

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

VALEANT PHARMACEUTICALS
NORTH AMERICA LLC; VALEANT
PHARMACEUTICALS IRELAND LTD.;
DOW PHARMACEUTICAL SCIENCES,
INC.; and KAKEN PHARMACEUTICAL
CO. LTD

Plaintiffs,

v.

KVK-TECH, INC.

Defendant.

Civil Action No. 3:19-12845 (PGS)(LHG)

KVK-TECH, INC'S ANSWER, DEFENSES AND COUNTERCLAIMS

Defendant KVK-Tech, Inc. (“KVK” or “Defendant”) for its answer to the Complaint filed by Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland, LTD., Dow Pharmaceutical Sciences, Inc. and Kaken Pharmaceutical Co., Ltd. (collectively “Plaintiffs”) states as follows:

The Parties

1. KVK lacks knowledge or information sufficient to admit or deny the allegations in paragraph 1 of the Complaint.
2. KVK lacks knowledge or information sufficient to admit or deny the allegations in paragraph 2 of the Complaint.
3. KVK lacks knowledge or information sufficient to admit or deny the allegations in paragraph 3 of the Complaint.

4. KVK lacks knowledge or information sufficient to admit or deny the allegations in paragraph 4 of the Complaint.

5. KVK Admits the allegations in paragraph 5 of the Complaint.

Nature of Action

6. KVK admits that Plaintiffs allege infringement of U.S. Patent No. 10,105,444 (“the ‘444 patent”) under the patent laws of the United States for KVK’s filing with the United States Food and Drug Administration (“FDA”) an Abbreviated New Drug Application (“ANDA”) seeking FDA approval to market its efinaconazole topical solution, 10%.

Jurisdiction and Venue

7. KVK admits that this Court has subject matter jurisdiction over this action.

8. KVK admits that, for the purpose of this action, KVK will not contest that this Court has jurisdiction over KVK, but denies the remaining allegations in paragraph 8 of the Complaint.

9. KVK admits that it has filed an ANDA seeking FDA approval to market its efinaconazole topical solution, 10%, but denies the remaining allegations in paragraph 9 of the Complaint.

10. KVK lacks knowledge or information sufficient to admit or deny the allegations in paragraph 10 of the Complaint.

11. KVK admits that, for the purpose of this action, KVK will not contest venue in this judicial district.

The Patent in Suit

12. KVK admits that the '444 patent issued on October 23, 2018, that the claims of the '444 patent speak for themselves, and that an alleged copy of the '444 patent is attached as Exhibit A to the Complaint, but denies the remaining allegations in paragraph 12 of the Complaint.

13. KVK admits that the Orange Book lists the '444 patent in connection with NDA No. 203567, but lacks knowledge or information sufficient to admit or deny the remaining allegations in paragraph 13 of the Complaint.

14. KVK admits that Jublia is marketed in the U.S. as an efinaconazole topical solution, 10%, but denies the remaining allegations in paragraph 14 of the Complaint.

KVK's Alleged Infringing ANDA Submission

15. KVK admits the allegations in paragraph 15 of the Complaint.

16. KVK admits that KVK submitted ANDA No. 212213 seeking FDA approval to sell efinaconazole topical solution, 10% in the U.S., but denies the remaining allegations in paragraph 16 of the Complaint.

17. KVK admits that the Notice of Certification for ANDA No. 212213 ("KVK Notice Letter") was made pursuant to Section 505(j)(2)(B)(ii)-(iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(iv), and 21 C.F.R. § 314.95(c) that included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), but denies the remaining allegations in paragraph 17 of the Complaint.

18. KVK admits that the KVK Notice Letter indicates that KVK submitted or caused

to be submitted to the FDA ANDA No. 212213 seeking approval of an efinaconazole topical solution, 10%, but denies the remaining allegations in paragraph 18 of the Complaint.

19. KVK admits that ANDA No. 212213 seeks approval of an efinaconazole topical solution, 10%, but denies the remaining allegations in paragraph 19 of the Complaint.

COUNT I

(Alleged Infringement of the ‘444 Patent under §271(e)(2))

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

21. KVK denies the allegations in paragraph 21 of the Complaint.

22. KVK denies the allegations in paragraph 22 of the Complaint.

23. KVK denies the allegations in paragraph 23 of the Complaint.

24. KVK denies the allegations in paragraph 24 of the Complaint.

COUNT II

(Declaratory Judgment of Infringement of the ‘444 Patent)

25. Paragraphs 1 to 24 are incorporated herein as set forth above.

26. KVK admits that Plaintiffs allege that these claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but denies the remaining allegations in paragraph 26 of the Complaint.

27. KVK admits that Plaintiffs allege that 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, but denies the remaining allegations in paragraph 27 of the Complaint.

28. KVK admits that it filed or caused to be filed ANDA No. 212213, but denies the remaining allegations in paragraph 28 of the Complaint.

29. KVK denies the allegations in paragraph 29 of the Complaint.

30. KVK denies the allegations in paragraph 30 of the Complaint.

Answer to Prayer for Relief

KVK denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief.

KVK's Affirmative Defenses

KVK asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs.

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

1. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

(Non-Infringement)

2. ANDA No. 212213, and the making, using or selling of KVK's efinaconazole topical solution, 10%, does not and will not infringe, either directly or indirectly, contributorily, or by inducement, any valid claim of the '444 patent, literally or under the doctrine of equivalence, willfully or otherwise.

THIRD AFFIRMATIVE DEFENSE

(Invalidity)

3. The '444 patent, and each of the claims thereof, are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE

(No Costs)

4. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

COUNTERCLAIMS

KVK, by way of its Counterclaims against Plaintiffs Valeant Pharmaceuticals North America LLC ("Valeant"), Valeant Pharmaceuticals Ireland, LTD. ("Valeant Ireland"), Dow

Pharmaceutical Sciences, Inc. (“Dow”) and Kaken Pharmaceutical Co., Ltd. (“Kaken”), states as follows:

1. KVK repeats and incorporates by reference each of the foregoing paragraphs of KVK’s Answer and Affirmative Defenses to the Complaint.

2. This is an action for a declaratory judgment of invalidity and non-infringement of one or more claims of United States Patent No. 10,105,444 (“the ‘444 patent”).

The Parties

3. KVK is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 110 Terry Drive, Suite 200, Newtown, PA 18940.

4. On information and belief, 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.

5. On information and belief, Valeant Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

6. On information and belief, Dow is a corporation organized and existing under the laws of Delaware having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

7. On information and belief, Kaken is a corporation organized and existing under the laws of Japan having its principal place of business at 20th Floor, Bunkyo Green Court, 28-8,

Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan.

Jurisdiction and Venue

8. This court has original jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, based on an actual controversy between KVK, on the one hand, and Plaintiffs, on the other hand, arising under the patent laws of the United States, 35 U.S.C. § 1 et seq.

9. This court has personal jurisdiction over Plaintiffs based on, *inter alia*, the filing by Plaintiffs of this lawsuit in this jurisdiction.

10. Venue is proper in this judicial district with respect to these counterclaims based on, *inter alia*, the filing by Plaintiffs of this lawsuit in this jurisdiction.

Relevant Facts

11. The United States Patent and Trademark Office (“PTO”) issued the ’444 patent on October 23, 2018, and Plaintiffs claim to hold all substantial rights in the patent.

12. Upon information and belief, Dow is the holder of New Drug Application (“NDA”) No. 203567 for Jublia®, which the FDA approved on June 6, 2014.

13. The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holders believe claim the “drug” for which their NDA is submitted, or patents covering a “method of using such drug.” 21 U.S.C. §§ 355(b)(1) and (c)(2).

14. Upon information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), Plaintiffs

caused the FDA to publish the '444 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," in connection with NDA No. 203567.

15. By maintaining the listing of the '444 patent in the Orange Book, Plaintiffs represents that these patents "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. §355(b)(1)(G).

16. KVK filed ANDA No. 212213 with the FDA seeking approval for efinaconazole topical solution, 10%, and certifying to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), that the product described in ANDA No. 212213 does not infringe any valid claim of the '444 patent, and/or that the claims of this patent are invalid.

17. Pursuant to 21 U.S.C. 355(j)(2)(B), KVK provided notice to Plaintiffs on or about May 13, 2019 of its Paragraph IV certification on the '444 patent with a detailed statement of the factual and legal bases for its Paragraph IV certifications on these patents (the "Notice Letter").

18. Despite the information in the Notice Letter and detailed statement, Plaintiffs filed the present Complaint against KVK, alleging that ANDA No. 212213 infringes the '444 patent.

19. As a result of the foregoing, Plaintiffs do not have any good faith factual basis to allege that KVK's ANDA No. 212213 seeking approval for its efinaconazole topical solution, 10% would infringe any claim of the '444 patent.

COUNT I

**(Declaratory Judgment of Non-Infringement of the
'444 Patent)**

20. KVK repeats and incorporates by reference each of the foregoing paragraphs of KVK's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

21. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court, exists between KVK on the one hand and Plaintiffs on the other concerning the non-infringement of the claims of the '444 patent.

22. Plaintiffs assert that KVK's ANDA No. 212213 will infringe the '444 patent.

23. KVK is entitled to a declaratory judgment that any valid claim of the '444 patent would not be infringed by KVK's ANDA No. 212213 and its efinaconazole topical solution, 10% manufactured pursuant to the specifications in that ANDA upon FDA approval.

COUNT II

(Declaratory Judgment of Invalidity of the '444 Patent)

24. KVK repeats and incorporates by reference each of the foregoing paragraphs of KVK's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

25. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court, exists between KVK on the one hand and Plaintiffs on the other concerning the invalidity of the claims of the '444 patent.

26. Plaintiffs assert that KVK's ANDA No. 212213 infringes the '444 patent.

27. The claims of the '444 patent are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 et seq., including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and 120.

28. KVK is entitled to a declaratory judgment that the claims of the '444 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, KVK prays that judgement be entered in its favor and the Court:

- A. Dismiss Plaintiffs' Complaint with prejudice;
- B. Declare that the KVK ANDA No. 212213 and the efinaconazole topical solution, 10% manufactured pursuant to ANDA No. 212213 will not infringe any valid claim of the '444 patent;
- C. Declare that the '444 patent claims are invalid;
- D. Declare that this case is exceptional;
- E. Award KVK any and all damages, including lost profits;
- F. Award KVK damages and its costs, expenses and reasonable attorneys' fees incurred in this action; and,
- G. Grant such further relief as the Court may deem just and proper.

Date: June 4, 2019

**KLEHR HARRISON HARVEY
BRANZBURG LLP**

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LOCAL CIVIL RULE 11.2 CERTIFICATION

The undersigned, attorney of record for Defendants, hereby certifies that to the best of my knowledge and based upon the information available to me, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding, with the exception that the above-captioned action concerns the same patents that are at issue in the following consolidated action pending in this district before the Honorable Peter G. Sheridan, U.S.D.J.: *In re Jublia, Civil Action No. 18-13635 (CONSOLIDATED)*.

I certify under penalty of perjury that the foregoing is true and correct.

Date: June 4, 2019

/s/ Carol Ann Slocum