

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

DOW PHARMACEUTICAL SCIENCES, )  
INC. and VALEANT PHARMACEUTICALS )  
NORTH AMERICA LLC, )  
)  
Plaintiffs, ) Civil Action No.:  
)  
v. )  
)  
TARO PHARMACEUTICALS U.S.A., INC. )  
and TARO PHARMACEUTICAL )  
INDUSTRIES LTD, )  
  
Defendants.

**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 Taro Pharmaceuticals U.S.A., Inc. (“Taro USA”) and Taro Pharmaceutical Industries Ltd (collectively “Taro”) 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, Taro USA is a New York corporation with a place of business at Five Skyline Drive, Hawthorne, New York 10532.
4. Upon information and belief, Taro Pharmaceutical Industries Ltd is an Israeli corporation with a place of business at 14 Hakitor Street, Haifa Bay, Israel 26110.

**NATURE OF THE ACTION**

5. This is an action for infringement of United States Patent Nos. 8,288,434 (“the ’434 patent”) and 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 Taro’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 generic clindamycin phosphate and benzoyl peroxide gel, 1.2%/2.5%, for topical use (“Taro’s generic clindamycin phosphate and benzoyl peroxide gel”).

**JURISDICTION AND VENUE**

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

7. Upon information and belief, this Court has jurisdiction over Taro USA. Upon information and belief, Taro USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products manufactured by Taro Pharmaceutical Industries Ltd. Upon information and belief, Taro USA directly, or indirectly, manufactures, markets and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Taro USA purposefully has conducted and continues to conduct business in this judicial district.

8. Upon information and belief, this court has jurisdiction over Taro Pharmaceutical Industries Ltd. Upon information and belief, Taro Pharmaceutical Industries Ltd 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 Taro’s generic clindamycin phosphate and benzoyl peroxide gel. Upon information and belief, Taro

Pharmaceutical Industries Ltd purposefully has conducted and continues to conduct business in this judicial district.

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

### **THE PATENTS IN SUIT**

10. 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.

11. The U.S. Patent and Trademark Office (“PTO”) issued the ’699 patent on March 4, 2014. 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 B.

12. 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 ’434 and ’699 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

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

### **TARO’S INFRINGING ANDA SUBMISSION**

14. Upon information and belief, Taro filed or caused to be filed with the FDA ANDA No. 206575, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

15. Upon information and belief, Taro's ANDA No. 206575 seeks FDA approval to sell in the United States Taro's generic clindamycin phosphate and benzoyl peroxide gel, intended to be a generic version of Acanya<sup>®</sup>.

16. Dow received a letter from Taro USA dated June 29, 2014, purporting to be a Notice of Certification for ANDA No. 206575 ("Taro'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).

17. Taro's notice letter alleges that Taro has submitted to the FDA ANDA No. 206575 seeking FDA approval to sell generic clindamycin phosphate and benzoyl peroxide gel, intended to be a generic version of Acanya<sup>®</sup>.

18. Upon information and belief, ANDA No. 206575 seeks approval of Taro's generic clindamycin phosphate and benzoyl peroxide gel that is the same, or substantially the same, as Acanya<sup>®</sup>.

19. Upon information and belief, Taro USA's actions relating to ANDA No. 206575 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Taro Pharmaceutical Industries Ltd.

### **COUNT I**

#### **Infringement of the '434 Patent Under 35 U.S.C. § 271(e)(2)**

20. Paragraphs 1-19 are incorporated herein as set forth above.

21. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '434 patent by submitting or causing to be submitted to the FDA ANDA No. 206575 seeking approval for the commercial marketing of Taro's generic clindamycin phosphate and benzoyl peroxide gel before the expiration date of the '434 patent.

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

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

## COUNT II

### **Infringement of the '699 Patent Under 35 U.S.C. § 271(e)(2)**

24. Paragraphs 1-23 are incorporated herein as set forth above.

25. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '699 patent by submitting or causing to be submitted to the FDA ANDA No. 206575 seeking approval for the commercial marketing of Taro's generic clindamycin phosphate and benzoyl peroxide gel before the expiration date of the '699 patent.

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

27. Upon information and belief, Taro will, through the manufacture, use import, offer for sale and/or sale of Taro'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.

**WHEREFORE**, Plaintiffs Dow and Valeant respectfully request that the Court enter judgment in their favor and against Defendants 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), Defendants have infringed at least one claim of the '434 patent by submitting or causing to be submitted ANDA No. 206575 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or

sale in the United States of Taro's generic clindamycin phosphate and benzoyl peroxide gel before the expiration of the '434 patent;

2. order that the effective date of any approval by the FDA of Taro's generic clindamycin phosphate and benzoyl peroxide 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 Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Taro's generic clindamycin phosphate and benzoyl peroxide gel until expiration of the '434 patent, or such later date as the Court may determine;

4. enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Taro's ANDA No. 206575 until expiration of the '434 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '699 patent by submitting or causing to be submitted ANDA No. 206575 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Taro's generic clindamycin phosphate and benzoyl peroxide gel before the expiration of the '699 patent;

6. order that the effective date of any approval by the FDA of Taro'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;

7. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Taro's generic clindamycin phosphate and benzoyl peroxide gel until expiration of the '699 patent, or such later date as the Court may determine;

8. enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Taro's ANDA No. 206575 until expiration of the '699 patent;

9. 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;

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

Dated: August 13, 2014

Respectfully submitted,

/s/ John F. Brenner

John F. Brenner

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