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

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.

ALEOR DERMACEUTICALS LTD.,

Defendant.

Civil Action No. 20-2735 (BRM) (LHG)

Document Electronically Filed

**DEFENDANT ALEOR DERMACEUTICALS LTD.'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS'
COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Aleor Dermaceuticals Ltd. (“Defendant” or “Aleor”) for its Answer, Affirmative Defenses and Counterclaims to Plaintiffs, Bausch Health US, LLC f/k/a Valeant Pharmaceuticals North America LLC (“Bausch”), Bausch Health Ireland Limited f/k/a Valeant Pharmaceuticals Ireland Ltd. (“Bausch Ireland”), Bausch Health Americas, Inc. f/k/a Valeant Pharmaceuticals International (“Bausch Americas”) and Kaken Pharmaceutical Co., Ltd.’s (“Kaken”) (collectively, “Plaintiffs”) Complaint for Patent Infringement, states as follows:

All averments not expressly admitted are denied.

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.

Answer: Aleor lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 1 and therefore denies them.

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.

Answer: Aleor lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore denies them.

3. Plaintiff Bausch Americas is a corporation organized and existing under the laws of Delaware, having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

Answer: Aleor lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore denies them.

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.

Answer: Aleor lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore denies them.

5. Upon information and belief, Aleor is an Indian corporation having a principal place of business at 5th Floor, Administrative Building Alembic Limited, Alembic Road, Vadodara, Vadodara, Gujarat, 390003, India.

Answer: Aleor admits that Aleor is an Indian corporation having a principal place of business at 5th Floor, Administrative Building Alembic Limited, Alembic Road, Vadodara 390 003, Gujarat, India.

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 Aleor’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% (“Aleor’s generic efinaconazole topical solution”).¹

Answer: The allegations in paragraph 6 are legal conclusions to which no answer is required.

To the extent an answer is required, Aleor admits that Plaintiffs’ Complaint against Aleor purports to be a civil action alleging 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”) pursuant to Title 35 of the United States Code. Aleor further admits that Aleor submitted Abbreviated New Drug Application (“ANDA”) No. 212027 to the United States Food and Drug Administration (“FDA”) seeking approval to engage in the manufacture, use, sale or offer to sell within, and/or importation into, the United States of efinaconazole topical solution, 10%. Aleor denies that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the efinaconazole topical solution, 10%, that is the subject of ANDA No. 212027 would directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’640, ’875, and ’601 patents. Aleor also denies the allegations in footnote 1 on the basis that Plaintiffs did not assert the ’506 patent against Aleor. *See* consolidated action No. 3:18-cv-13635 ECF No. 92. Aleor incorporates its Answers, Affirmative Defenses, and Counterclaims in that consolidated action. Aleor denies all other allegations in paragraph 6.

¹ A related action against Aleor 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”) is pending in this District. *See* No. 3:18-cv-13954 and consolidated action No. 3:18-cv-13635.

JURISDICTION AND VENUE

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

Answer: The allegations in paragraph 7 are legal conclusions to which no answer is required.

To the extent an answer is required, Aleor does not contest subject matter jurisdiction in this Court solely for purposes of this action and solely as they apply to the proposed product described in ANDA No. 212027. Aleor denies all other allegations in paragraph 7.

8. Upon information and belief, this Court has jurisdiction over Aleor. Upon information and belief, Aleor is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Aleor 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 Aleor's generic efinaconazole topical solution. Upon information and belief, Aleor has a related corporate entity located in New Jersey. Upon information and belief, Aleor purposefully has conducted and continues to conduct business in this judicial district. Aleor 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.

Answer: The allegations in paragraph 8 are legal conclusions to which no answer is required.

To the extent an answer is required, Aleor does not contest personal jurisdiction in this Court solely for purposes of this action and solely as they apply to the proposed product described in ANDA No. 212027. Aleor admits that it has previously been named as a defendant and asserted counterclaims in consolidated case No. 3:18-cv-13635 in the District of New Jersey. Aleor denies all other allegations in paragraph 8.

9. Aleor 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 State of New Jersey and elsewhere. Aleor's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Aleor intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Aleor will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

Answer: The allegations in paragraph 9 are legal conclusions to which no answer is required. To the extent an answer is required, Aleor does not contest personal jurisdiction in this Court solely for purposes of this action and solely as they apply to the proposed product described in ANDA No. 212027. Aleor admits that Aleor submitted ANDA No. 212027 to FDA seeking approval to engage in the manufacture, use, sale or offer to sell within, and/or importation into, the United States of efinaconazole topical solution, 10%. Aleor denies all other allegations in paragraph 9.

10. Aleor 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[®].

Answer: Aleor admits only that the prescribing information for JUBLIA[®] (efinaconazole) topical solution, 10%, revised 09/2016, recites, in part:

Manufactured for: Valeant Pharmaceuticals North America LLC Bridgewater, NJ 08807 USA
Manufactured by: Valeant Pharmaceuticals International, Inc., Laval, Quebec H7L 4A8, Canada

Aleor denies all other allegations in paragraph 10.

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

Answer: The allegations in paragraph 11 are legal conclusions to which no answer is required. To the extent that a response is required, Aleor does not contest venue in this Court solely for purposes of this action and solely as they apply to the proposed product described in ANDA No. 212027. Aleor denies all other allegations in paragraph 11.

12. Venue is proper against Aleor, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

Answer: The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent that a response is required, Aleor does not contest venue in this Court solely for purposes of this action and solely as they apply to the proposed product described in ANDA No. 212027. Aleor denies all other allegations in paragraph 12.

THE PATENT IN SUIT

13. 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.

Answer: Aleor admits that the ’640 patent lists December 24, 2019 as the Date of Patent.

Aleor admits that the ’640 patent lists Bausch Health Ireland Limited as the Assignee. Aleor admits on information and belief that what purports to be a copy of the ’640 patent is attached to the Complaint as Exhibit A. Aleor denies all other allegations in paragraph 13.

14. 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.

Answer: Aleor admits that the ’875 patent lists July 9, 2019 as the Date of Patent. Aleor

admits that the ’875 patent lists Bausch Health Ireland Limited as the Assignee. Aleor admits on information and belief that what purports to be a copy of the ’875 patent is attached to the Complaint as Exhibit B. Aleor denies all other allegations in paragraph 14.

15. 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.

Answer: Aleor admits that the ’601 patent lists November 19, 2019 as the Date of Patent.

Aleor admits that the ’601 patent lists Kaken Pharmaceutical Co Ltd as the Assignee. Aleor admits on information and belief that what purports to be a copy of the ’601 patent is attached to the Complaint as Exhibit C. Aleor denies all other allegations in paragraph 15.

16. 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, ’875 and ’601 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”)

Answer: Aleor admits that New Drug Application (“NDA”) No. 203567 is listed in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”), which lists the ’640, ’875 and ’601 patents in connection with NDA No. 203567. Aleor denies all other allegations in paragraph 16.

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

Answer: Aleor lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 17 and therefore denies them.

ALEOR’S [ALLEGEDLY] INFRINGING ANDA SUBMISSION

18. Upon information and belief, Aleor filed or caused to be filed with the FDA ANDA No. 212027, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

Answer: Aleor admits that Aleor submitted ANDA No. 212027 to FDA under 21 U.S.C. § 355(j) seeking approval to engage in the manufacture, use, sale or offer to sell within, and/or importation into, the United States of efinaconazole topical solution, 10%. Aleor denies all other allegations in paragraph 18.

19. Upon information and belief, Aleor’s ANDA No. 212027 seeks FDA approval to sell in the United States Aleor’s generic efinaconazole topical solution, intended to be a generic version of Jublia[®].

Answer: Aleor admits that Aleor submitted ANDA No. 212027 to FDA seeking approval to engage in the manufacture, use, sale or offer to sell within, and/or importation into, the United States of efinaconazole topical solution, 10%. Aleor denies all other allegations in paragraph 19.

20. Upon information and belief, ANDA No. 212027 seeks approval of Aleor’s generic efinaconazole topical solution that is the same, or substantially the same, as Jublia[®].

Answer: Aleor admits that Aleor submitted ANDA No. 212027 to FDA seeking approval to engage in the manufacture, use, sale or offer to sell within, and/or importation into, the United States of efinaconazole topical solution, 10%. Aleor denies all other allegations in paragraph 20.

COUNT I AGAINST ALEOR

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

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

Answer: Aleor restates and realleges its answers to each of the preceding paragraphs 1-20 as if fully set forth herein.

22. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '640 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '640 patent.

Answer: Denied.

23. Upon information and belief, Aleor'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.

Answer: Denied.

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

Answer: Denied

25. If Aleor'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.

Answer: Denied.

COUNT II AGAINST ALEOR

Declaratory Judgment of Infringement of the '640 Patent

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

Answer: Aleor restates and realleges its answers to each of the preceding paragraphs 1-25 as if fully set forth herein.

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

Answer: The allegations in paragraph 27 are legal conclusions to which no answer is required. To the extent an answer is required, Aleor denies all allegations in paragraph 27.

28. 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.

Answer: The allegations in paragraph 28 are legal conclusions to which no answer is required. To the extent an answer is required, Aleor denies all allegations in paragraph 28.

29. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '640 patent, including Aleor's filing of ANDA No. 212027.

Answer: Denied

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

Answer: Denied

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

Answer: Denied.

COUNT III AGAINST ALEOR

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

32. Paragraphs 1–31 are incorporated herein as set forth above.

Answer: Aleor restates and realleges its answers to each of the preceding paragraphs 1-31 as if fully set forth herein.

33. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '875 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '875 patent.

Answer: Denied

34. Upon information and belief, Aleor'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.

Answer: Denied.

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

Answer: Denied.

36. If Aleor'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.

Answer: Denied.

COUNT IV AGAINST ALEOR

Declaratory Judgment of Infringement of the '875 Patent

37. Paragraphs 1-36 are incorporated herein as set forth above.

Answer: Aleor restates and realleges its answers to each of the preceding paragraphs 1-36 as if fully set forth herein.

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

Answer: The allegations in paragraph 38 are legal conclusions to which no answer is required. To the extent an answer is required, Aleor denies all allegations in paragraph 38.

39. 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.

Answer: The allegations in paragraph 39 are legal conclusions to which no answer is required. To the extent an answer is required, Aleor denies all allegations in paragraph 39.

40. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '875 patent, including Aleor's filing of ANDA No. 212027.

Answer: Denied.

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

Answer: Denied.

42. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aleor's generic efinaconazole topical solution will constitute infringement of at least one claim of the '875 patent.

Answer: Denied.

COUNT V AGAINST ALEOR

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

43. Paragraphs 1-42 are incorporated herein as set forth above.

Answer: Aleor restates and realleges its answers to each of the preceding paragraphs 1-42 as if fully set forth herein.

44. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '601 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '601 patent.

Answer: Denied.

45. Upon information and belief, Aleor'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.

Answer: Denied.

46. Upon information and belief, Aleor will, through the manufacture, use, import, offer for sale, and/or sale of Aleor's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '601 patent.

Answer: Denied.

47. If Aleor'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.

Answer: Denied.

COUNT VI AGAINST ALEOR

Declaratory Judgment of Infringement of the '978 Patent

48. Paragraphs 1-47 are incorporated herein as set forth above.

Answer: Aleor restates and realleges its answers to each of the preceding paragraphs 1-47 as if fully set forth herein.

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

Answer: The allegations in paragraph 49 are legal conclusions to which no answer is required. To the extent an answer is required, Aleor denies all allegations in paragraph 49.

50. 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.

Answer: The allegations in paragraph 50 are legal conclusions to which no answer is required. To the extent an answer is required, Aleor denies all allegations in paragraph 50.

51. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '601 patent, including Aleor's filing of ANDA No. 212027.

Answer: Denied

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

Answer: Denied.

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

Answer: Denied.

PRAYER FOR RELIEF

Aleor specifically denies that Plaintiffs are entitled to the general or specific relief requested against Aleor, or to any relief whatsoever, and pray for judgment in favor of Aleor dismissing this action with prejudice, and awarding Aleor its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Aleor avers and asserts the following Affirmative Defenses to Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE (Noninfringement of U.S. Patent No. 10,512,640)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and or importation into, the United States of the proposed efinaconazole topical solution, 10%, that is the subject of ANDA No. 212027 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '640 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,512,640)

Upon information and belief, the claims of the '640 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,342,875)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and or importation into, the United States of the proposed efinaconazole topical solution, 10%, that is the subject of ANDA No. 212027 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '875 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,342,875)

Upon information and belief, the claims of the '875 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,478,601)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and or importation into, the United States of the proposed efinaconazole topical solution, 10%, that is the subject of ANDA No. 212027 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '601 patent.

**SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,478,601)**

Upon information and belief, the claims of the '601 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

RESERVATION OF DEFENSES

Aleor hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

COUNTERCLAIMS

Aleor Dermaceuticals Ltd. (“Aleor” or “Counterclaimant”), by its attorneys, alleges the following Counterclaims against Bausch Health US, LLC f/k/a Valeant Pharmaceuticals North America LLC (“Bausch”), Bausch Health Ireland Limited f/k/a Valeant Pharmaceuticals Ireland Ltd. (“Bausch Ireland”), Bausch Health Americas, Inc. f/k/a Valeant Pharmaceuticals International (“Bausch Americas”) and Kaken Pharmaceutical Co., Ltd. (“Kaken”) (collectively, “Counterclaim Defendants”).

1. Aleor is an Indian corporation having a principal place of business at 5th Floor, Administrative Building Alembic Limited, Alembic Road, Vadodara 390 003, Gujarat, India.
2. On information and belief, 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.
3. On information and belief, Bausch Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

4. On information and belief, Bausch Americas is a corporation 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, 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.

6. As a consequence of Counterclaim Defendants' Complaint against Aleor, there is now an existing and continuing actual controversy between Counterclaim Defendants and Aleor concerning the alleged infringement and validity of United States Patent Nos. 10,512,640 ("the '640 patent"), 10,342,875 ("the '875 patent"), and 10,478,601 ("the '601 patent")..

7. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 *et seq.*

8. This Court may declare the rights and legal relation of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

9. This Court has personal jurisdiction over Counterclaim Defendants at least because Counterclaim Defendants commenced and continue to maintain this action against Aleor in this district.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II) at least because Counterclaim Defendants commenced and continue to maintain this action against Aleor in this district.

COUNT I
(Declaration of Invalidity of U.S. Patent No. 10,512,640)

11. Aleor repeats and realleges the allegations in paragraphs 1-10 above as though fully set forth herein.

12. By asserting their claim against Aleor for alleged infringement of the claims of the '640 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the claims of the '640 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

13. The claims of the '640 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

COUNT II
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,512,640)

14. Aleor repeats and realleges the allegations in paragraphs 1-13 above as though fully set forth herein.

15. By asserting their claim against Aleor for alleged infringement of the claims of the '640 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the claims of the '640 patent.

16. The manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed efinaconazole topical solution, 10%, that is the subject of ANDA No. 212027 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '640 patent.

COUNT III
(Declaration of Invalidity of U.S. Patent No. 10,342,875)

17. Aleor repeats and realleges the allegations in paragraphs 1-16 above as though fully set forth herein.

18. By asserting their claim against Aleor for alleged infringement of the claims of the '875 patent, Counterclaim Defendants have created a case or controversy regarding the validity of

the claims of the '875 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

19. The claims of the '875 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

COUNT IV
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,342,875)

20. Aleor repeats and realleges the allegations in paragraphs 1-19 above as though fully set forth herein.

21. By asserting their claim against Aleor for alleged infringement of the claims of the '875 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the claims of the '875 patent.

22. The manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed efinaconazole topical solution, 10%, that is the subject of ANDA No. 212027 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '875 patent.

COUNT V
(Declaration of Invalidity of U.S. Patent No. 10,478,601)

23. Aleor repeats and realleges the allegations in paragraphs 1-22 above as though fully set forth herein.

24. By asserting their claim against Aleor for alleged infringement of the claims of the '601 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the claims of the '601 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

25. The claims of the '601 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

COUNT VI
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,478,601)

26. Aleor repeats and realleges the allegations in paragraphs 1-25 above as though fully set forth herein.

27. By asserting their claim against Aleor for alleged infringement of the claims of the '601 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the claims of the '601 patent.

28. The manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed efinaconazole topical solution, 10%, that is the subject of ANDA No. 212027 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '601 patent.

PRAYER FOR RELIEF

WHEREFORE, Aleor respectfully requests the Court to enter judgment against Counterclaim Defendants as follows:

A. A judgment declaring that Aleor has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '640 patent;

B. A declaration that the claims of the '640 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103, and/or 112;

C. A judgment declaring that Aleor has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '875 patent;

D. A declaration that the claims of the '875 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103, and/or 112;

E. A judgment declaring that Aleor has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '601 patent;

F. A declaration that the claims of the '601 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103, and/or 112;

G. A declaration that Counterclaim Defendants take nothing by their Complaint;

H. A dismissal of Counterclaim Defendants' Complaint with prejudice;

I. An award to Aleor of its reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

J. An award of any other and further relief that this Court may deem just and proper.

Dated: April 24, 2020

By: s/Theodora McCormick

Theodora McCormick

Robert Lufrano

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Attorneys for Defendant

Aleor Dermaceuticals Ltd.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, Defendant Aleor Dermaceuticals Ltd., by its undersigned counsel, certifies that, to the best of its knowledge, information, and belief the matter in controversy in this action is related to the following actions in this district:

(1) involving the same Plaintiffs, and ANDA submissions referencing the same Jublia[®] (efinaconazole topical solution 10%) product

- *In re: Jublia*, C.A. No. 18-13635 (BRM) (LHG) (consolidated)

(2) involving the same patents, the same Plaintiffs, and ANDA submissions referencing the same Jublia[®] (efinaconazole topical solution 10%) product in this district

- *Bausch Health US, LLC, et al. v. Aleor Dermaceuticals Ltd.*, No. 20-2735;
- *Bausch Health US, LLC, et al. v. Alkem Laboratories Ltd.*, No. 20-2737;
- *Bausch Health US, LLC, et al. v. Aurobindo Pharma USA Inc., et al.*, No. 20-2738;
- *Bausch Health US, LLC, et al. v. KVK-Tech, Inc.*, No. 20-2742;
- *Bausch Health US, LLC, et al. v. Lupin Ltd., et al.*, No. 20-2744;
- *Bausch Health US, LLC, et al. v. Strides Pharma Inc., et al.*, No. 20-2746;
- *Bausch Health US, LLC, et al. v. Taro Pharmaceuticals U.S.A., Inc., et al.*, No. 20-2747;
- *Bausch Health US, LLC et al v. Mylan Pharmaceuticals Inc. et al.*, No. 20-cv-2749.

Dated: April 24, 2020

By: s/ Theodora McCormick
Theodora McCormick

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Counterclaimant hereby certifies that Counterclaimant seeks primarily declaratory judgment relief. Therefore, this action is not appropriate for compulsory arbitration.

Dated: April 24, 2020

By: s/Theodora McCormick
Theodora McCormick