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. _____
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Galderma Laboratories, L.P. ("Galderma") and TCD Royalty Sub LP ("TCD") (collectively, "Plaintiffs"), for their Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL" 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 Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

4. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-377, Road No. 3, Banjara Hills, Hyderabad, 50034, India.

5. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a generic pharmaceutical company that, in coordination with, and at the direction of, Dr. Reddy's Laboratories, Ltd., 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 Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Defendant Dr. Reddy's Laboratories, Ltd.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 7,749,532 ("the '532 patent") and United States Patent No. 8,206,740 ("the '740 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 Dr. Reddy's Laboratories, Inc.'s submission of Abbreviated New Drug Application No. 218034 ("DRL'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 ("DRL'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 DRL by virtue of the fact that, *inter alia*, DRL has committed, aided, abetted, contributed to, or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) in filing its ANDA that has led to foreseeable harm and injury to Plaintiffs, including in the State of Delaware.

10. This Court has personal jurisdiction over DRL because it engaged and continues to engage in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products, throughout the United States, including in the State of Delaware.

11. Upon information and belief, if DRL's ANDA is approved, Defendants will directly or indirectly market and/or sell DRL's ANDA Product within the United States, including in the State of Delaware.

12. Upon information and belief, Dr. Reddy's Laboratories, Ltd. has participated and collaborated with Dr. Reddy's Laboratories, Inc. in the preparation, filing, and seeking FDA approval of DRL's ANDA for DRL's ANDA Product; continues to participate and collaborate in seeking FDA approval of DRL's ANDA; and intends to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of DRL's ANDA Product throughout the United States, including in the State of Delaware.

13. This Court also has personal jurisdiction over DRL by virtue of the fact that DRL has previously consented to personal jurisdiction in this Court (*see e.g.*, *Novartis Pharms. Corp. v. Dr. Reddy's Laboratories, Inc.*, C.A. No. 19-02053 (D. Del. Oct. 29, 2019)) and has previously availed itself of the rights and benefits of Delaware law, including by the assertion of counterclaims in this jurisdiction (*see e.g.*, *Merck Sharp & Dohme Corp. v. Dr. Reddy's Laboratories, Inc.*, C.A.

No. 20-00847 (D. Del. June 24, 2020); *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc.*, C.A. No. 19-02045 (D. Del. Oct. 29, 2019)).

14. Alternatively, if the exercise of personal jurisdiction over Dr. Reddy's Laboratories, Ltd. in this Court is not held to be proper, then, upon information and belief, Dr. Reddy's Laboratories, Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and therefore personal jurisdiction over Dr. Reddy's Laboratories, Ltd. in this Court is proper pursuant to Fed. R. Civ. P. 4(k)(2).

15. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b) because DRL has participated in acts of infringement in this district, including preparation and filing of the DRL ANDA.

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

15. 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.

16. 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.

17. 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.

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

19. 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.

DRL'S ANDA AND NOTICE LETTER

20. Upon information and belief, Dr. Reddy's Laboratories, Inc., with the collaboration and assistance of Dr. Reddy's Laboratories, Ltd., submitted Abbreviated New Drug Application No. 218034 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 DRL's ANDA Product prior to the expiration of the patents-in-suit.

21. On behalf of Defendant Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc. sent a letter to Plaintiffs dated May 18, 2023 representing that it had filed a Paragraph IV Certification in ANDA No. 218034 with respect to the '532 and '740 patents, and that it is seeking approval of DRL's ANDA Product under ANDA No. 218034 prior to the expiration of those patents ("DRL's Notice Letter").

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

23. DRL's Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain DRL confidential information regarding DRL's ANDA Product. Counsel for Plaintiffs subsequently negotiated with DRL in an effort to agree on reasonable terms for DRL's OCA. The parties were not able to reach an agreement with respect to the reasonable revisions to

the terms of DRL's OCA that Plaintiffs proposed. Further, Plaintiffs would have insufficient time to further evaluate any confidential information that may be produced by DRL under an OCA.

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

DRL'S INFRINGEMENT OF THE PATENTS-IN-SUIT

25. Plaintiffs re-allege paragraphs 1-24 as if fully set forth herein.

26. DRL has notified Plaintiffs that it seeks FDA approval for its ANDA No. 218034 for Doxycycline Capsules, 40 mg, and that the reference drug is Galderma's ORACEA® (doxycycline) Capsules, 40 mg. Upon information and belief, DRL has submitted to FDA bioequivalence data between its ANDA Product and Galderma's ORACEA® Product. Upon information and belief, DRL's ANDA Product meets the limitations of at least Claim 1 of each of the patents-in-suit.

27. By seeking approval of ANDA No. 218034 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of DRL's ANDA Product prior to the expiration of the '532 and '740 patents, DRL has infringed those patents under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

28. Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. are jointly and severally liable for infringement of the '532 and '740 patents under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of ANDA No. 218034 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the

United States, or importation into the United States, of DRL's ANDA Product prior to the expiration of the patents-in-suit.

29. Moreover, if DRL manufactures, uses, offers for sale, sells, or imports into the United States DRL's ANDA Product, or induces or contributes to any such conduct, prior to the expiration of the '532 and '740 patents, including any applicable exclusivities or extensions, DRL 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.

30. 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. 218034 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.

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

32. DRL was aware of the patents-in-suit before it filed its ANDA No. 218034. It had no reasonable basis to believe that it did not infringe those patents.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have infringed the '532 and '740 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 218034 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 DRL's ANDA No. 218034 will not be earlier than the expiration dates of

the ’532 and ’740 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 DRL’s ANDA Product in the United States, or importation of that product into the United States, would infringe the ’532, and ’740 patents under 35 U.S.C. § 271(a), (b) and/or (c);

D. An Order permanently enjoining Defendants Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd., 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 DRL’s ANDA Product identified in this Complaint, or any product that infringes the ’532 and ’740 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 and ’740 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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