THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES, INC.; GALDERMA LABORATORIES, L.P.; and SUPERNUS PHARMACEUTICALS, Plaintiffs v. MYLAN PHARMACEUTICALS INC., Defendants. MYLAN PHARMACEUTICALS INC., Plaintiffs v. THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES, INC.; GALDERMA LABORATORIES, L.P.; and SUPERNUS PHARMACEUTICALS, Defendants.

Civ. No. 09-184-LPS,Civ. No. 10-892-LPS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

809 F. Supp. 2d 296*; *2011 U.S. Dist. LEXIS 96181

August 26, 2011, Decided
August 26, 2011, Filed

SUBSEQUENT HISTORY: Findings of fact/conclusions of law at *Research Found. of State Univ. of N.Y. v. Mylan Pharms. Inc., 2012 U.S. Dist. LEXIS 80737 (D. Del., May 16, 2012)*
Affirmed in part and vacated in part by, Remanded by *Research Found. of State Univ. of N.Y. v. Mylan Pharms. Inc., 2013 U.S. App. LEXIS 16284 (Fed. Cir., Aug. 7, 2013)*

PRIOR HISTORY: *Mylan Pharms., Inc. v. Galderma Labs., Inc., 2011 U.S. Dist. LEXIS 30555 (D. Del., Mar. 24, 2011)*

COUNSEL: [1]** For Research Foundation of State University of New York, Galderma Laboratories Inc. (1:09-cv-00184-LPS), Plaintiffs: Jack B. Blumenfeld, LEAD ATTORNEY, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE; Gerald J. Flattmann , Jr., PRO HAC VICE.

For New York University, Galderma Laboratories LP, Plaintiffs: Jack B. Blumenfeld, LEAD ATTORNEY, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE.

For Mylan Pharmaceuticals Inc., Defendant: Richard L. Horwitz, LEAD ATTORNEY, David Ellis Moore, Potter Anderson & Corroon, LLP, Wilmington, DE; Lorelei Westin, Michael D Nguyen, PRO HAC VICE.

For Mylan Pharmaceuticals Inc., Counter Claimant: Richard L. Horwitz, LEAD ATTORNEY, David Ellis Moore, Potter Anderson & Corroon, LLP, Wilmington, DE.

For Mylan Pharmaceuticals Inc. (1:10-cv-00892-LPS), Plaintiff: Richard L. Horwitz, LEAD ATTORNEY, David Ellis Moore, Potter Anderson & Corroon, LLP, Wilmington, DE; David S. Steuer, Kirin K. Gill, Lorelei P Westin, Matthew R. Reed, Michael D Nguyen, Tung-On Kong, PRO HAC VICE.

For Galderma Laboratories Inc., Galderma Laboratories LP, Supernus Pharmaceuticals Inc., Defendants: Jack B. Blumenfeld, Maryellen Noreika, Morris, Nichols, Arsht & Tunnell, Wilmington, **[**2]** DE.

For Galderma Laboratories LP, Galderma Laboratories Inc., Supernus Pharmaceuticals Inc., Counter Claimants:

Maryellen Noreika, Morris, Nichols, Arsht & Tunnell, Wilmington, DE.

For Mylan Pharmaceuticals Inc., Counter Defendant: Richard L. Horwitz, LEAD ATTORNEY, David Ellis Moore, Potter Anderson & Corroon, LLP, Wilmington, DE.

JUDGES: Leonard P. Stark, U.S. District Judge.

OPINION BY: Leonard P. Stark

OPINION

[*298] Stark, U.S. District Judge:

In July 2011, the Court held a four-day bench trial in this patent infringement action brought pursuant to the Hatch-Waxman Act. The case arises from Defendant's efforts to bring to market a generic version of Plaintiffs' Oracea® drug product, a once-daily 40 milligram (mg) administration of doxycycline indicated for the treatment of acne rosacea. Plaintiffs assert that claims of five separate patents are infringed. Defendants contend that all five patents are invalid. [1] As explained below, the Court concludes that the asserted claims of one patent-in-suit are infringed and valid. The preliminary injunction entered in July 2010 will remain in effect pending the Court's receipt and review of supplemental briefing as to an appropriate permanent remedy. [2]

1 There are five patents-in-suit. **[**3]** The "Ashley Patents" are *U.S. Patent No. 7,211,267* ("the *'267 patent*") (PTX 1) and *U.S. Patent No. 7,232,572* ("the *'572 patent*") (PTX 2). The "Amin Patents" are *U.S. Patent No. 5,789,395* ("the *'395 patent*") (PTX 3) and *U.S. Patent No. 5,919,775* ("the *'775 patent*") (PTX 4). Finally, the "Chang Patent" is *U.S. Patent No. 7,749,532* ("the *'532 patent*"). (PTX 5)

2 This opinion constitutes the Court's findings of fact and conclusions of law pursuant to *Fed. R. Civ. Proc. 52(a)*.

FINDINGS OF FACT

I. PARTIES

1. Plaintiff The Research Foundation of State University of New York ("RF SUNY") is a private, non-profit corporation organized and existing under the laws of the State of New York, having a principal place of business in Albany, New York. (Statement of Uncontested Facts (C.A. 09-184-LPS D.I. 257-1 [3]) ("SUF") ¶ 1)

3 All citations to Docket Index ("D.I.") entries are to C.A. 09-184-LPS, unless otherwise noted.

2. Plaintiff New York University ("NYU") is a private, non-profit corporation organized and existing under the laws of the State of New York, having a place of business in New York, New York. (SUF ¶ 2)

3. Plaintiff Galderma Laboratories Inc. ("GLI") is a corporation organized and existing **[*299]** under **[**4]** the laws of the State of Delaware, having a principal place of business in Fort Worth, Texas. (SUF ¶ 3)

4. Plaintiff Galderma Laboratories, L.P. ("GLLP") is a privately held partnership registered in the State of Texas, having a principal place of business in Fort Worth, Texas. (SUF ¶ 4)

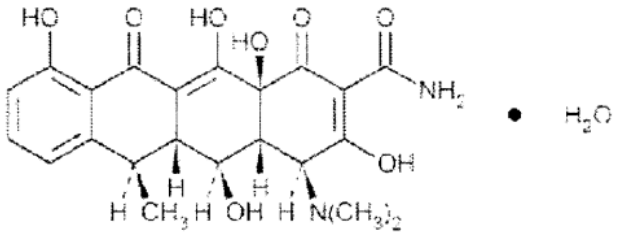
5. Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in Rockville, Maryland. (SUF ¶ 5) [4]

4 Plaintiffs RF, SUNY, NYU, GLI, GLLP, and Supernus are referred to collectively throughout this Opinion as "Plaintiffs" or "Galderma."

6. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business in Morgantown, West Virginia. (SUF ¶ 6)

II. DOXYCYCLINE

7. The structural formula of doxycycline monohydrate is:



(SUF ¶ 41)

8. Doxycycline is a member of the tetracycline class of antibacterial drugs. (SUF ¶ 42)

9. Doxycycline is an antibiotic tetracycline compound. (SUF ¶ 44)

10. There are two general categories of antibiotics: bacteriostatic agents, which inhibit bacterial growth; and bactericidal **[**5]** agents, which kill bacteria. (SUF ¶ 45)

11. Generic doxycycline is commercially available in at least 50 mg, 75 mg, 100 mg, 150 mg, and 200 mg dosage forms. (SUF ¶ 46)

12. Periostat® is a 20 mg dose of doxycycline administered twice-daily to a human and is indicated for treatment of periodontal disease. (SUF ¶ 47)

13. According to its approved label, Periostat® has a steady state C_{max} of 0.790 µg/ml. (SUF ¶ 48)

III. ROSACEA AND ITS TREATMENT

14. Rosacea is a long-lasting, chronic inflammatory disorder. (Tr. 71) [5]

5 The trial transcript is docketed at D.I. 270, 271, 272, and 273. All references to the trial transcript are in the format "Tr." followed by the page number.

15. Historically, rosacea has been treated by oral administration of antibiotics in antibiotic dosages and/or administration of topical gels and creams to treat the signs and symptoms of the disease. (PTX 209 at 1249; Tr. 75, 534-36)

16. The most common oral treatments for rosacea prior to the launch of Oracea® were antibiotic doses of tetracyclines. (PTX 209 at 1249; Tr. 534-36)

[*300] IV. Oracea®

17. Plaintiff GLLP currently holds New Drug Application ("NDA") 50-805 on Oracea® brand doxycycline capsules ("Oracea®"), which was approved **[**6]** by the U.S. Food and Drug Administration ("FDA") on May 26, 2006. (SUF ¶ 49)

18. GLLP is the exclusive distributor of Oracea® in the United States. (SUF ¶ 50)

19. The active ingredient in Oracea® is doxycycline monohydrate. (SUF ¶ 51)

20. Oracea® is a capsule dosage form for oral administration. (SUF ¶ 52)

21. The dosage strength of Oracea® is 40 mg. (SUF ¶ 53)

22. Oracea® is an oral pharmaceutical composition of doxycycline to be administered once-daily. (SUF ¶ 54)

23. Oracea® is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. (SUF ¶ 56)

24. Oracea® is a hard shell gelatin capsule filled with two types of doxycycline beads, 30 mg immediate-release ("IR") beads and 10 mg delayed-release ("DR") beads (coated with an enteric polymer). (SUF ¶¶ 57-58)

25. Oracea® does not contain a bisphosphonate compound. (SUF ¶ 59)

26. Oracea® contains one or more pharmaceutical excipients. (SUF ¶ 60)

27. Oracea® is the first and only orally administered, systemically delivered drug approved by the FDA for the treatment of rosacea. (PTX 426 at GAL 0229992; Tr. 540)

28. Oracea® treats rosacea in a human. (PTX 426 at GAL 0229992; PTX 381 at GAL 0240969-70; **[**7]** Tr. 73, 129-30)

29. Oracea®, when administered once-daily, is administered in an amount that reduces lesion count and an amount that is effective to treat the papules and pustules of rosacea. (PTX 426 at GAL 0229996-97; PTX 381 at GAL 0240969-70; Tr. 73, 287-88, 727)

30. Oracea® is administered long-term, i.e., over a period of time longer than eight to ten days. (PTX 426 at GAL 0229993, -96-97; SUF ¶ 38)

31. Oracea® is administered by "sustained release," i.e., a method of drug delivery to achieve a certain level of the drug over a particular period of time. (PTX 426 at GAL 0229993, - 95, -96)

32. Oracea®, when administered once daily, is administered in an amount that results in no reduction of skin microflora during a six-month treatment. (PTX 426 at GAL 0229996; PTX 394; 459, 612-15)

33. *In vivo* microbiological studies utilizing a similar drug exposure to Oracea® for up to 18 months demonstrated no detectable long-term effects on bacterial flora of the oral cavity, skin, intestinal tract, and vagina. (PTX 426 at GAL 0229996; PTX 394; PTX 413; PTX 200; PTX 201)

34. Oracea® should not be used for treating bacterial infections, providing antibacterial prophylaxis, or reducing the numbers **[**8]** or eliminating microorganisms associated with any bacterial disease. (PTX 426 at GAL 0229996)

35. Patients should not take Oracea® to treat infections caused by bacteria germs or viruses. (PTX 426 at GAL 0229998)

V. MYLAN'S GENERIC PRODUCT

36. Defendant Mylan submitted Abbreviated New Drug Application ("ANDA") 90-855 to the FDA under *§ 505(j)* of the Federal Food, Drug and Cosmetic Act ("FFDCA"), seeking FDA approval for the commercial manufacture, use, and sale of a **[*301]** generic version of Oracea® ("Mylan's Generic Product" or "Mylan's ANDA Product") before the expiration of the *'267 patent*, the *'572 patent*, the *'395 patent*, and the *'775 patent*. (SUF ¶ 61)

37. ANDA 90-855 identifies Mylan as the manufacturer of Mylan's Generic Product. (SUF ¶ 62)

38. The FDA approved ANDA 90-855 on July 1, 2010. (SUF ¶ 63)

39. Mylan's Generic Product will contain the package insert approved by the FDA for Mylan's Generic Product ("Mylan's Label," "Mylan Label," or "Label"). (SUF ¶ 64)

40. The active ingredient in Mylan's Generic Product is doxycycline. (SUF ¶ 65)

41. The dosage strength of Mylan's Generic Product is 40 mg. (SUF ¶ 66)

42. Mylan's Generic Product is a hard shell gelatin capsule filled with two types **[**9]** of doxycycline beads, 30 mg IR and 10 mg DR. (SUF ¶ 67)

43. Mylan's Generic Product does not contain a bisphosphonate compound. (SUF ¶ 68)

44. FDA has found Mylan's Generic Product to be bioequivalent to Oracea®. (SUF ¶ 69)

45. The statements in the approved package insert for Mylan's Generic Product are true. (Memorandum Opinion granting Preliminary Injunction (D.I. 177) at 9; *see also 18 U.S.C. § 1001*; *21 U.S.C. §§ 355b(a)(1), 355c(a)*; Tr. 323)

46. The doxycycline in Mylan's Generic Product is doxycycline monohydrate. (DTX 2091 at MYL-D118692-93; DTX 2267 at MYL-D000206; Tr. 98-99)

47. Mylan's Label instructs doctors and patients that one doxycycline capsule (40 mg) of Mylan's Generic Product should be taken once-daily by oral administration. (DTX 2091 at MYL-D118686-87; DTX 2267 at MYL-D000220; Tr. 83, 100-01)

48. Mylan's Generic Product is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. (DTX 2091 at MYL-D118686-87; Tr. 82)

49. Mylan's Label instructs doctors and patients to use Mylan's Generic Product to treat rosacea in a human. (DTX 2091 at MYL-D118686-87, -97; Tr. 82)

50. Mylan's Generic Product, when administered once-daily **[**10]** in accordance with Mylan's Label, is administered in an amount that reduces lesion count and that is effective to treat the papules and pustules of rosacea. (DTX 2091 at MYL-D118695-96; Tr. 82-83)

51. Mylan's Generic Product is administered long-term, i.e., over a period of time longer than eight to ten days. (DTX 2091 at MYL-D118687, -95-96; Tr. 84)

VI. PATENTS-IN-SUIT

A. The Ashley Patents

1. Ashley *'267 Patent*

52. U.S. Application Number 10/117,709, from

which the *'267 patent* issued, was filed on April 5, 2002. (SUF ¶ 7)

53. The *'267 patent* issued on May 1, 2007, naming Robert A. Ashley as the sole inventor and listing CollaGenex Pharmaceuticals, Inc. as assignee. (SUF ¶ 8) The *'267 patent* is entitled "Methods of Treating Acne." (PTX 1)

54. GLI is the current assignee of the *'267 patent*. (SUF ¶ 9)

55. The *'267 patent* claims priority from provisional application no. 60/325,489, filed September 26, 2001 and provisional application no. 60/281,916, filed April 5, 2001. (SUF ¶ 10)

[*302] 56. The *'267 patent* is set to expire on April 5, 2022. (SUF ¶ 11)

2 Ashley *'572 Patent*

57. U.S. Application Number 11/061,866, from which the *'572 patent* issued, was filed on February 18, 2005. (SUF ¶ 12)

58. The *'572 patent* **[**11]** issued on June 19, 2007, naming Robert A. Ashley as the sole inventor and listing CollaGenex Pharmaceuticals, Inc. as assignee. (SUF ¶ 13) The *'572 patent* is entitled, "Methods of Treating Rosacea." (PTX 2)

59. GLI is the current assignee of the *'572 patent*. (SUF ¶ 14)

60. The *'572 patent* is a continuation of application no. 10/272,499, filed on October 15, 2002, and issued as *U.S. Patent No. 7,014,858*, which is a continuation of application no. 10/117,709, which issued as the *'267 patent*. (SUF ¶ 15)

61. The *'572 patent* claims priority from provisional application no. 60/281,916, filed April 5, 2001 and provisional application no. 60/325,489, filed September 26, 2001. (SUF ¶ 16)

62. The *'572 patent* is set to expire on April 5, 2022. (SUF ¶ 17)

3. Facts relating to infringement and validity of Ashley Patents

63. Dr. Webster, who was called at trial by Galderma, is an expert in the field of clinical dermatology and microbiology. (Tr. 70; PTX 248) [6]

6 There is no dispute that each of the experts who testified at trial is a person having at least ordinary skill in the art with respect to the patents about which that expert testified.

64. Dr. Chambers, who was called at trial by Mylan, is an expert **[**12]** in the field of infectious diseases and antimicrobial agents, including antibiotic resistance and the pharmacokinetics and pharmacodynamics of antimicrobial agents. (Tr. 552; DTX 2102)

65. Dr. Randall Stafford, who was called at trial by Mylan, is an expert in the field of clinical epidemiology, including the use prescription patterns generated by IMS Health. (Tr. 416; DTX 2208)

66. Dr. Barbara Gilchrest, who was called at trial by Mylan, is an expert in the field of clinical dermatology with a specific focus in the treatment of acne and rosacea. (Tr. 449; DTX 2135)

67. A microorganism is a single cellular life form or sub-life form, including a bacterium, a virus, a yeast, or protozoan. (Tr. 557)

68. Microorganisms live everywhere on and in our bodies. (Tr. 557)

69. Approximately 100,000,000,000,000 bacterial cells inhabit the human body. (Tr. 149-50, 557)

70. In our bodies, the number of bacterial cells is greater than the number of human cells by a factor of 10. (Tr. 557)

71. Doxycycline is among the most potent known antimicrobial agents. (Tr. 558)

72. Doxycycline is "broad spectrum," which means that it affects a large number of organisms. (Tr. 558)

73. Doxycycline is a protein synthesis **[**13]** inhibitor that inhibits the growth of microorganisms by paralyzing their protein machinery. (Tr. 559)

74. When administered orally, doxycycline is absorbed into the bloodstream and travels wherever blood goes in the body. (Tr. 558-59)

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