

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

Plaintiffs,)

v.)

Civil Action No.: _____

TOLMAR, INC.,)

Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Dow Pharmaceutical Sciences, Inc. (“Dow”) and Valeant Pharmaceuticals North America LLC (“Valeant”) (collectively “Plaintiffs”) by way of Complaint against Defendant Tolmar, Inc. (“Tolmar”) 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, CA 94954. Dow is the registered holder of approved New Drug Application No. 050819, which covers Acanya®.

2. Plaintiff 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, Defendant Tolmar is a corporation organized and existing under the laws of Delaware, having a principal place of business at 701 Centre Ave, Fort Collins, CO 80526.

NATURE OF THE ACTION

4. 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 Tolmar’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 (“Tolmar’s generic clindamycin phosphate and benzoyl peroxide gel”).

JURISDICTION AND VENUE

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

6. This Court has jurisdiction over Tolmar. Tolmar is a Delaware corporation. Upon information and belief, Tolmar is in the business of manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Tolmar 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 Tolmar’s generic clindamycin phosphate and benzoyl peroxide gel. Upon information and belief, Tolmar purposefully has conducted and continues to conduct business in this judicial district.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

8. 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, including the right to sue for infringement thereof. Dow is the assignee of the '434 patent. A copy of the '434 patent is attached hereto as Exhibit A.

9. The 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, including the right to sue for infringement thereof. Dow is the assignee of the '699 patent. A copy of the '699 patent is attached hereto as Exhibit B.

10. Dow is the holder of New Drug Application ("NDA") No. 050819 for Acanya[®], which the FDA approved on Oct 23, 2008. In conjunction with NDA No. 050819, the '434 patent and the '699 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

11. Clindamycin phosphate and benzoyl peroxide gel, 1.2%/2.5%, is sold in the United States under the trademark Acanya[®].

TOLMAR'S INFRINGING ANDA SUBMISSION

12. Upon information and belief, Tolmar submitted to the FDA ANDA No. 207194, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

13. Upon information and belief, Tolmar's ANDA No. 207194 seeks FDA approval to sell in the United States Tolmar's generic clindamycin phosphate and benzoyl peroxide gel, intended to be a generic version of Acanya[®].

14. Valeant received a letter from Tolmar dated September 24, 2015, purporting to be a Notice of Certification for ANDA No. 207194 ("Tolmar'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).

15. Tolmar's notice letter alleges that Tolmar has submitted to the FDA ANDA No. 207194 seeking approval to sell generic clindamycin phosphate and benzoyl peroxide gel, intended to be a generic version of Acanya[®].

16. Upon information and belief, ANDA No. 207194 seeks approval of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel that is the same, or substantially the same, as Acanya[®].

COUNT I
Infringement of the '434 Patent under § 271(e)(2)

17. Paragraphs 1-16 are incorporated herein as set forth above.

18. Under 35 U.S.C. § 271(e)(2), Tolmar has infringed at least one claim of the '434 patent by submitting, or causing to be submitted to the FDA, ANDA No. 207194 seeking approval for the commercial marketing of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel before the expiration date of the '434 patent.

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

20. Upon information and belief, Tolmar will, through the manufacture, use import, offer for sale and/or sale of Tolmar'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
Declaratory Judgment of Infringement of the '434 Patent

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

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

23. 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.

24. Tolmar has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Tolmar's generic clindamycin phosphate and benzoyl peroxide gel before the expiration date of the '434 patent, including Tolmar's filing of ANDA No. 207194.

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

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

COUNT III
Infringement of the '699 patent under § 271(e)(2)

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

28. Under 35 U.S.C. § 271(e)(2), Tolmar has infringed at least one claim of the '699 patent by submitting, or causing to be submitted to the FDA, ANDA No. 207194 seeking approval for the commercial marketing of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel before the expiration date of the '699 patent.

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

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

COUNT IV
Declaratory Judgment of Infringement of the '699 Patent

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

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

33. 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.

34. Tolmar has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Tolmar's generic clindamycin phosphate and benzoyl peroxide gel before the expiration date of the '699 patent, including Tolmar's filing of ANDA No. 207194.

35. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '699 patent.

36. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel will constitute infringement of at least one claim of the '699 patent.

PRAYER FOR RELIEF

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

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Tolmar has infringed at least one claim of the '434 patent through Tolmar's submission of ANDA No. 207194 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel before the expiration of the '434 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Tolmar has infringed at least one claim of the '699 patent through Tolmar's submission of ANDA No. 207194 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel before the expiration of the '699 patent;

3. order that the effective date of any approval by the FDA of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel be a date that is not earlier than the expiration of the '434 patent and the '699 patent, or such later date as the Court may determine;

4. enjoin Tolmar from the commercial manufacture, use, import, offer for sale and/or sale of Tolmar's generic clindamycin phosphate and benzoyl peroxide gel until expiration of the '434 patent and the '699 patent, or such later date as the Court may determine;

5. enjoin Tolmar and all persons acting in concert with Tolmar from seeking, obtaining or maintaining approval of Tolmar's ANDA No. 207194 until expiration of the '434 patent and the '699 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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