IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P.; NESTLÉ SKIN HEALTH S.A.; and TCD ROYALTY SUB, LLC, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD.; DR. REDDY'S LABORATORIES, INC.; and PROMIUS PHARMA, LLC, Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Galderma Laboratories, L.P. ("Galderma"), Nestlé Skin Health S.A. ("NSH") and TCD Royalty Sub, LLC ("TCD") (collectively, "Plaintiffs"), for their Complaint against Defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd."), Dr. Reddy's Laboratories, Inc. ("DRL Inc."), and Promius Pharma, LLC ("Promius") (collectively, "DRL" or "Defendants"), hereby allege as follows:

THE PARTIES

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

2. Plaintiff NSH is a "societe anonyme" organized and existing under the laws of Switzerland, having a principal place of business at Avenue Gratta Paille 2, 1018 Lausanne, Switzerland.

3. Plaintiff TCD is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 222 Delaware Avenue, Suite 1200, Wilmington, DE 19801.

4. Upon information and belief, Defendant Promius is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Somerset Corporate Blvd, Bridgewater, New Jersey 08540, and is a wholly-owned subsidiary and agent of Defendants DRL Inc. and DRL Ltd.

5. Upon information and belief, Defendant DRL 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, and is a wholly-owned subsidiary and agent of Defendant DRL Ltd.

6. Upon information and belief, Defendant DRL Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, Telangana, India.

NATURE OF THE ACTION

7. This is a civil action for infringement of United States Patent Nos. 7,211,267 ("the '267 patent"); 7,232,572 ("the '572 patent"); 8,603,506 ("the '506 patent"); 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"). (Exhibits A-I.) 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.

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

10. This Court has personal jurisdiction over Defendants Promius, DRL Inc. and DRL Ltd. 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 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 DRL's New Drug Application ("NDA") No. 208286 of a 40 mg doxycycline capsules product proposed for the indication of "treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients" ("DRL's NDA Product"), before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

11. Upon information and belief, Promius, as a subsidiary and agent of DRL Inc. and DRL Ltd., "focus[es] on [DRL's] U.S. Specialty Business, which is engaged in the development and sales of branded specialty products in the therapeutic areas of dermatology and neurology." Upon information and belief, Promius is the "commercial arm" of DRL Ltd.'s Proprietary Products Group. Upon information and belief, Promius "leverages [DRL Ltd.'s] research, development and manufacturing facilities in Hyderabad, India," including with respect to DRL's NDA No. 208286 and DRL's NDA Product.

12. Upon information and belief, DRL Inc. is the agent for DRL Ltd. for purposes of making regulatory submissions to the United States Food and Drug Administration ("FDA"), including DRL's NDA No. 208286 at issue in this litigation.

13. Upon information and belief, Promius, DRL Inc. and DRL Ltd. have acted in concert with respect to the preparation and filing of NDA No. 208286 for DRL's NDA Product and in preparation to sell the NDA Product in the United States, including in the State of Delaware.

14. Upon information and belief, following approval of NDA No. 208286 by the FDA, Promius will act in concert with DRL Ltd. and DRL Inc. to commercialize DRL's NDA Product throughout the United States, including in the State of Delaware. Upon information and belief, DRL has estimated potential U.S. sales of DRL's NDA Product of $50-75 million in the near term.

15. DRL's infringing activities with respect to its filing of NDA No. 208286 and intent to commercialize DRL's NDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs, including to TCD, a Delaware company located in Wilmington, Delaware.

16. This Court also has personal jurisdiction over Promius by virtue of the fact that, upon information and belief, *inter alia*, it is organized and existing under the laws of the State of Delaware, has availed itself of the rights and benefits of Delaware law, and has engaged in systematic and continuous contacts with the State of Delaware.

17. This Court also has personal jurisdiction over DRL Inc. and DRL Ltd. by virtue of the fact that, upon information and belief, *inter alia*, DRL Inc. and DRL Ltd. have availed themselves of the rights and benefits of Delaware law, and have engaged in systematic and continuous contacts with the State of Delaware.

18. Upon information and belief, DRL Inc. and DRL Ltd., directly or through their subsidiaries, affiliates or agents, develop, formulate, manufacture, market, import and sell pharmaceutical products, including branded drug products and generic drug products, throughout the United States, including in the State of Delaware.

19. Upon information and belief, Promius, on behalf of DRL Inc. and DRL Ltd. as their subsidiary and agent, sells branded dermatologic pharmaceutical products in the United States, including in the State of Delaware, through its sales force including 54 sales

representatives, six regional sales managers and one sales director. Upon information and belief, Promius's sales force targets approximately 8000 physicians in the field of dermatology and is supported by a direct marketing team and a public relations program.

20. Upon information and belief, DRL Ltd. directs the operations, management and activities of Promius and DRL Inc. in the United States. Upon information and belief, DRL Ltd. and Promius share executive officers in common, including Dr. Raghav Chari, who upon information and belief is the Executive Vice President of Proprietary Products of DRL Ltd. and a member of the Management Council of DRL Ltd., and is also the President and Head of Promius.

21. This Court also has personal jurisdiction over Defendants DRL Inc. and DRL Ltd. because they have previously submitted to the jurisdiction of this Court and have affirmatively availed themselves of the legal protections of the State of Delaware, having asserted counterclaims in this jurisdiction. *See Novartis Pharmaceuticals Corp. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 14-157-LPS (D. Del.); *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al*, C.A. No. 15-179-GMS (D. Del.); *Allos Therapeutics, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 14-778-RGA (D. Del.); *Genzyme Corporation et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-1506-GMS (D. Del); *Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 15-306-GMS (D. Del.); *Teijin Ltd. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 13-1780-SLR (D. Del.); and *Pfizer Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 13-989-SLR (D. Del.).

THE PATENTS-IN-SUIT

22. 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.

23. On May 1, 2007, the '267 patent, entitled "Methods of Treating Acne" was duly and legally issued to CollaGenex Pharmaceuticals, Inc. A copy of the '267 patent is attached as Exhibit A.

24. NSH is the current owner of the '267 patent.

25. On June 19, 2007, the '572 patent, entitled "Methods of Treating Rosacea" was duly and legally issued to CollaGenex Pharmaceuticals, Inc. A copy of the '572 patent is attached as Exhibit B.

26. NSH is the current owner of the '572 patent.

27. On December 10, 2013, the '506 patent, entitled "Methods of Treating Acne" was duly and legally issued to Galderma Laboratories, Inc. A copy of the '506 patent is attached as Exhibit C.

28. NSH is the current owner of the '506 patent.

29. On July 6, 2010, the '532 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the '532 patent is attached as Exhibit D.

30. TCD is the current owner of the '532 patent.

31. On June 26, 2012, the '740 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the '740 patent is attached as Exhibit E.

32. TCD is the current owner of the ’740 patent.

33. On March 12, 2013, the ’405 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’405 patent is attached as Exhibit F.

34. TCD is the current owner of the ’405 patent.

35. On March 12, 2013, the ’406 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’406 patent is attached as Exhibit G.

36. TCD is the current owner of the ’406 patent.

37. On June 25, 2013, the ’364 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’364 patent is attached as Exhibit H.

38. TCD is the current owner of the ’364 patent.

39. On April 29, 2014, the ’478 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’478 patent is attached as Exhibit I.

40. TCD is the current owner of the ’478 patent.

41. The patents-in-suit are listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for ORACEA® Capsules.

DRL’S NDA AND NOTICE LETTERS

42. Upon information and belief, DRL Inc., with the collaboration or assistance of Promius and DRL Ltd., submitted NDA No. 208286 to the FDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), including a certification with respect to

the patents-in-suit under § 505(b)(2)(A)(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 NDA Product prior to the expiration of the patents-in-suit.

43. Upon information and belief, DRL has used the name "DFD-09" in public statements to refer to DRL's NDA Product.

44. Upon information and belief, DRL has stated that the proposed labeling for DRL's NDA Product is "similar" to the FDA approved labeling for ORACEA® Capsules.

45. Upon information and belief, DRL has stated that it has successfully completed bioequivalence studies comparing DRL's NDA Product to ORACEA® Capsules.

46. DRL Inc., on behalf of DRL Ltd. sent a letter to Galderma dated June 22, 2015, signed by Lee Banks Esq., Vice President, Intellectual Property, DRL Inc., representing that DRL Ltd. had filed a Paragraph IV Certification in NDA No. 208286 with respect to the '267, '572 and '506 patents (collectively, the "Ashley patents"), and that DRL is seeking approval of its NDA Product under NDA No. 208286 prior to the expiration of those patents ("the Ashley Notice Letter").

47. DRL Inc., on behalf of DRL Ltd. sent a letter to Galderma and TCD dated June 22, 2015, signed by Lee Banks Esq., Vice President, Intellectual Property, DRL Inc., representing that DRL Ltd. had filed a Paragraph IV Certification in NDA No. 208286 with respect to the '532, '740, '405, '406, '364, and '478 patents (collectively, the "Chang patents"), and that DRL is seeking approval of its NDA Product under NDA No. 208286 prior to the expiration of those patents ("the Chang Notice Letter").

48. Galderma received the Ashley Notice Letter on June 25, 2015 via U.S. Certified Mail. Galderma and TCD received the Chang Notice Letter on June 25, 2015 via U.S. Certified mail.

49. This action is being commenced by Plaintiffs within 45 days of the date of the receipt of DRL's Ashley Notice Letter and Chang Notice Letter.

50. Both DRL's Ashley Notice Letter and Chang Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain DRL confidential information regarding the DRL NDA Product. Galderma subsequently, over the course of several weeks, 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 Galderma proposed.

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

DRL'S INFRINGEMENT OF THE PATENTS-IN-SUIT

52. Plaintiffs re-allege paragraphs 1-51 as if fully set forth herein.

53. By seeking approval of their NDA No. 208286 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 NDA Product prior to the expiration of the '267, '572, '506, '532, '740, '405, '406, '364, and '478 patents, Defendants have infringed those patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

54. Defendants Promius, DRL Inc. and DRL Ltd. are jointly and severally liable for infringement of the '267, '572, '506, '532, '740, '405, '406, '364, and '478 patents under 35

U.S.C. § 271(e)(2)(A). Upon information and belief, Promius, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of NDA No. 208286 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 NDA Product prior to the expiration of the patents-in-suit.

55. Moreover, if Defendants manufacture, use, offer for sale, or import into the United States any of the DRL NDA Product, or induce or contribute to any such conduct, prior to the expiration of the '267, '572, '506, '532, '740, '405, '406, '364, and '478 patents, including any applicable exclusivities or extensions, Defendants would infringe the one or more claims of those patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c).

56. 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 the NDA No. 208286 be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiffs become entitled.

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

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants Promius, DRL Inc. and DRL Ltd. have infringed the '267, '572, '506, '532, '740, '405, '406, '364, and '478 patents by submitting NDA No. 208286 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 NDA No. 208286 will not be earlier than the expiration date

of the ’267, ’572, ’506, ’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 permanently enjoining Defendants Promius, DRL Inc. and DRL 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 NDA Product identified in this Complaint, or any product that infringes the ’267, ’572, ’506, ’532, ’740, ’405, ’406, ’364, or ’478 patents, prior to the expiration of the patents-in-suit, including any extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offers 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 ’267, ’572, ’506, ’532, ’740, ’405, ’406, ’364, or ’478 patents, within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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