IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P. and TCD ROYALTY SUB LP,	)	
Plaintiffs,	)	
v.	)	C.A. No._____
LUPIN INC. and LUPIN LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Galderma Laboratories, L.P. ("Galderma") and TCD Royalty Sub LP ("TCD") (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Inc. and Lupin Limited (collectively, "Lupin" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Galderma is a limited partnership registered in the State of Texas, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

2. Plaintiff TCD is a limited partnership organized and existing under the laws of the State of Delaware, having a registered address at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

3. Upon information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 11 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

4. Upon information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, having a principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

5. Upon information and belief, Defendant Lupin Inc. is a generic pharmaceutical company that, in coordination with, and at the direction of, Lupin Limited, develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States. Upon information and belief, Defendant Lupin Inc. is a wholly-owned indirect subsidiary of Defendant Lupin Limited.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent Nos. 7,749,532 ("the '532 patent"); 8,206,740 ("the '740 patent"); 8,394,405 ("the '405 patent"); 8,394,406 ("the '406 patent"); 8,470,364 ("the '364 patent"); and 8,709,478 ("the '478 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

7. This action relates to Lupin Inc.'s submission of Abbreviated New Drug Application No. 216631 ("Lupin's ANDA"), under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking U.S. Food and Drug Administration ("FDA") approval to commercially manufacture, use, import, offer to sell, and/or sell Doxycycline Capsules, 40 mg ("Lupin's ANDA Product"), before the expiration of the patents-in-suit.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Defendants Lupin Inc. and Lupin Limited by virtue of the fact that, *inter alia*, Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to Plaintiffs, including

in the State of Delaware. Defendants state that they intend to engage in the commercial manufacture, use, and/or sale under Lupin's ANDA of Lupin's ANDA Product before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

10. This Court has personal jurisdiction over Defendant Lupin Inc. by virtue of the fact that Lupin Inc. has availed itself of the rights and benefits of Delaware law, including by virtue of its incorporation in Delaware, and has engaged in systematic and continuous contacts with the State of Delaware.

11. This Court also has personal jurisdiction over Defendant Lupin Inc. because, upon information and belief, Lupin Inc., directly or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in the State of Delaware. Upon information and belief, Lupin Inc. has purposefully conducted and continues to conduct business in the State of Delaware, and the State of Delaware is a likely destination of Defendants' generic drug products, including Lupin's ANDA Product.

12. This Court has personal jurisdiction over Defendant Lupin Limited. Upon information and belief, Lupin Limited is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin Limited, directly or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in the State of Delaware. Upon information and belief, Lupin Limited has purposefully conducted and continues to conduct business in the State of Delaware, and the State of Delaware is a likely destination of Defendants' generic drug products, including Lupin's ANDA Product.

13. Upon information and belief, Defendants Lupin Inc. and Lupin Limited hold themselves out as a unitary entity and operate as a single integrated business with respect to the

regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in the State of Delaware.

14. Upon information and belief, Defendants Lupin Inc. and Lupin Limited, together with other Lupin companies (such as Lupin Pharmaceuticals, Inc.), are engaged in the submission and seeking approval of ANDAs for the U.S. market, stating that Lupin entities have "received more than 250 FDA approvals and market[ed] a total of 180 generic products" and describe themselves "as one of the fastest-growing pharmaceutical companies in the U.S." (https://www.lupin.com/US/generics/ (accessed December 3, 2021).)

15. Upon information and belief, Defendants Lupin Inc. and Lupin Limited have participated and collaborated in the preparation, filing, and seeking FDA approval of Lupin's ANDA for Lupin's ANDA Product; continue to participate and collaborate in seeking FDA approval of Lupin's ANDA; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of Lupin's ANDA Product throughout the United States, including in the State of Delaware.

16. This Court also has personal jurisdiction over Defendants Lupin Inc. and Lupin Limited because they have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Novartis Pharmaceuticals Corp. v. Lupin Inc.*, C.A. No. 21-1105-LPS (D. Del.) (D.I. 8); *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A. et al.*, C.A. No. 21-229-LPS (D. Del.) (D.I. 28); *Vifor Fresenius Medical Care Renal Pharma Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 20-911-MN (D. Del.) (D.I. 9); *Otsuka*

Pharm. Co., Ltd. v. Lupin Ltd., et al., C.A. No. 20-1296-LPS (D. Del.) (D.I. 8); and *Ferring Pharm. Inc. v. Lupin Inc., et al.*, C.A. No. 19-913-RGA (D. Del.) (D.I. 18).

17. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

GALDERMA'S ORACEA® PRODUCT AND THE PATENTS-IN-SUIT

18. Plaintiff Galderma holds New Drug Application ("NDA") No. 50-805 on ORACEA® (doxycycline, USP) 40 mg Capsules, and is the exclusive distributor of ORACEA® Capsules in the United States.

19. On July 6, 2010, the '532 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). A copy of the '532 patent is attached as Exhibit A.

20. On June 26, 2012, the '740 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued by the USPTO. A copy of the '740 patent is attached as Exhibit B.

21. On March 12, 2013, the '405 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued by the USPTO. A copy of the '405 patent is attached as Exhibit C.

22. On March 12, 2013, the '406 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued by the USPTO. A copy of the '406 patent is attached as Exhibit D.

23. On June 25, 2013, the '364 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued by the USPTO. A copy of the '364 patent is attached as Exhibit E.

24. On April 29, 2014, the '478 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued by the USPTO. A copy of the '478 patent is attached as Exhibit F.

25. TCD is the owner of each of the patents-in-suit. Galderma has an exclusive license under each of the patents-in-suit.

26. The patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for ORACEA® Capsules, which are sold by Galderma.

LUPIN'S ANDA AND NOTICE LETTER

27. Upon information and belief, Lupin Inc., with the collaboration or assistance of Lupin Limited, submitted Abbreviated New Drug Application No. 216631 to the FDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including a certification with respect to the patents-in-suit under Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Lupin's ANDA Product prior to the expiration of the patents-in-suit.

28. Defendant Lupin Inc. sent a letter to Plaintiffs dated October 21, 2021, representing that it had filed a Paragraph IV Certification in ANDA No. 216631 with respect to the '532, '740, '405, '406, '364, and '478 patents, and that it is seeking approval of Lupin's ANDA Product under ANDA No. 216631 prior to the expiration of those patents ("Lupin's Notice Letter").

29. This action is being commenced by Plaintiffs within 45 days of the receipt of Lupin's Notice Letter.

30. Lupin's Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain Lupin confidential information regarding Lupin's ANDA Product. Counsel for Plaintiffs subsequently negotiated with Lupin in an effort to agree on reasonable terms for Lupin's OCA. The parties were not able to reach an agreement with respect to the reasonable revisions to the terms of Lupin's OCA that Plaintiffs proposed. Further, Plaintiffs would have insufficient time to further evaluate any confidential information that may be produced by Lupin under an OCA.

31. To date, Lupin has not provided Plaintiffs with a copy of any portions of Lupin's ANDA or any information regarding Lupin's ANDA Product, beyond the information that was set forth in Lupin's Notice Letter.

LUPIN'S INFRINGEMENT OF THE PATENTS-IN-SUIT

32. Plaintiffs re-allege paragraphs 1-31 as if fully set forth herein.

33. Lupin has notified Plaintiffs that it seeks FDA approval for its ANDA No. 216631 for Doxycycline Capsules, 40 mg, and that the reference drug is Galderma's ORACEA® (doxycycline) Capsules, 40 mg. Upon information and belief, Lupin has submitted to FDA bioequivalence data between its ANDA Product and Galderma's ORACEA® Product. Upon information and belief, Lupin's ANDA Product meets the limitations of at least Claim 1 of each of the patents-in-suit.

34. By seeking approval of ANDA No. 216631 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Lupin's ANDA Product prior to the expiration of the '532, '740, '405, '406, '364, and '478 patents, Lupin has infringed those patents under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

35. Defendants Lupin Inc. and Lupin Limited are jointly and severally liable for infringement of the '532, '740, '405, '406, '364, and '478 patents under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants Lupin Inc. and Lupin Limited actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of ANDA No. 216631 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Lupin's ANDA Product prior to the expiration of the patents-in-suit.

36. Moreover, if Lupin manufactures, uses, offers for sale, sells, or imports into the United States Lupin's ANDA Product, or induces or contributes to any such conduct, prior to the expiration of the '532, '740, '405, '406, '364, and '478 patents, including any applicable exclusivities or extensions, Lupin would infringe at least Claim 1 of each of those patents under 35 U.S.C. § 271(a), (b), and/or (c), either literally or under the doctrine of equivalents.

37. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 216631 be a date that is not earlier than the expiration dates of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiffs are or become entitled.

38. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

39. Lupin was aware of the patents-in-suit before it filed its ANDA No. 216631. It had no reasonable basis to believe that it did not infringe those patents.

40. Indeed, in previous litigation in this Court (C.A. No. 10-1112-LPS), in which Lupin Limited and Lupin Pharmaceuticals, Inc. were parties, several claims of the '532 patent were held

to be infringed by a Lupin ANDA product and not invalid in a Judgment dated July 18, 2012, which was affirmed by the Court of Appeals for the Federal Circuit on August 7, 2013.

41. This is an exceptional case.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants Lupin Inc. and Lupin Limited have infringed the '532, '740, '405, '406, '364, and '478 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 216631 to the FDA;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Lupin's ANDA No. 216631 will not be earlier than the expiration dates of the '532, '740, '405, '406, '364, and '478 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents-in-suit to which Plaintiffs are or become entitled;

C. An Order adjudging and decreeing that the commercial manufacture, use, offer to sell, or sale of Lupin's ANDA Product in the United States, or importation of that product into the United States, would infringe the '532, '740, '405, '406, '364, and '478 patents under 35 U.S.C. § 271(a), (b) and/or (c);

D. An Order permanently enjoining Defendants Lupin Inc. and Lupin Limited, their directors, officers, agents, attorneys, affiliates, divisions, successors, and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing Lupin's ANDA Product identified in this Complaint, or any product that infringes the '532, '740, '405, '406, '364, and '478 patents, prior to the expiration of the patents-in-suit, including any extensions to which Plaintiffs are or become entitled;

E. That Plaintiffs be awarded damages to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the '532, '740, '405, '406, '364, and '478 patents, prior to the expiration of those patents, and that any such damages be awarded to Plaintiffs, together with prejudgment interest;

F. Declaring that this is an exceptional case and awarding Plaintiffs their reasonable attorneys' fees incurred in prosecuting this action; and

G. Granting such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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