IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs The Research Foundation of State University of New York; New York University; Galderma Laboratories Inc.; and Galderma Laboratories, L.P. (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc., hereby allege as follows:

PARTIES

1. Plaintiff The Research Foundation of State University of New York (hereinafter, "RF") is a private, non-profit corporation organized and existing under the laws of the State of New York, having a principal place of business at 35 State Street, Albany, New York 12207.

2. Plaintiff New York University (hereinafter, "NYU") is a private, non-profit corporation organized and existing under the laws of the State of New York, having a principal place of business at 70 Washington Square South, New York, New York 10012.

3. Plaintiff Galderma Laboratories Inc. (hereinafter, "GLI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

4. Plaintiff Galderma Laboratories, L.P. (hereinafter, "GLLP") 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. Upon information and belief, Defendant Lupin Limited (hereinafter, "Lupin Ltd.") is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

6. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. (hereinafter, "Lupin Pharma") is a Virginia corporation and a wholly-owned subsidiary and agent of Defendant Lupin Ltd., having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21 Floor, Baltimore, Maryland 21202.

NATURE OF THE ACTION

7. This is a civil action for infringement of United States Patents Nos. 7,232,572 ("the '572 patent"); 7,211,267 ("the '267 patent"); 5,789,395 ("the '395 patent"); and 5,919,775 ("the '775 patent"). (Exhibits A-D.) This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Defendant Lupin Ltd. by virtue of, *inter alia*, its having availed itself of the rights and benefits of Delaware law, and having

engaged in substantial and continuing contacts with the State. Upon information and belief, Defendant Lupin Ltd. researches, develops, and manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Defendant Lupin Ltd., itself or through its wholly-owned subsidiary and agent Defendant Lupin Pharma, distributes numerous generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, Lupin Ltd. has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Lupin Ltd. admitted jurisdiction (for the purpose of the litigation) and filed counterclaims in *Forest Laboratories, Inc., et al. v. Dr. Reddy's Laboratories, Inc., et al.*, C.A. No. 08-21 (consolidated) (D. Del.), *Glaxo Group Ltd., et al. v. Lupin Ltd., et al.*, C. A. No. 08-551 (D. Del.) and *Pfizer Inc., et al. v. Lupin Ltd., et al.*, C.A. No 09-309 (D.Del.).

10. This Court has personal jurisdiction over Defendant Lupin Pharma by virtue of, *inter alia*, its having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. Upon information and belief, Defendant Lupin Pharma distributes numerous generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, Lupin Pharma has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Defendant Lupin Pharma admitted jurisdiction (for the purpose of the litigation) and filed counterclaims in *Forest Laboratories, Inc., et al. v. Dr. Reddy's Laboratories, Inc., et al.*, C.A. No. 08-21 (consolidated) (D. Del.) and *Pfizer Inc., et al. v. Lupin Ltd., et al.*, C.A. No 09-309 (D.Del.), and admitted jurisdiction in *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, C. A. No. 09-37 (D. Del.).

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

THE PATENTS-IN-SUIT

12. GLLP holds New Drug Application ("NDA") No. 50-805 on Oracea® brand doxycycline capsules, and is the exclusive distributor of Oracea® in the United States.

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

14. The '572 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

15. GLI is the current assignee of the '572 patent.

16. Plaintiffs GLI and GLLP have the right to sue and recover for any infringement of the '572 patent.

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

18. The '267 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

19. GLI is the current assignee of the '267 patent.

20. Plaintiffs GLI and GLLP have the right to sue and recover for any infringement of the '267 patent.

21. On August 4, 1998, the '395 patent, entitled "Method of Using Tetracycline Compounds for Inhibition of Endogenous Nitric Oxide Production" was duly and

legally issued to RF and Hospital for Joint Diseases (a predecessor in interest to NYU) as assignees. A copy of the '395 patent is attached hereto as Exhibit C.

22. The '395 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

23. GLI is the licensee of the '395 patent.

24. Plaintiffs have the right to sue and recover for any infringement of the '395 patent.

25. On April 16, 1998, the '775 patent, entitled "Method for Inhibiting Expression of Inducible Nitric Oxide Synthase with Tetracycline" was duly and legally issued to RF and Hospital for Joint Diseases (a predecessor in interest to NYU) as assignees. A copy of the '775 patent is attached hereto as Exhibit D.

26. The '775 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Oracea®.

27. GLI is the licensee of the '775 patent.

28. Plaintiffs have the right to sue and recover for any infringement of the '775 patent.

ACTS GIVING RISE TO THIS ACTION

Count I – Infringement of the '572 Patent

29. Plaintiffs restate all of the preceding paragraphs as if fully set forth herein.

30. Upon information and belief, Lupin Ltd., through its subsidiary and agent Lupin Pharma, submitted ANDA No. 91-277 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FFDCA") (21 U.S.C. § 355(j)).

31. ANDA No. 91-277 seeks FDA approval for the commercial manufacture, use and sale of generic doxycycline delayed-release capsules, 40mg, for oral administration ("the Generic Products").

32. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA Lupin Ltd. alleged in ANDA No. 91-277 that claims of the '572 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

33. ANDA No. 91-277 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '572 patent.

34. Plaintiffs received written notification of ANDA No. 91-277 and its § 505(j)(2)(A)(vii)(IV) allegations by letter dated May 29, 2009.

35. Lupin Ltd.'s submission of ANDA No. 91-277 to the FDA, through its subsidiary and agent Lupin Pharma, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '572 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Ltd. commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '572 patent under 35 U.S.C. § 271(a), (b) and/or (c).

36. Lupin Pharma is jointly and severally liable for any infringement of the '572 patent. Upon information and belief, Lupin Pharma participated in, contributed to, aided, abetted and/or induced Lupin Ltd.'s submission of ANDA No. 91-277 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

37. Lupin Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-227 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '572 patent under 35 U.S.C. § 271(e)(2)(A). Moreover,

if Lupin Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '572 patent under 35 U.S.C. § 271(a), (b) and/or (c).

38. Plaintiffs will be irreparably harmed by Lupin Ltd.'s and Lupin Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

39. This is an exceptional case under 35 U.S.C. § 285 because Lupin Ltd. and Lupin Pharma were aware of the existence of the '572 patent at the time of the submission of ANDA No. 91-277 and § 505(j)(2)(A)(vii)(IV) allegations to the FDA, and were aware that the filing constituted infringement of that patent.

Count II – Infringement of the '267 Patent

40. Plaintiffs restate all of the preceding paragraphs as if fully set forth herein.

41. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Lupin Ltd. alleged in ANDA No. 91-277 that claims of the '267 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

42. ANDA No. 91-277 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '267 patent.

43. Lupin Ltd.'s submission of ANDA No. 91-277 to the FDA, through its subsidiary and agent Lupin Pharma, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '267 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Ltd. commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '267 patent under 35 U.S.C. § 271(a), (b) and/or (c).

44. Lupin Pharma is jointly and severally liable for any infringement of the '267 patent. Upon information and belief, Lupin Pharma participated in, contributed to, aided, abetted and/or induced Lupin Ltd.'s submission of ANDA No. 91-277 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

45. Lupin Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-227 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '267 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '267 patent under 35 U.S.C. § 271(a), (b) and/or (c).

46. Plaintiffs will be irreparably harmed by Lupin Ltd.'s and Lupin Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

47. This is an exceptional case under 35 U.S.C. § 285 because Lupin Ltd. and Lupin Pharma were aware of the existence of the '267 patent at the time of the submission of ANDA No. 91-277 and § 505(j)(2)(A)(vii)(IV) allegations to the FDA, and were aware that the filing constituted infringement of that patent.

Count III – Infringement of the '395 Patent

48. Plaintiffs restate all of the preceding paragraphs as if fully set forth herein.

49. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Lupin Ltd. alleged in ANDA No. 91-277 that claims of the '395 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

50. ANDA No. 91-277 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '395 patent.

51. Lupin Ltd.'s submission of ANDA No. 91-277 to the FDA, through its subsidiary and agent Lupin Pharma, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '395 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Ltd. commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '395 patent under 35 U.S.C. § 271(a), (b) and/or (c).

52. Lupin Pharma is jointly and severally liable for any infringement of the '395 patent. Upon information and belief, Lupin Pharma participated in, contributed to, aided, abetted and/or induced Lupin Ltd.'s submission of ANDA No. 91-277 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

53. Lupin Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-227 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '395 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '395 patent under 35 U.S.C. § 271(a), (b) and/or (c).

54. Plaintiffs will be irreparably harmed by Lupin Ltd.'s and Lupin Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

55. This is an exceptional case under 35 U.S.C. § 285 because Lupin Ltd. and Lupin Pharma were aware of the existence of the '395 patent at the time of the submission of

ANDA No. 91-277 and § 505(j)(2)(A)(vii)(IV) allegations to the FDA, and were aware that the filing constituted infringement of that patent.

Count IV – Infringement of the '775 Patent

56. Plaintiffs restate all of the preceding paragraphs as if fully set forth herein.

57. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Lupin Ltd. alleged in ANDA No. 91-277 that claims of the '775 patent are invalid and/or not infringed by the commercial manufacture, use or sale of the Generic Products.

58. ANDA No. 91-277 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '775 patent.

59. Lupin Ltd.'s submission of ANDA No. 91-277 to the FDA, through its subsidiary and agent Lupin Pharma, including its § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '775 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Ltd. commercially manufactures, uses, offers to sell, sells, or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '775 patent under 35 U.S.C. § 271(a), (b) and/or (c).

60. Lupin Pharma is jointly and severally liable for any infringement of the '775 patent. Upon information and belief, Lupin Pharma participated in, contributed to, aided, abetted and/or induced Lupin Ltd.'s submission of ANDA No. 91-277 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

61. Lupin Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-227 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '775 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the

Generic Products, or induces or contributes to any such conduct, it would further infringe the '775 patent under 35 U.S.C. § 271(a), (b) and/or (c).

62. Plaintiffs will be irreparably harmed by Lupin Ltd.'s and Lupin Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

63. This is an exceptional case under 35 U.S.C. § 285 because Lupin Ltd. and Lupin Pharma were aware of the existence of the '775 patent at the time of the submission of ANDA No. 91-277 and § 505(j)(2)(A)(vii)(IV) allegations to the FDA, and were aware that the filing constituted infringement of that patent.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Lupin Ltd. has infringed the '572, '267, '395, and '775 patents;

B. That Lupin Pharma has infringed the '572, '267, '395, and '775 patents;

C. That, pursuant to 35 U.S.C. § 271(e)(4) (A), the effective date of any approval of ANDA No. 91-277 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '572, '267, '395, and '775 patents, including any extensions;

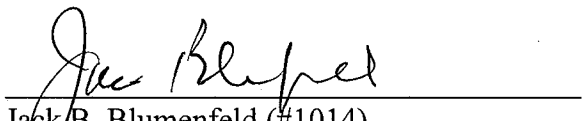
D. That Lupin Ltd., its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling or importing any Generic Products, prior to the expiration of the '572, '267, '395, and '775 patents, including any extensions;

E. That Lupin Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling or importing any Generic Products, prior to the expiration of the '572, '267, '395, and '775 patents, including any extensions;

F. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

G. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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