IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, INC. and DR. FALK PHARMA GmbH,	)	
Plaintiffs,	)	C.A. No. 12-cv-1104-GMS
v.	)	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH (collectively "Salix") bring this action for patent infringement against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin"). This action concerns patents related to Salix's pharmaceutical product, Apriso® (mesalamine), a prescription drug indicated for the maintenance of remission of ulcerative colitis in adults.

PARTIES

1. Salix Pharmaceuticals, Inc. is a corporation existing under the laws of California having its corporate offices and principal place of business at 8510 Colonnade Center Drive, Raleigh. North Carolina 27615. Salix Pharmaceuticals, Inc. is engaged in the business of development, marketing and sale of branded pharmaceutical products.

2. Dr. Falk Pharma GmbH, Inc. is a corporation existing under the laws of Germany having its corporate offices and principal place of business at Leinenweberstr. 5, 79108 Freiburg im Breisgau, Germany. Dr. Falk Pharma GmbH is engaged in the business of development and sales of pharmaceutical products for indications in, *inter alia*, gastroenterology.

3. Upon information and belief, Lupin Limited ("Lupin Ltd.") is a corporation existing under the laws of India having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

4. Upon information and belief, Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a corporation existing under the laws of Virginia having a principal place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

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

6. Upon information and belief, Lupin Pharma, itself and on behalf of its parent corporation Lupin Ltd., distributes, markets, and/or sells generic drugs in Delaware and throughout the United States.

7. Upon information and belief, Lupin Ltd., itself and through its wholly-owned subsidiary and agent Lupin Pharma, is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States.

JURISDICTION AND VENUE

8. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue in this Court is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over Lupin Ltd. and Lupin Pharma by virtue of, *inter alia*, their marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

11. Upon information and belief, Lupin Ltd. is subject to personal jurisdiction in Delaware because, among other things, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Pharma, has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Upon information and belief, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Pharma, manufactures, markets, and/or sells generic drugs throughout the United States and within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Lupin Ltd. is subject to personal jurisdiction in Delaware on the basis of its inducement of and/or contribution to Lupin Pharma's acts of infringement in Delaware. In addition, Lupin Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Lupin Pharma and therefore the activities of Lupin Pharma in this jurisdiction are attributed to Lupin Ltd.

12. Upon information and belief, this Court has personal jurisdiction over Lupin Pharma because Lupin Pharma has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Upon information and belief, Lupin Pharma manufactures, markets, and/or sells generic drugs throughout the United States and within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

13. This Court has personal jurisdiction over both Lupin Ltd. and Lupin Pharma because they have previously been sued in this district and have not challenged personal jurisdiction, and they have affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Pfizer Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc., and PF Prism C.V. v. Lupin Ltd. and Lupin Pharmaceuticals Inc*., 12-cv-00811; *Novartis*

Pharmaceuticals Corporation v. Lupin Ltd. and Lupin Pharmaceuticals Inc., 12-cv-00595; *Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd., and Allegan, Inc. v. Lupin Ltd. and Lupin Pharmaceuticals Inc.*, 11-cv-00271.

NATURE OF THIS ACTION

14. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* This action relates to Abbreviated New Drug Application ("ANDA") No. 204202 filed by Lupin with the United States Food and Drug Administration ("FDA") for approval to market generic copies of Salix's Apriso® pharmaceutical products that are sold in the United States.

BACKGROUND

15. Dr. Falk Pharma GmbH is the owner by assignment of U.S. Patent No. 6,551,620 ("the '620 patent"), entitled "Pellet Formulation for the Treatment of the Intestinal Tract." The '620 patent was duly and legally issued by the United States Patent and Trademark Office on April 22, 2003. A true and correct copy of the '620 patent is attached as Exhibit A.

16. Salix Pharmaceuticals, Inc. is Dr. Falk Pharma's exclusive licensee of the '620 patent.

17. In accordance with 21 C.F.R. § 314.53, Salix Pharmaceuticals, Inc. listed the '620 patent in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Salix's Apriso® drug product.

18. Dr. Falk Pharma GmbH is the owner by assignment of U.S. Patent No. 8,337,886 ("the '886 patent"), entitled "Pellet Formulation for the Treatment of the Intestinal Tract." The '886 patent was duly and legally issued by the United States Patent and Trademark Office on December 25, 2012. A true and correct copy of the '886 patent is attached as Exhibit B.

19. Salix Pharmaceuticals, Inc. is Dr. Falk Pharma's exclusive licensee of the '886 patent.

20. In accordance with 21 C.F.R. § 314.53, Salix Pharmaceuticals, Inc. listed the '886 patent in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Salix's Apriso® drug product.

21. Dr. Falk Pharma GmbH is the owner by assignment of U.S. Patent No. 7,547,451 ("the '451 patent), entitled "Pellet Formulation for the Treatment of the Intestinal Tract." The '451 patent was duly and legally issued by the United States Patent and Trademark Office on June 16, 2009. A true and correct copy of the '451 patent is attached as Exhibit C.

22. Salix Pharmaceuticals, Inc. is Dr. Falk Pharma's exclusive licensee of the '451 patent.

23. The '451 patent claims, *inter alia*, a process for preparing an orally administrable pharmaceutical pellet formulation.

24. Dr. Falk Pharma GmbH is the owner by assignment of U.S. Patent No. 8,496,965 ("the '965 patent), entitled "Pellet Formulation for the Treatment of the Intestinal Tract." The '965 patent was duly and legally issued by the United States Patent and Trademark Office on July 30, 2013. A true and correct copy of the '965 patent is attached as Exhibit D.

25. Salix Pharmaceuticals, Inc. is Dr. Falk Pharma's exclusive licensee of the '965 patent.

26. On July 30, 2013, in accordance with 21 C.F.R. § 314.53, Salix Pharmaceuticals, Inc. listed the '965 patent in the "Orange Book" as covering Salix's Apriso® drug product.

27. Salix Pharmaceuticals, Inc. is the holder of approved New Drug Application ("NDA") No. 22-301 for the use of Apriso® (mesalamine) Extended Release Capsules in a

0.375g dosage strength, as indicated for the maintenance of remission of ulcerative colitis in adults.

28. On information and belief, Lupin filed ANDA No. 204202 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of mesalamine extended-release capsules in 0.375g dosage strengths ("Lupin's generic mesalamine products") before the expiration of the '620 patent. On information and belief, as part of its ANDA, Lupin filed a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the '620 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of" Lupin's generic mesalamine products that are the subject of Lupin's ANDA No. 204202.

29. Lupin caused to be sent to Salix a letter ("the Notice Letter"), dated July 27, 2012, notifying Salix that Lupin Ltd. had filed ANDA No. 204202 seeking approval to market Lupin's generic mesalamine products prior to the expiration of the '620 patent, and stating that Lupin was providing information to Salix pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Salix received the Notice Letter on or about July 30, 2012.

30. On information and belief, on or about February 11, 2013, Lupin amended ANDA No. 204202 to include a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the '886 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of "Lupin's generic mesalamine products" that are the subject of Lupin's ANDA No. 204202.

31. Lupin caused to be sent to Salix a letter ("the '886 Notice Letter"), dated February 11, 2013, notifying Salix that Lupin Ltd. had filed ANDA No. 204202 seeking approval to market Lupin's generic mesalamine products prior to the expiration of the '886 patent and stating

that Lupin was providing information to Salix pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Salix received the '886 Notice Letter on or about February 12, 2013.

COUNT I

Infringement of the '620 Patent Under 35 U.S.C. § 271(e)(2)

32. Salix realleges and incorporates by reference paragraphs 1-31.

33. Lupin has filed or caused to be filed ANDA No. 204202 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Lupin's generic mesalamine products before the expiration of the '620 patent. Upon information and belief, Lupin also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '620 patent is invalid, unenforceable, or not infringed.

34. By submitting its ANDA No. 204202 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's generic mesalamine products before the expiration of the '620 patent, Lupin Ltd. has infringed the '620 patent under 35 U.S.C. § 271(e)(2).

35. Upon information and belief, Lupin Pharma has acted in concert with Lupin Ltd., actively supporting, participating in, encouraging, and inducing Lupin Ltd.'s filing of ANDA No. 204202 for Lupin's generic mesalamine products, and in the preparation to sell in the United States Lupin's generic mesalamine products.

36. The FDA requires Lupin's proposed label for Lupin's generic mesalamine products to contain the same prescribing, dosage and administration, and side effect information as found on the Apriso® label. *See* 21 C.F.R. § 314.94(8)(iv).

37. Upon information and belief, Lupin intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Lupin's generic

mesalamine products with a product insert that will direct physicians and patients in the use of Lupin's generic mesalamine products.

38. Upon FDA approval of Lupin's ANDA No. 204202, Lupin will infringe the '620 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Lupin's generic mesalamine products in the United States under 35 U.S.C. § 271(a), and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c).

39. Upon information and belief, Lupin Pharma will actively aid, abet, encourage, and induce Lupin Ltd. and others in the production, importation, sale, offer for sale, and use of Lupin's generic mesalamine products.

40. Upon information and belief, Lupin Pharma and Lupin Ltd. will both actively aid, abet, encourage, participate, and induce others to participate in the production, importation, sale, offer for sale, and use of Lupin's generic mesalamine products.

41. Upon information and belief, the offer to sell, sale, and/or importation of Lupin's generic mesalamine products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '620 patent, either literally or under the doctrine of equivalents.

42. Upon information and belief, Lupin has knowledge of the '620 patent and knows that it will aid and abet another's direct infringement of at least one of the claims of the '620 patent, either literally or under the doctrine of equivalents.

43. On information and belief, Lupin's generic mesalamine products are especially made or adapted for the maintenance of remission of ulcerative colitis in adults, and Lupin is aware that its generic mesalamine products are so made or so adapted and, if approved, will be used in contravention of Plaintiffs' rights under the '620 patent.

44. Upon information and belief, the offer to sell, sale, and/or importation of Lupin's generic mesalamine products would contributorily infringe under 35 U.S.C. § 271(c) at least one of the claims of the '620 patent, either literally or under the doctrine of equivalents.

45. Lupin has knowledge of the '620 patent and is knowingly infringing the '620 patent.

46. As a result of Lupin's infringement of the '620 patent, Salix has been and will continue to be damaged unless said infringement is enjoined by this Court. Salix has no adequate remedy at law.

COUNT II

Infringement of the '886 Patent Under 35 U.S.C. § 271(e)(2)

47. Salix realleges and incorporates by reference paragraphs 1-46.

48. Lupin has filed or caused to be filed ANDA No. 204202 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Lupin's generic mesalamine products before the expiration of the '886 patent. Upon information and belief, Lupin also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '886 patent is invalid, unenforceable, or not infringed.

49. By submitting its ANDA No. 204202 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's generic mesalamine products before the expiration of the '886 patent, Lupin Ltd. has infringed the '886 patent under 35 U.S.C. § 271(e)(2).

50. Upon information and belief, Lupin Pharma has acted in concert with Lupin Ltd., actively supporting, participating in, encouraging, and inducing Lupin Ltd.'s filing of ANDA

No. 204202 for Lupin's generic mesalamine products, and in the preparation to sell in the United States Lupin's generic mesalamine products.

51. The FDA requires Lupin's proposed label for Lupin's generic mesalamine products to contain the same prescribing, dosage and administration, and side effect information as found on the Apriso® label. *See* 21 C.F.R. § 314.94(8)(iv).

52. Upon information and belief, Lupin intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Lupin's generic mesalamine products with a product insert that will direct physicians and patients in the use of Lupin's generic mesalamine products.

53. Upon FDA approval of Lupin's ANDA No. 204202, Lupin will infringe the '886 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Lupin's generic mesalamine products in the United States under 35 U.S.C. § 271(a), and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c).

54. Upon information and belief, Lupin Pharma will actively aid, abet, encourage, and induce Lupin Ltd. and others in the production, importation, sale, offer for sale, and use of Lupin's generic mesalamine products.

55. Upon information and belief, Lupin Pharma and Lupin Ltd. will both actively aid, abet, encourage, participate, and induce others to participate in the production, importation, sale, offer for sale, and use of Lupin's generic mesalamine products.

56. Upon information and belief, the offer to sell, sale, and/or importation of Lupin's generic mesalamine products would actively induce infringement under 35 U.S.C. § 271(b) of at least one claim of the '886 patent, either literally or under the doctrine of equivalents.

57. Upon information and belief, Lupin has knowledge of the ’886 patent and knows that it will aid and abet another’s direct infringement of at least one of the claims of the ’886 patent, either literally or under the doctrine of equivalents.

58. On information and belief, Lupin’s generic mesalamine products are especially made or adapted for the maintenance of remission of ulcerative colitis in adults, and Lupin is aware that its generic mesalamine products are so made or so adapted and, if approved, will be used in contravention of Plaintiffs’ rights under the ’886 patent.

59. Upon information and belief, the offer to sell, sale, and/or importation of Lupin’s generic mesalamine products would contributorily infringe under 35 U.S.C. § 271(c) at least one of the claims of the ’886 patent, either literally or under the doctrine of equivalents.

60. Lupin has knowledge of the ’886 patent and is knowingly infringing the ’886 patent.

61. As a result of Lupin’s infringement of the ’886 patent, Salix has been and will continue to be damaged unless said infringement is enjoined by this Court. Salix has no adequate remedy at law.

COUNT III

Declaratory Judgment of Infringement of the ‘451 Patent Under 35 U.S.C. § 271(g)

62. Salix realleges and incorporates by reference paragraphs 1-61.

63. Upon information and belief, Lupin will infringe at least one claim of the ‘451 patent under 35 U.S.C. § 271(g) by commercially manufacturing Lupin’s generic mesalamine products under ANDA No. 204202 by a process patented in the United States and, without authority, importing into the United States or offering to sell, selling, or using in the United States Lupin’s generic products.

64. As a result of Lupin's infringement of the '451 patent, Salix will be substantially and irreparably harmed unless said infringement is enjoined by this Court. Salix has no adequate remedy at law.

65. An actual controversy exists relating to Lupin's threatened infringement of the '451 patent.

COUNT IV

Infringement of the '965 Patent under 35 U.S.C. § 271(e)(2)

66. Salix realleges and incorporates by reference paragraphs 1-65.

67. Lupin has filed or caused to be filed ANDA No. 204202 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Lupin's generic mesalamine products before the expiration of the '965 patent. Upon information and belief, Lupin will file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '965 patent is invalid, unenforceable, or not infringed.

68. By submitting its ANDA No. 204202 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's generic mesalamine products before the expiration of the '965 patent, Lupin Ltd. has infringed the '965 patent under 35 U.S.C. § 271(e)(2).

69. Upon information and belief, Lupin Pharma has acted in concert with Lupin Ltd., actively supporting, participating in, encouraging, and inducing Lupin Ltd.'s filing of ANDA No. 204202 for Lupin's generic mesalamine products, and in the preparation to sell in the United States Lupin's generic mesalamine products.

70. Upon FDA approval of Lupin's ANDA No. 204202, Lupin will infringe the '965 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell,

selling, and/or importing Lupin's generic mesalamine products in the United States under 35 U.S.C. § 271(a).

71. As a result of Lupin's infringement of the '965 patent, Salix has been and will continue to be damaged unless said infringement is enjoined by this Court. Salix has no adequate remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiffs Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH pray for judgment and relief including:

A. A declaration that the claims of United States Patent No. 6,551,620; United States Patent No. 8,337,886; United States Patent No. 7,547,451; and United States Patent No. 8,496,965 are valid and enforceable;

B. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Lupin's submission to the FDA of ANDA No. 204202 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Lupin's generic mesalamine products before the expiration of United States Patent No. 6,551,620; United States Patent No. 8,337,886; and United States Patent No. 8,496,965 was an act of infringement;

C. A declaration that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Lupin's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 204202 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Lupin's generic mesalamine products before the expiration of United States Patent No. 6,551,620 and United States Patent No. 8,337,886 were acts of infringement of the patents-in-suit;

D. A declaration that Lupin would infringe one or more claims of United States Patent No. 6,551,620; United States Patent No. 8,337,886; and U.S. Patent No. 8,496,965 under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Lupin's generic mesalamine products prior to expiration of said patents-in-suit and any additional dates of exclusivity therefor;

E. A declaration that Lupin would infringe one of more claims of United States Patent No. 7,547,451 under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using in the United States Lupin's generic mesalamine products made by a patented process claimed in the '451 patent before expiration of the '451 patent;

F. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Lupin, and all officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing any claims of the patent-in-suit with Lupin's generic mesalamine products prior to the expiration date of United States Patent No. 6,551,620; United States Patent No. 8,337,886; United States Patent No. 7,547,451; and United States Patent No. 8,496,965, and any additional dates of exclusivity;

G. A permanent injunction enjoining Lupin and all persons acting in concert with Lupin from seeking, obtaining, or maintaining approval of Lupin's ANDA No. 204202 until the expiration date of United States Patent No. 6,551,620; United States Patent No. 8,337,886; and United States Patent No. 8,496,965, and any additional dates of exclusivity;

H. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Lupin's generic mesalamine products is not to be earlier than the expiration date of United States Patent No. 6,551,620; United States Patent No. 8,337,886; and United States Patent No. 8,496,965, and any additional dates of exclusivity therefor.

I. A declaration that Lupin has no legal or equitable defense to Plaintiffs' allegations of infringement;

J. An award declaring this case exceptional pursuant to 35 U.S.C. § 285 and granting Plaintiffs their attorney's fees;

K. An award of Plaintiffs' costs and expenses in this action; and

L. An award of any further and additional relief as this Court may deem just and proper.

Dated: August 19, 2013

Respectfully submitted,

/s/ *Mary W. Bourke*

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CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of August, 2013, I served a true and correct copy of **SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT** via email on the below individuals:

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