

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

FILED

MAR 13 2020

U.S. DISTRICT COURT-WVND
WHEELING, WV 26003

Civil Action No.: 1:20-cv-46

Keeler

BAUSCH HEALTH US, LLC f/k/a VALEANT
PHARMACEUTICALS NORTH AMERICA
LLC; BAUSCH HEALTH IRELAND LIMITED
f/k/a VALEANT PHARMACEUTICALS
IRELAND LTD.; BAUSCH HEALTH
AMERICAS, INC. f/k/a VALEANT
PHARMACEUTICALS INTERNATIONAL
and KAKEN PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health US, LLC (“Bausch,” formerly known as Valeant Pharmaceuticals North America LLC), Bausch Pharmaceuticals Ireland Ltd. (“Bausch Ireland,” formerly known as Valeant Pharmaceuticals Ireland Ltd.), and Bausch Health Americas, Inc. (“Bausch Americas,” formerly known as Valeant Pharmaceuticals International), and Kaken Pharmaceutical Co., Ltd. (“Kaken”) (collectively, “Plaintiffs”) by way of this Complaint against Mylan Pharmaceuticals Inc. (“Mylan”) allege as follows:

THE PARTIES

1. Plaintiff Bausch 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 Bausch 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 Bausch Americas 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, Mylan is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent Nos. 10,512,640 (“the ’640 patent”); 10,342,875 (“the ’875 patent”); and 10,478,601 (“the ’601 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 Mylan’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% (“Mylan’s generic efinaconazole topical solution”).¹

¹ Plaintiffs previously brought actions 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”), 9,877,955 (“the ’955 patent”), and 10,105,444 (“the ’444 patent”). Those actions are currently pending in this Court as Case Nos. 1:18-cv-184-IMK (Lead) and 1:19-cv-37-IMK, and Plaintiffs hereby incorporate by reference their original Complaint against Mylan (ECF No. 1) in the lead action.

JURISDICTION AND VENUE

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

8. Upon information and belief, this Court has jurisdiction over Mylan. Upon information and belief, Mylan is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan 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 Mylan’s generic efinaconazole topical solution. Upon information and belief, Mylan purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Upon information and belief, Mylan 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, including in actions related to the same ANDA at issue in this suit. Mylan’s notice letter invoked the jurisdiction and venue of this judicial district.

9. Mylan 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 Northern District of West Virginia and elsewhere. Mylan’s ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Mylan intends to direct sales of its drugs into the Northern District of West Virginia, among other places, once it has the

requested FDA approval to market them. Upon information and belief, Mylan will engage in marketing of its proposed ANDA products in the Northern District of West Virginia upon approval of its ANDA.

10. Mylan knows or should know that Jublia® is manufactured for Bausch, formerly known as Valeant Pharmaceuticals North America LLC, in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Jublia®.

11. 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

12. The United States Patent and Trademark Office (“PTO”) issued the ’640 patent on December 24, 2019. The ’640 patent claims, generally speaking, *inter alia*, methods of treatment of onychomycosis comprising topically applying pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate and a triazole antifungal agent. Plaintiffs hold all substantial rights in the ’640 patent and have the right to sue for infringement thereof. The ’640 patent is valid and enforceable. A copy of the ’640 patent is attached hereto as Exhibit A.

13. The PTO issued the ’875 patent on July 9, 2019. The ’875 patent claims, generally speaking, *inter alia*, methods of treatment of onychomycosis comprising topically applying pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate, butylated hydroxytoluene (BHT), a salt of ethylenediaminetetraacetic acid (EDTA), citric acid and a triazole antifungal agent. Plaintiffs hold all substantial rights in the ’875 patent and have the right to sue for infringement thereof. The ’875 patent is valid and enforceable. A copy of the ’875 patent is attached hereto as Exhibit B.

14. The PTO issued the '601 patent on November 19, 2019. The '601 patent claims, generally speaking, *inter alia*, drug applicators with specific physical characteristics, and methods of using said applicators to treat, among other diseases, tinea unguium (onychomycosis). Plaintiffs hold all substantial rights in the '601 patent and have the right to sue for infringement thereof. The '601 patent is valid and enforceable. A copy of the '601 patent is attached hereto as Exhibit C.

15. Bausch Americas 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 '640 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

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

MYLAN'S INFRINGING ANDA SUBMISSION

17. Upon information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 212064, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

18. Upon information and belief, Mylan's ANDA No. 212064 seeks FDA approval to sell in the United States Mylan's generic efinaconazole topical solution, intended to be a generic version of Jublia®.

19. Plaintiffs received a letter dated January 28, 2020 from Mylan purporting to be a Notice of Certification for ANDA No. 212064 ("Mylan's notice letter") under Section 505(j)(2)(B)(ii), 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).

20. Mylan's notice letter alleges that Mylan has submitted to the FDA ANDA No. 212064 seeking FDA approval to sell Mylan's generic efinaconazole topical solution, intended to

be a generic version of Jublia®.

21. Upon information and belief, ANDA No. 212064 seeks approval of Mylan's generic efinaconazole topical solution that is the same, or substantially the same, as Jublia®.

COUNT I AGAINST MYLAN

Infringement of the '640 Patent under § 271(e)(2)

22. Paragraphs 1–21 are incorporated herein as set forth above.

23. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '640 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before the expiration date of the '640 patent.

24. Upon information and belief, Mylan'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 '640 patent.

25. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '640 patent.

26. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '640 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II AGAINST MYLAN

Declaratory Judgment of Infringement of the '640 Patent

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

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

2202.

29. 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.

30. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '640 patent, including Mylan's filing of ANDA No. 212064.

31. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '640 patent.

32. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '640 patent.

COUNT III AGAINST MYLAN

Infringement of the '875 Patent under § 271(e)(2)

33. Paragraphs 1–32 are incorporated herein as set forth above.

34. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '875 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before the expiration date of the '875 patent.

35. Upon information and belief, Mylan'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 '875 patent.

36. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '875 patent.

37. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '875 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV AGAINST MYLAN

Declaratory Judgment of Infringement of the '875 Patent

38. Paragraphs 1–37 are incorporated herein as set forth above.

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

40. 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.

41. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '875 patent, including Mylan's filing of ANDA No. 212064.

42. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '875 patent.

43. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical

solution will constitute infringement of at least one claim of the '875 patent.

COUNT V AGAINST MYLAN

Infringement of the '601 Patent under § 271(e)(2)

44. Paragraphs 1–43 are incorporated herein as set forth above.
45. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '601 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before the expiration date of the '601 patent.
46. Upon information and belief, Mylan'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 '601 patent.
47. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '601 patent.
48. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '601 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI AGAINST MYLAN

Declaratory Judgment of Infringement of the '601 Patent

49. Paragraphs 1–48 are incorporated herein as set forth above.
50. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
51. 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.

52. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '601 patent, including Mylan's filing of ANDA No. 212064.

53. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '601 patent.

54. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '601 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Mylan 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), Mylan has infringed at least one claim of the '640 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '640 patent;
2. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '875 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA

to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '875 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '601 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '601 patent;

4. order that the effective date of any approval by the FDA of Mylan's generic efinaconazole topical solution be a date that is not earlier than the expiration of the '640 patent, the '875 patent, and the '601 patent, or such later date as the Court may determine;

5. enjoin Mylan from the commercial manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution until expiration of the '640 patent, the '875 patent, and the '601 patent, or such later date as the Court may determine;

6. enjoin Mylan and all persons acting in concert with Mylan from seeking, obtaining, or maintaining approval of Mylan's ANDA No. 212064 until expiration of the '640 patent, the '875 patent, and the '601 patent;

7. 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; and

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

Dated: March , 2020

Respectfully submitted,

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