New York Avenue, NW  
Washington, DC 20001-4413  
(202) 408-4000