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. _____
MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Galderma Laboratories, L.P. ("Galderma") and TCD Royalty Sub LP ("TCD") (collectively, "Plaintiffs"), for their Complaint against Defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, "Macleods" 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 Macleods Pharmaceuticals Ltd. ("MPL") is a corporation organized and existing under the laws of India, with a place of business at 304 Atlanta Arcade, Marol Church Rd., Andheri (East), Mumbai, India 400059.

4. Upon information and belief, Defendant Macleods Pharma USA, Inc. ("Macleods USA") is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 103 College Road East, Second Floor, Princeton, New Jersey 08540.

5. Upon information and belief, Macleods USA is a wholly-owned subsidiary of MPL, and is controlled and dominated by MPL.

6. Upon information and belief, Macleods USA is a generic pharmaceutical company that, in coordination with, and at the direction of, MPL, develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

7. Upon information and belief, MPL, acting in concert with Macleods USA, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, Macleods USA is the United States regulatory agent for MPL. On information and belief, as part of these ANDAs, MPL, acting in concert with Macleods USA, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

NATURE OF THE ACTION

8. 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.

9. This action relates to Macleods' submission of Abbreviated New Drug Application No. 210381 ("Macleods' 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 ("Macleods' ANDA Product"), before the expiration of the patents-in-suit.

JURISDICTION AND VENUE

10. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

12. MPL is subject to personal jurisdiction in Delaware, because, among other things, MPL itself, and through its wholly-owned subsidiary, Macleods USA, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, MPL, itself and through its wholly-owned subsidiary, Macleods USA, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, MPL is subject to personal jurisdiction in Delaware because, on information and belief, it controls Macleods USA and therefore the activities of Macleods USA in this jurisdiction are attributed to MPL.

13. This Court has personal jurisdiction over MPL by virtue of the fact that, among other things, MPL 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.

14. Upon information and belief, and consistent with their practice with respect to other generic products, Macleods USA has participated and collaborated with MPL in the preparation, filing, and seeking FDA approval of Macleods' ANDA for Macleods' ANDA Product; continues to participate and collaborate in seeking FDA approval of Macleods' ANDA; and intends to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of Macleods' ANDA Product throughout the United States, including in the State of Delaware.

15. Upon information and belief, following any FDA approval of ANDA No. 210381, MPL and Macleods USA will market, distribute, offer for sale, and sell Macleods' ANDA Product throughout the United States and within Delaware.

16. Further, this Court has personal jurisdiction over Macleods because MPL and Macleods USA regularly engage in patent litigation concerning FDA approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., ZS Pharma, Inc. v. Macleods Pharmaceuticals Ltd. and Macleods Pharma 6 USA, Inc.*, C.A. No. 22-1100-GBW, D.I. 18 (D. Del. Oct. 14, 2022); *Anacor Pharmaceuticals, Inc. v. Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.*, C.A. No. 21-1350-CFC, D.I. 14 (D. Del. Nov. 17, 2021); *Merck Sharp & Dohme Corp. v. Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.*, C.A. No. 19-316-RGA, D.I. 11 (D. Del. Apr. 8, 2019).

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

18. Venue is proper in this district for MPL pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, among other things, MPL is a company organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

19. Venue is proper in this district for Macleods USA pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, among other things, Macleods USA is incorporated in Delaware and Macleods is subject to personal jurisdiction in this judicial district.

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

20. 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.

21. 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.

22. 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.

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

24. 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.

MACLEODS' ANDA AND NOTICE LETTER

25. Upon information and belief, MPL, with the collaboration and assistance of Macleods USA, submitted Abbreviated New Drug Application No. 210381 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 Macleods' ANDA Product prior to the expiration of the patents-in-suit.

26. MPL sent a letter to Plaintiffs dated August 21, 2024 representing that it had filed a Paragraph IV Certification in ANDA No. 210381 with respect to the '532 and '740 patents, and that it is seeking approval of Macleods' ANDA Product under ANDA No. 210381 prior to the expiration of those patents ("Macleods' Notice Letter").

27. This action is being commenced by Plaintiffs within 45 days of the receipt of Macleods' Notice Letter.

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

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

MACLEODS' INFRINGEMENT OF THE PATENTS-IN-SUIT

30. Plaintiffs re-allege paragraphs 1-29 as if fully set forth herein.

31. Macleods has notified Plaintiffs that it seeks FDA approval for its ANDA No. 210381 for Doxycycline Capsules, 40 mg, and that the reference drug is Galderma's ORACEA® (doxycycline) Capsules, 40 mg. Upon information and belief, Macleods has submitted to FDA bioequivalence data between its ANDA Product and Galderma's ORACEA® Product. Upon information and belief, Macleods' ANDA Product meets the limitations of at least Claim 1 of each of the patents-in-suit.

32. By seeking approval of ANDA No. 210381 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Macleods' ANDA Product prior to the expiration of the '532 and '740 patents, Macleods has infringed those patents under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

33. Defendants Macleods USA and MPL 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. 210381 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Macleods' ANDA Product prior to the expiration of the patents-in-suit.

34. Moreover, if Macleods manufactures, uses, offers for sale, sells, or imports into the United States Macleods' 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, Macleods 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.

35. 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. 210381 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.

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

37. Macleods was aware of the patents-in-suit before it filed its ANDA No. 210381. 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 Macleods USA and MPL have infringed the '532 and '740 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210381 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 Macleods' ANDA No. 210381 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 Macleods' 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 Macleods USA and MPL, 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 Macleods' 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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