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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS NORTH AMERICA LLC; VALEANT PHARMACEUTICALS IRELAND LTD.; DOW PHARMACEUTICAL SCIENCES, INC.; and KAKEN PHARMACEUTICAL CO., LTD., Plaintiffs, v. CIPLA LTD. and CIPLA USA INC., Defendants.	Civil Action No. 19-00988 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals North America LLC ("Valeant"), Valeant Pharmaceuticals Ireland Ltd. ("Valeant Ireland"), Dow Pharmaceutical Sciences, Inc. ("Dow"), and Kaken Pharmaceutical Co., Ltd. ("Kaken") (collectively, "Plaintiffs") by way of this Complaint against Cipla Ltd. ("Cipla India") and Cipla USA Inc. ("Cipla USA") (collectively, "Cipla") allege as follows:

THE PARTIES

1. 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.

2. Plaintiff Valeant Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff 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.

4. Plaintiff 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.

5. Upon information and belief, Cipla India is an Indian corporation having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

6. Upon information and belief, Cipla USA is a Delaware corporation that is establishing its headquarters at 10 Independence Boulevard, Warren NJ 07059.

7. Upon information and belief, Cipla USA is the United States wholly owned subsidiary of Cipla India.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent No. 10,105,444 ("the '444 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 Cipla India'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 its generic efinaconazole topical solution, 10% ("Cipla's generic

efinaconazole topical solution"). [1]

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201-02.

10. Upon information and belief, this Court has jurisdiction over Cipla India. Upon information and belief, Cipla India is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Cipla India 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 Cipla's generic efinaconazole topical solution. Upon information and belief, Cipla India purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Cipla India 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. Cipla India has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the New Jersey and elsewhere. Cipla India's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Cipla India intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market

[1] Plaintiffs previously brought an action for infringement of United States Patent Nos. 7,214,506 ("the '506 patent"), 8,039,494 ("the '494 patent"), 8,486,978 ("the '978 patent"), 9,302,009 ("the '009 patent"), 9,566,272 ("the '272 patent"), 9,662,394 ("the '394 patent"), 9,861,698 ("the '698 patent"), and 9,877,955 ("the '955 patent"). That action is currently pending in this Court as Case No. 3:18-cv-14225 (PGS) (LHG), and Plaintiffs hereby incorporate by reference their Complaint against Cipla (ECF No. 1) in that action.

them. Upon information and belief, Cipla India will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

12. Upon information and belief, this Court has jurisdiction over Cipla USA. Upon information and belief, Cipla USA is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Cipla USA 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 Cipla's generic efinaconazole topical solution. Upon information and belief, Cipla USA purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Cipla USA is establishing its headquarters at 10 Independence Boulevard, Warren NJ 07059. Upon information and belief, Cipla USA 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, Cipla has previously availed itself of this Court by asserting counterclaims in civil actions initiated in this jurisdiction. *See, e.g.*, *Astrazeneca AB et al. v. Cipla Ltd. and Cipla Pharms., Inc.*, No. 1:16-cv-09583, ECF No. 8 (D.N.J. Feb. 3, 2017); *The United States Department of Health and Human Services et al. v. Cipla Ltd. and Cipla Pharms., Inc.*, No. 2:14-cv-5135, ECF No. 6 (D.N.J. Sept. 26, 2014); *Janssen Prods., L.P. et al. v. Cipla Ltd. and Cipla Pharms., Inc.*, No. 2:14-cv-5093, ECF No. 9 (D.N.J. Sept. 10, 2014).

14. Cipla India and Cipla USA know or should know that Julia® is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Julia®.

15. Upon information and belief, venue is proper in this judicial district under

28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

16. Venue is proper against Cipla India, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

17. Venue is proper against Cipla USA because, *inter alia*, it maintains a regular and established place of business in this judicial district.

THE PATENT IN SUIT

18. The United States Patent and Trademark Office ("PTO") issued the '444 patent on October 23, 2018. The '444 patent claims, generally speaking, *inter alia*, pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate and antioxidant. Plaintiffs hold all substantial rights in the '444 patent and have the right to sue for infringement thereof. The '444 patent is valid and enforceable. A copy of the '444 patent is attached hereto as Exhibit A.

19. Dow is the holder of New Drug Application ("NDA") No. 203567 for Jublia®, which the FDA approved on June 6, 2014. In conjunction with NDA No. 203567, the '444 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

20. Efinaconazole topical solution, 10% is sold in the United States under the trademark Jublia®.

CIPLA'S INFRINGING ANDA SUBMISSION

21. Upon information and belief, Cipla India filed or caused to be filed with the FDA ANDA No. 212111, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

22. Upon information and belief, Cipla India's ANDA No. 212111 seeks FDA approval to sell in the United States Cipla's generic efinaconazole topical solution, intended to

be a generic version of Julia®. Upon information and belief, Cipla USA intends to market Cipla's generic efinaconazole topical solution in the United States.

23. Dow received a letter dated December 7, 2018 from Cipla India purporting to be a Notice of Certification for ANDA No. 212111 ("Cipla's notice letter") under Section 505(j)(2)(B)(i)-(iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(i)-(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).

24. Cipla's notice letter alleges that Cipla India has submitted to the FDA ANDA No. 212111 seeking FDA approval to sell Cipla's generic efinaconazole topical solution, intended to be a generic version of Julia®.

25. Upon information and belief, ANDA No. 212111 seeks approval of Cipla's generic efinaconazole topical solution that is the same, or substantially the same, as Julia®.

COUNT I AGAINST CIPLA

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

26. Paragraphs 1-25 are incorporated herein as set forth above.

27. Under 35 U.S.C. § 271(e)(2), Cipla has infringed at least one claim of the '444 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212111 seeking approval for the commercial marketing of Cipla's generic efinaconazole topical solution before the expiration date of the '444 patent.

28. Upon information and belief, Cipla's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '444 patent.

29. Upon information and belief, Cipla will, through the manufacture, use, import, offer for sale, and/or sale of Cipla's generic efinaconazole topical solution, directly infringe,

contributorily infringe, and/or induce infringement of at least one claim of the ’444 patent.

30. If Cipla’s marketing and sale of its generic efinaconazole topical solution prior to the expiration of the ’444 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II AGAINST CIPLA

Declaratory Judgment of Infringement of the ’444 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. Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Cipla’s generic efinaconazole topical solution before the expiration date of the ’444 patent, including Cipla’s filing of ANDA No. 212111.

35. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Cipla’s generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’444 patent.

36. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Cipla’s generic efinaconazole topical solution will constitute infringement of at least one claim of the ’444 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Cipla 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), Cipla has infringed at least one claim of the '444 patent by submitting or causing to be submitted ANDA No. 212111 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Cipla's generic efinaconazole topical solution before the expiration of the '444 patent;

2. order that that the effective date of any approval by the FDA of Cipla's generic efinaconazole topical solution be a date that is not earlier than the expiration of the '444 patent, or such later date as the Court may determine;

3. enjoin Cipla from the commercial manufacture, use, import, offer for sale, and/or sale of Cipla's generic efinaconazole topical solution until expiration of the '444 patent, or such later date as the Court may determine;

4. enjoin Cipla and all persons acting in concert with Cipla from seeking, obtaining, or maintaining approval of Cipla's ANDA No. 212111 until expiration of the '444 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 attorney's fees;

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

Dated: January 23, 2019
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 certify under penalty of perjury that the foregoing is true and correct.

Dated: January 23, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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