

**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 and
Counterclaim Defendants,

v.

DR. REDDY’S LABORATORIES, LTD.; DR.
REDDY’S LABORATORIES, INC.; and
PROMIUS PHARMA, LLC,

Defendants and
Counterclaim Plaintiffs,

v.

GALDERMA S.A.,

Counterclaim Defendant.

ANSWER TO COMPLAINT, ADDITIONAL DEFENSES AND COUNTERCLAIMS

Defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd."), Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Promius Pharma, LLC ("Promius") (collectively "DRL" or "Defendants") by their attorneys, as for their answer to the complaint of Galderma Laboratories, L.P. ("Galderma"), Nestlé Skin Health S.A. ("Nestlé") and TCD Royalty Sub, LLC ("TCD") (collectively "Plaintiffs") states as follows:

THE PARTIES

1. Apart from the mailing address alleged in paragraph 1, which, based on information and belief, DRL admits is a known address of Galderma, DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1, and therefore denies them.

2. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore denies them.

3. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3, and therefore denies them.

4. DRL denies that Promius is, in all circumstances, an agent of DRL Inc. and DRL Ltd., and, for purposes of this action, admits the remaining allegations of paragraph 4.

5. DRL denies that DRL Inc. is, in all circumstances, an agent of DRL Ltd., and, for purposes of this action, admits the remaining allegations of paragraph 5.

6. DRL admits the allegations of paragraph 6.

NATURE OF THE ACTION

7. Answering paragraph 7 of the complaint, DRL admits that Plaintiffs purport to allege claims of patent infringement arising 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, in asserting the patents-in-suit (collectively U.S. Patent Nos. 7,211,267; 7,232,572; 8,603,506; 7,749,532; 8,206,740; 8,394,405; 8,394,406; 8,470,364; and 8,709,478), but DRL denies that Plaintiffs have a legally sufficient, valid, or meritorious claim against DRL under those provisions.

JURISDICTION AND VENUE

8. DRL admits that this Court purportedly has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), but DRL denies that Plaintiffs have a valid or meritorious claim against DRL under those provisions.

9. DRL admits the allegations of paragraph 9 as to DRL Inc.; DRL denies that this district is a proper venue for the present dispute with regard to DRL Ltd. or Promius; but DRL does not contest venue in this district for the purposes of this action.

10. Answering paragraph 10 of the complaint, DRL admits that this Court has personal jurisdiction over DRL, Inc.; DRL denies that this Court has personal jurisdiction over DRL Ltd. or Promius, but DRL does not contest personal jurisdiction in this Court for the purposes of this action; DRL admits that it filed NDA No. 208286 with the U.S. Food & Drug Administration (“FDA”), and DRL admits that it is intending to commercialize, manufacture, use, and/or sell the DRL’s NDA Product before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware, following approval of DRL’s NDA Product by the FDA; DRL denies the remaining allegations of paragraph 10.

11. DRL admits that Promius is a subsidiary of DRL Inc. and DRL Ltd., but denies that Promius is an agent of DRL Inc. and DRL Ltd. and thus denies the remaining allegations of paragraph 11.

12. DRL denies that DRL Inc., in all circumstances, is an agent of DRL Ltd., but otherwise admits that DRL Inc. submitted DRL’s NDA No. 208286 to the FDA on behalf of DRL Ltd.

13. DRL denies the allegations in paragraph 13.

14. DRL is without knowledge or information sufficient to form a belief as to the truth of Plaintiffs’ assertion of an estimated potential of U.S. sales of DRL’s NDA Product and whether Promius may have any involvement in any such commercialization, and therefore denies the allegations of paragraph 14.

15. DRL denies the allegations of paragraph 15.

16. DRL admits that Promius is organized and existing under the laws of the State of Delaware. DRL otherwise denies the allegations of paragraph 16, but DRL does not contest personal jurisdiction over Promius for the purposes of this action.

17. DRL denies the allegations of paragraph 17, but DRL does not contest personal jurisdiction over DRL Inc. and DRL Ltd. for the purposes of this action.

18. DRL admits the allegations of paragraph 18 as to DRL Inc., but DRL denies the allegations of paragraph 18 as to DRL Ltd.

19. DRL admits that Promius is a subsidiary of DRL Inc. and DRL Ltd., and DRL admits that Promius sells branded dermatologic pharmaceutical products, but denies that Promius is an agent of DRL Inc. and DRL Ltd. and thus denies the remaining allegations of paragraph 19.

20. DRL denies that DRL Ltd. directs the operations, management and activities of Promius and DRL Inc. in the United States, and thus denies the allegations of paragraph 20.

21. Answering paragraph 21 of the complaint, DRL denies that it can be deemed to have availed itself of the protections afforded by the Court by having asserted compulsory counterclaims in this judicial district in other, unrelated cases; DRL admits that it has asserted compulsory counterclaims in this jurisdiction; and otherwise admits the allegations of paragraph 21.

THE PATENTS-IN-SUIT

22. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22, and therefore denies them.

23. DRL admits the allegations of paragraph 23, but denies that the '267 Patent was duly and legally issued.

24. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24, and therefore denies them.

25. DRL admits the allegations of paragraph 25, but denies that the '572 Patent was duly and legally issued.

26. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26, and therefore denies them.

27. DRL admits the allegations of paragraph 27, but denies that the '506 Patent was duly and legally issued.

28. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28, and therefore denies them.

29. DRL admits the allegations of paragraph 29, but denies that the '532 Patent was duly and legally issued.

30. DRL admits the allegations of paragraph 30 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 30, and therefore denies them.

31. DRL admits the allegations of paragraph 31, but denies that the '740 Patent was duly and legally issued.

32. DRL admits the allegations of paragraph 32 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 32, and therefore denies them.

33. DRL admits the allegations of paragraph 33, but denies that the '405 Patent was duly and legally issued.

34. DRL admits the allegations of paragraph 34 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to

form a belief as to the truth of the remaining allegations of paragraph 34, and therefore denies them.

35. DRL admits the allegations of paragraph 35, but denies that the '406 Patent was duly and legally issued.

36. DRL admits the allegations of paragraph 36 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 36, and therefore denies them.

37. DRL admits the allegations of paragraph 37, but denies that the '364 patent was duly and legally issued.

38. DRL admits the allegations of paragraph 38 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 38, and therefore denies them.

39. DRL admits the allegations of paragraph 39, but denies that the '478 patent was duly and legally issued.

40. DRL admits the allegations of paragraph 40 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 40, and therefore denies them.

41. DRL admits that the patents-in-suit are listed in the Orange Book for ORACEA®, but denies that they were properly listed pursuant to 21 U.S.C. § 355(b)(1) or any attendant FDA regulations.

DRL'S NDA AND NOTICE LETTERS

42. DRL admits that DRL Inc. submitted NDA No. 208286 to the FDA on behalf of DRL Ltd., and DRL admits that it is intending 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 following approval of DRL's NDA Product by the FDA. DRL denies the remaining allegations of paragraph 42.

43. DRL admits the allegations of paragraph 43.

44. DRL denies the allegations of paragraph 44, though DRL admits that ORACEA® is the listed drug which its § 505(b)(2) application references.

45. DRL admits the allegations of paragraph 45 as to studies conducted under fasting conditions.

46. DRL admits the allegations of paragraph 46.

47. DRL admits the allegations of paragraph 47.

48. DRL admits that Galderma received the Ashley and Chang notice letters on June 25, 2015, but denies that TCD received the Chang notice letter on June 25, 2015, as TCD received the Chang notice letter on June 23, 2015.

49. DRL admits the allegations of paragraph 49.

50. DRL admits that the Ashley and Chang notice letters included an OCA, which was conditionally accepted by Galderma in its letter of July 6, 2015. DRL denies that Galderma negotiated with DRL in an effort to agree on reasonable terms for the OCA, and denies the remaining allegations of paragraph 50.

51. DRL admits the allegations of paragraph 51, however, notes that DRL offered reasonable terms under the OCA but Galderma refused to accept those terms.

DRL'S INFRINGEMENT OF THE PATENTS-IN-SUIT

52. DRL repeats and realleges its responses to the preceding allegations as if fully set forth herein.

53. DRL denies the allegations of paragraph 53.

54. DRL admits that DRL Inc. submitted NDA No. 208286 on behalf of DRL Ltd., and DRL admits that it is 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 following approval of DRL's NDA Product by the FDA. DRL denies the remaining allegations of paragraph 54.

55. DRL denies the allegations of paragraph 55.

56. DRL denies the allegations of paragraph 56.

57. DRL denies the allegations of paragraph 57.

ANSWER TO PRAYER FOR RELIEF

DRL denies that Plaintiffs are entitled to any of the judgments and relief prayed for in paragraphs A through E of the complaint.

ADDITIONAL DEFENSES

DRL alleges and asserts the following additional defenses in response to the allegations contained in Plaintiffs' complaint:

First Additional Defense

(Noninfringement)

58. The manufacture, use, offer for sale, sale, or importation of the products described in DRL's NDA No. 208286 do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid claim of any of the patents-in-suit.

Second Additional Defense
(Invalidity Of The Patents-In-Suit)

59. The claims of the patents-in-suit are invalid under Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, and/or for double patenting.

Third Additional Defense
(Collateral Estoppel)

60. The manufacture, use, offer for sale, sale, or importation of the products described in DRL's NDA No. 208286 do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any claim of at least the '267 and '572 Patents under principles of collateral estoppel, based on the construction of the claims of these patents in *Research Found. of State Univ. v. Mylan Pharms., Inc.*, 809 F. Supp. 2d 296, 313-15 (D. Del. Aug. 26, 2011), *aff'd in part, vacated in part, and remanded*, No. 2012-1523, 2013 U.S. App. LEXIS 16284 (Fed. Cir. Aug. 7, 2013) ("the *Research Decision*"), which was litigated to a final judgment adversely to Plaintiffs, as set forth more particularly in the counterclaims that follow.

Fourth Additional Defense
(Prosecution History Estoppel)

61. The claims of the patents-in-suit are so limited as not to cover the manufacture, use, offer for sale, sale, or importation of the products described in DRL's NDA 208286 due to the arguments, statements, representations, and/or amendments made by Plaintiffs to the United States Patent and Trademark Office during the prosecution of the respective applications leading to issuance of each of the patents-in-suit.

Fifth Additional Defense

(Safe Harbor)

62. Manufacturing, using, selling or offering to sell within the United States, or importing into the United States, DRL's NDA Product, solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs, including the submission and prosecution of a New Drug Application under § 505(b)(2), is not an act of infringement under the safe harbor provisions of 35 U.S.C. § 271(e)(1).

Sixth Additional Defense

(Failure To State A Claim Upon Which Relief Can Be Granted)

63. Each of Plaintiffs' allegations of infringement of each of the patents-in-suit under 35 U.S.C. § 271 fails to state a claim upon which relief can be granted.

Seventh Additional Defense

(Failure To Join A Necessary Party)

64. Plaintiffs failed to name Galderma S.A., which, based on information and belief, 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. Galderma S.A., also based on information and belief, is a successor company of Galderma and is now the owner of the patents-in-suit and/or the NDA No. 50-805 on ORACEA®.

RESERVATION OF DEFENSES

65. To the extent not already pled, DRL reserves the right to add additional defenses pending further investigation and discovery.

WHEREFORE, DRL denies that Plaintiffs are entitled to any relief as prayed for in the complaint or otherwise and, accordingly, DRL respectfully prays for entry of judgment:

A. Dismissing Plaintiffs' complaint against DRL with prejudice;

B. Finding that DRL has not infringed and is not infringing upon any valid claim of the patents-in-suit;

C. Finding that each claim of the patents-in-suit asserted against DRL is invalid;

D. Enjoining Plaintiffs and/or any of their successors and attorneys, and all persons in active concert or participation with any of them, from directly or indirectly asserting infringement against, or instituting any further action for infringement of the patents-in-suit against DRL, or any of its customers, agents, successors, and assigns;

E. Finding that this case is exceptional and awarding DRL its reasonable attorney fees, expenses, and costs incurred in connection with this action pursuant to 35 U.S.C. § 285, Fed. R. Civ. P. 11, and/or other applicable law;

F. Assessing the costs of this action against Plaintiffs; and

G. Awarding to DRL such other and further relief as the Court may deem just and proper under the circumstances.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Defendant-Counterclaim Plaintiffs Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively "DRL" or "Counterclaim Plaintiffs") by their attorneys, hereby state their counterclaims for declaratory relief against Plaintiff-Counterclaim Defendants Galderma Laboratories, L.P. ("Galderma"), Nestlé Skin Health S.A. ("Nestlé"), and TCD Royalty Sub, LLC ("TCD"), and Additional Counterclaim Defendant Galderma S.A. ("Galderma S.A.") (collectively "Counterclaim Defendants") as follows:

1. These Counterclaims seek, *inter alia*, a judgment declaring that the claims of U.S. 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”) are invalid and/or not infringed by DRL.

THE PARTIES

2. Counterclaim Plaintiff DRL Ltd. is an Indian corporation, with its principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

3. Counterclaim Plaintiff DRL Inc. is a New Jersey corporation, with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

4. On information and belief, Counterclaim Defendant 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.

5. On information and belief, Additional Counterclaim Defendant Galderma S.A. 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.

6. On information and belief, Counterclaim Defendant Nestlé 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.

7. On information and belief, Counterclaim Defendant 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, Delaware 19801.

NATURE OF THE ACTION

8. This is an action for declaratory judgment of patent noninfringement and invalidity arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, as well as the patent laws, Title 35, United States Code.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over the counterclaims asserted herein pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

10. On July 31, 2015, Plaintiffs-Counterclaim Defendants filed in this Court a complaint for patent infringement, alleging that DRL infringes the patents-in-suit listed in the U.S. Food & Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). By filing this complaint, Plaintiffs-Counterclaim Defendants have consented to the personal jurisdiction of this Court.

11. Upon information and belief, Galderma S.A. exists as a result of the recent acquisition of Galderma by Nestlé. Upon information and belief, Galderma is a predecessor entity to Galderma S.A.

12. Upon information and belief, Galderma S.A. is a subsidiary of Nestlé.

13. Upon information and belief, Galderma S.A. is the alter ego of Galderma, and as such, this Court has personal jurisdiction over Galderma S.A. for the same reasons as it has personal jurisdiction over Galderma.

14. This Court also has personal jurisdiction over Galderma S.A. because, based upon information and belief, it directly or through its subsidiaries, affiliates or agents, develops, formulates, manufactures, markets, imports, and sells pharmaceutical products throughout the United States, including in the State of Delaware.

15. Venue is proper in this district pursuant to 28 U.S.C. § 1391. By filing its Complaint, Plaintiffs-Counterclaim Defendants have consented to venue in this district.

16. Plaintiffs-Counterclaim Defendants, and now including Galderma S.A., by their Orange Book listings and by their Complaint herein, have asserted and continue to assert that DRL is infringing patents listed in the Orange Book. DRL, by notice letters and this answer, has

asserted and continues to assert that it does not infringe these patents and/or that they are invalid. Thus, an actual, concrete, ripe, and justiciable controversy exists between Counterclaim Defendants, on the one hand, and DRL, on the other hand, concerning infringement and validity of the patents-in-suit.

BACKGROUND OF THE PARTIES

17. Galderma is listed in the Orange Book as the alleged holder of NDA No. 050805 for doxycycline capsules, for oral use, in 40mg dosage, which is sold under the trademark ORACEA®.

18. Galderma asserted to the public that, *inter alia*, the patents-in-suit claim the ORACEA® product and/or a method of using such product, and that a claim of infringement can reasonably be made under these patents as these patents are listed in the Orange Book pursuant to 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53.

19. The label for ORACEA®, as provided to the FDA on July 25, 2013 (“ORACEA® label”), recites that ORACEA® is “a tetracycline-class drug indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.”

20. The ORACEA® label recites in section 11, “Description,” that ORACEA® capsules, 40mg, are “filled with two types of doxycycline beads (30 = mg immediate release and 10 mg delayed release) that together provide a dose of 40 mg of anhydrous doxycycline.”

21. The ORACEA® label recites in the “Warnings and Precautions” section that “[b]acterial resistance to tetracyclines may develop in patients using ORACEA®.”

22. The ORACEA® label also lists pseudomembranous colitis in the “Warnings and Precautions” section as a potential issue for a patient or doctor to monitor.

23. The ORACEA® label states in section 6, “Adverse Reactions,” that certain side effects including diarrhea, headaches, and nausea are possible. Such side effects are well known to be common when taking antibiotics.

24. DRL Ltd. is the owner of NDA No. 208286, filed by DRL Inc. on behalf of DRL Ltd. under 21 U.S.C. § 355(b)(2), which seeks approval of the FDA to market a doxycycline capsule, 40mg (“DRL’s NDA Product”). DRL’s NDA Product is also referred to as ZENAVOD™ or DFD-09.

25. ZENAVOD™ is a tetracycline-class drug indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.

26. ZENAVOD™ capsules, 40mg, include modified release beads containing doxycycline hyclate equivalent to 40 mg of doxycycline.

27. DRL’s NDA No. 208286 included a certification by DRL Ltd. with respect to each of the patents-in-suit under 21 U.S.C. § 355(b)(2)(A)(IV) and 21 C.F.R. § 314.50(i)(1)(i)(A)(4), certifying that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell in the United States, or importation into the United States of DRL’s NDA Product.

28. DRL sent a letter to Galderma dated June 22, 2015, advising that DRL Ltd. had filed patent certifications with NDA No. 208286 as to the ‘267, ‘572, and ‘506 Patents (collectively “the Ashley Patents”) that, *inter alia*, the Ashley Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell in the United States, or importation into the United States of DRL’s NDA Product.

29. As of June 22, 2015, Galderma, as Galderma Laboratories, Inc., was the recorded owner of the Ashley Patents in the United States Patent & Trademark Office (USPTO)

assignment database. Upon information and belief, Galderma Laboratories, Inc. was a predecessor to Galderma.

30. Upon information and belief, Nestlé is now the owner of the Ashley Patents, though Nestlé's ownership has not been recorded in the USPTO assignment database.

31. DRL sent a letter to Galderma, TCD, and Supernus Pharmaceuticals, Inc. dated June 22, 2015, advising that DRL Ltd. had filed patent certifications with NDA No. 208286 as to the '532, '740, '405, '406, '364, and '478 Patents (collectively "the Chang Patents") that, *inter alia*, the Chang Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell in the United States, or importation into the United States of DRL's NDA Product.

32. As of June 22, 2015, TCD, via a recent transfer from Supernus Pharmaceuticals, Inc., was the recorded owner of the Chang Patents in the USPTO assignment database.

33. Upon information and belief, Galderma received and reviewed DRL's June 22, 2015 letter, which included the notice of patent certification under 21 U.S.C. § 355(b)(2)(A)(IV) and 21 C.F.R. § 314.50(i)(1)(i)(A)(4), certifying that the Ashley Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell in the United States or importation into the United States of DRL's NDA Product.

34. Upon information and belief, Galderma, TCD, and Supernus Pharmaceuticals, Inc. received and reviewed DRL's June 22, 2015 letter, which included the notice of patent certification under 21 U.S.C. § 355(b)(2)(A)(IV) and 21 C.F.R. § 314.50(i)(1)(i)(A)(4), certifying that the Chang Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell in the United States, or importation into the United States of DRL's NDA Product.

35. DRL's June 22, 2015 letter concerning the Ashley Patents included an Offer of Confidential Access ("OCA").

36. DRL's June 22, 2015 letter concerning the Chang Patents included an OCA.

37. DRL is not licensed to practice medicine in any state of the United States; does not practice medicine anywhere in the United States; and does not treat patients of any kind in the United States.

BACKGROUND OF SKIN CONDITIONS AND
TREATMENT USING TETRACYCLINES

38. DRL incorporates by reference each of the preceding allegations as if fully set forth herein.

39. Rosacea is a common skin condition that includes various symptoms, including papules and pustules.

40. Prior to the earliest priority date of the patents-in-suit, papules and pustules of rosacea were known to be inflammatory in nature.

41. Prior to the earliest priority date of the patents-in-suit, tetracyclines, including doxycycline, were well known antibiotics, and were well known to be effective as anti-inflammatory agents.

42. Prior to the earliest priority date of the patents-in-suit, tetracyclines, including doxycycline, had long been used to treat rosacea and specifically the papules and pustules of rosacea.

43. Prior to the earliest priority date of the patents-in-suit, tetracyclines, including doxycycline, were well known to be effective as anti-inflammatory agents at doses lower than those that were allegedly used for antibiotic therapy.

44. Prior to the earliest priority date of the patents-in-suit, no medical necessity was known to exist for giving antibiotic doses of doxycycline to treat papules and pustules of rosacea. Indeed, just the opposite was true. Advantages of lower doses, such as cost and pill size, in addition to possibly avoiding the known antibiotic-level side effects of that drug and reducing the prospect of creating drug resistant bacteria, were well known, and would provide particular benefit for the long-term treatment of the papules and pustules of rosacea.

45. Prior to the earliest priority date of the patents-in-suit, dermatologists would have been motivated to use, or at least try, lower doses of doxycycline to treat inflammatory conditions like rosacea and its symptoms because they knew doxycycline was effective in treating rosacea, and that doxycycline was active as an anti-inflammatory at almost any level.

46. Prior to the earliest priority date of the patents-in-suit, CollaGenex Pharmaceuticals, Inc. which upon information and belief was, along with the '267, '572, and '506 Patents, acquired by Galderma, knew of both the availability of, and the success achieved by, using 40mg of doxycycline in treating periodontitis, another chronic inflammatory condition involving some of the same underlying mechanisms.

47. PERIOSTAT®, a FDA-approved commercially available 40mg doxycycline dosage form, was owned, manufactured, and sold by CollaGenex prior to the earliest priority date of the patents-in-suit. PERIOSTAT® was marketed by CollaGenex for the treatment of periodontitis.

48. Prior to the earliest priority date of the patents-in-suit, FDA-approved commercially available pharmaceuticals had long been used for indications, treatments, and/or uses other than for those indications and uses for which such pharmaceuticals were approved.

49. Prior to the earliest priority date of the patents-in-suit, dermatologists could have used PERIOSTAT® to treat papules and pustules of rosacea.

50. Prior to the earliest priority date of the patents-in-suit, it was known that PERIOSTAT® had a potential side benefit in that it also improved complexion and acne in patients taking the drug. Indeed, Brian Gallagher, then CollaGenex's Chairman and Chief Executive Officer, publicly stated: "What led us to this discovery was patients with periodontal disease who were coming back to their dentists and saying since they started taking the drug they were noticing their complexion was improving and their acne was improving." (<http://www.bizjournals.com/philadelphia/stories/2002/01/28/story4.html?s=print>)

51. Following these initial reports, CollaGenex then surveyed its 120-member sales force and "found out virtually every person has heard an anecdote from a dentist about a patient whose acne or other skin condition had improved." (*Id.*)

FIRST COUNTERCLAIM

Declaration Of Noninfringement Of The Chang Patents

52. DRL incorporates by reference each of the preceding allegations as if fully set forth herein.

53. Each of the claims of each of the Chang Patents recites two formulations or portions of doxycycline — an immediate release ("IR") formulation or portion and a delayed release ("DR") formulation or portion.

54. Each claim of the Chang Patents requires both IR and DR formulations or portions.

55. Each claim of the Chang Patents requires the amount of IR must exceed the amount of DR.

56. Each claim of the Chang Patents requires the amount of IR must exceed the amount of DR by a ratio of at least 2.33:1.

57. The specification of each of the Chang Patents defines the IR formulation as intending “to release substantially all of the active ingredient on administration with no enhanced, delayed or extended release effect.”

58. Conversely, the specification of each of the Chang Patents describes the DR as, “[u]nlike the [IR] pellet, the second unit delayed-release component has a controlling coat applied to the surface of the pellet such that the release of the drug from the pellet is delayed. This is accomplished by applying a coating of enteric materials.”

59. Enteric materials are defined in the specification of each of the Chang Patents as “polymers that are substantially insoluble in the acidic environment of the stomach, but are predominantly soluble in intestinal fluids at specific pHs.”

60. In a prior case before this Court concerning the patents-in-suit, *Research Found. of State Univ. v. Mylan Pharms., Inc.*, 809 F. Supp. 2d 296, 313-15 (D. Del. Aug. 26, 2011), *aff’d in part, vacated in part, and remanded*, No. 2012-1523, 2013 U.S. App. LEXIS 16284 (Fed. Cir. Aug. 7, 2013) (“the *Research* Decision”), this Court adjudicated the Chang Patents, and in doing so, this Court determined that the claims were valid, since none of the prior art taught the “secret sauce” of the IR/DR ratio claimed throughout the Chang Patents.

61. As set forth in paragraph 26 of DRL’s counterclaims above, DRL’s NDA Product, also referred to as DFD-09 or ZENAVOD™, includes modified release beads containing doxycycline hyclate equivalent to 40 mg of doxycycline.

62. DRL’s NDA Product includes a single form of doxycycline.

63. DRL's NDA Product includes 40mg of doxycycline total, the entirety of which is formulated as modified release beads.

64. DRL's NDA Product includes 40mg of doxycycline total, none of which is formulated for immediate release.

65. All of the beads in DRL's NDA Product, which together contain all of the 40mg doxycycline, include a coating of at least an enteric material.

66. Since DRL's NDA Product does not include an immediate release formulation or portion, and as such, DRL's NDA Product also does not include a majority of the total doxycycline in an immediate release formulation or portion.

67. To the extent there is any immediate release from the modified release beads of DRL's NDA Product, data underlying DRL's NDA No. 208286 shows that such an immediate release constituted less than 20 percent of the total 40mg doxycycline.

68. DRL does not and has not infringed any valid claim of the Chang Patents either directly, contributorily, by way of inducement, literally or under the doctrine of equivalents.

69. Without limiting the generality of the foregoing, if and when DRL's NDA No. 208286 is approved by FDA, DRL will not be directly infringing any valid claim of any of the Chang Patents under 35 U.S.C. § 271(a), will not be actively inducing infringement of any valid claim of any of the Chang Patents under 35 U.S.C. § 271(b), and will not be contributorily infringing any valid claim of any of the Chang Patents pursuant to 35 U.S.C. § 271(c).

70. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201-2202, DRL is entitled to a declaratory judgment that it does not infringe, and has not infringed, any valid claim of the Chang Patents.

SECOND COUNTERCLAIM

Declaration Of Noninfringement Of The '267 And '572 Patents

71. DRL incorporates by reference each of the preceding allegations as if fully set forth herein.

72. Each of the claims of the '267 Patent recites administering a tetracycline in a subantibacterial amount, and each of the claims of the '572 Patent recites administering either a tetracycline or a hydrate of doxycycline in an amount that has substantially no antibiotic activity.

73. The specification of the '267 and '572 Patents considers an "antibiotic dose" to include doses of at least 50mg/day of doxycycline.

74. The specification of the '267 and '572 Patents describes "non-antibiotic doses" of 20mg/twice a day, and 30-60mg/day, which "maintains a concentration in human plasma below the threshold for a significant antibiotic effect."

75. The specification of the '267 and '572 Patents thus describes a 50mg dose of doxycycline as both an antibiotic amount and a nonantibiotic amount.

76. The specification of the '267 and '572 Patents provides an example of an antibiotic dose of doxycycline as 100mg. Each of the claims of the '267 and '572 Patents states that the dose of tetracycline, or hydrate of doxycycline, is 10-80% of an antibiotic dose. Using the example of the specification, 10% of 100mg is 10 mg, which is considered "non-antibiotic" in the specification, but 80% of 100mg is 80mg, which is considered "antibiotic" in the specification.

77. The claim limitations "sub-antibacterial amount" and "substantially no antibiotic activity" in the claims of the '267 and '572 Patents must be construed to mean "an amount that does not significantly inhibit growth of microorganisms."

78. This Court, in the *Research* Decision, construed the claim limitations “sub-antibacterial amount” and “substantially no antibiotic activity” of the ‘267 and ‘572 Patents.

79. This Court, in the *Research* Decision, as affirmed by the Federal Circuit, ruled that the claim limitation “sub-antibacterial amount” should be construed as “an amount that does not significantly inhibit the growth of microorganisms.”

80. This Court, in the *Research* Decision, as affirmed by the Federal Circuit, ruled that the claim limitation of, *inter alia*, “substantially no antibiotic activity,” means “an amount that is effective to treat the papules and pustules of rosacea but does not significantly inhibit the growth of microorganisms, e.g., bacteria.”

81. This Court, in the *Research* Decision, as affirmed by the Federal Circuit, held that Galderma failed to prove that “Mylan’s ANDA product does not significantly inhibit the growth of microorganisms,” and further found to the contrary, noting that “*in vivo* studies show that 40 mg doxycycline administered once-daily **does** significantly inhibit the growth of some microorganisms in some locations of some humans at some times.” (Emphasis in original.)

82. This Court further determined that, in light of these studies, the ORACEA® product itself, and the earlier PERIOSTAT® product (as potential invalidating prior art), are also not encompassed by the claims of the ‘267 and ‘572 Patents.

83. As with Mylan’s product, both ORACEA® and PERIOSTAT® have *some* antibiotic activity for some period of time somewhere in the body following administration.

84. This Court also noted, in the *Research* Decision, that “it may be impossible to prove infringement of a claim that requires no significant inhibition in the growth of any [bacterial cells].”

85. In light of the *Research* Decision, the doctrine of collateral estoppel applies here as to DRL's NDA Product and precludes a finding of infringement.

86. The doctrine of collateral estoppel applies where: (1) the issue was identical to one decided in an earlier action; (2) the issue was actually litigated in the earlier action; (3) resolution of the issue was essential to a final judgment on the merits; and (4) the plaintiff had a full and fair opportunity to litigate the issue in the earlier action.

87. The claim elements at issue in the *Research* Decision are the same as are at issue here as to DRL's NDA Product.

88. The issues in the *Research* Decision were actually litigated, including an appeal to the Court of Appeals for the Federal Circuit.

89. The determination of claim construction as to "sub-antibacterial amount" and "substantially no antibiotic activity" was essential to the final ruling of noninfringement.

90. Galderma had a full and fair opportunity to litigate these claim construction determinations, and the resulting final ruling of noninfringement, in the earlier action.

91. The doctrine of collateral estoppel also applies to Galderma S.A. and Nestlé, as successors-in-interest.

92. DRL's NDA Product is also a once-a-day 40 mg dose of doxycycline, like ORACEA®, PERIOSTAT® and Mylan's accused product from the *Research* Decision.

93. Since none of ORACEA®, PERIOSTAT® and Mylan's accused product from the *Research* Decision met the claim elements "sub-antibacterial amount" and "substantially no antibiotic activity" as construed in the *Research* Decision, neither can DRL's NDA Product.

94. The application of collateral estoppel to the claim construction of “sub-antibacterial amount” and “substantially no antibiotic activity” in the *Research* Decision requires a finding of noninfringement in this case as to both the ‘267 and ‘572 Patents.

95. Without limiting the foregoing, if and when DRL’s NDA No. 208286 is approved by FDA, DRL will not be directly infringing any valid claim of any of the Ashley Patents under 35 U.S.C. § 271(a), will not be actively inducing infringement of any valid claim of any of the Ashley Patents under 35 U.S.C. § 271(b), and will not be contributorily infringing any valid claim of any of the Ashley Patents pursuant to 35 U.S.C. § 271(c).

96. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201-2202, DRL is entitled to a declaratory judgment that it does not infringe, and has not infringed, any valid claim of the ‘267 and ‘572 Patents.

THIRD COUNTERCLAIM

Declaration Of Invalidity Of The Patents-In-Suit

97. DRL incorporates by reference each of the preceding allegations as if fully set forth herein.

98. One or more claims of each of the patents-in-suit are invalid for failure to comply with one or more provisions of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, including without limitation 35 U.S.C. §§ 101, 102, 103, and/or 112.

99. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201-2202, DRL is entitled to a declaratory judgment that one or more claims of each of the patents-in-suit are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. pray for the following relief:

A. Dismissal of the complaint with prejudice, granting DRL's additional defenses and DRL's counterclaims and denying each request for relief made by Plaintiffs;

B. A declaration that:

1. no valid claim of the patents-in-suit is infringed by DRL;
2. each of the claims of the patents-in-suit are invalid;
3. Plaintiffs shall obtain no relief from the allegations in their complaint, and the complaint is dismissed with prejudice;

C. An injunction preventing Plaintiffs and Counterclaim Defendants and/or any of their successors and attorneys, and all persons in active concert or participation with any of them, from directly or indirectly asserting infringement against, or instituting any further action for infringement of the patents-in-suit against DRL, or any of its customers, agents, successors, and assigns;

D. An award to DRL of its reasonable attorney fees and costs pursuant to 35 U.S.C. § 285, Fed. R. Civ. P. 11, and/or other applicable law;

E. Assessing the costs of this action against Counterclaim Defendants; and

F. Such other and further relief that this Court deems just and proper.

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