IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, INC. and DR. FALK PHARMA GmbH,	)	
Plaintiffs,	)	C.A. No.
v.	)	
NOVEL LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Salix Pharmaceuticals, Inc. ("Salix") and Dr. Falk Pharma GmbH ("Falk") (collectively, "Plaintiffs") bring this action for patent infringement against Defendant Novel Laboratories, Inc. ("Novel"). 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 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 development and sale of pharmaceutical products for indications in, *inter alia*, gastroenterology.

3. On information and belief, Novel Laboratories, Inc. is a corporation existing under the laws of Delaware having a principal place of business at 400 Campus Drive, Somerset, NJ 08873.

4. On information and belief, Novel is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells throughout the United States, including within the State of Delaware.

JURISDICTION AND VENUE

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

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

7. On information and belief, this Court has personal jurisdiction over Novel by virtue of, *inter alia*, its 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.

8. On information and belief, Novel is subject to personal jurisdiction in Delaware because, among other things, Novel has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. On information and belief, Novel 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.

9. This Court has personal jurisdiction over Novel because it previously has been sued in this district and has not challenged personal jurisdiction, and because it has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*,

Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V., and Northwestern University v. Novel Laboratories, Inc., No. 11-cv-00027 (D. Del.); *CIMA Labs, Inc., Azur Pharma Limited, and Azur Pharma International III Limited v. Novel Laboratories, Inc.*, No. 08-cv-00886 (D. Del.).

NATURE OF THIS ACTION

10. This is an action for patent infringement arising under the food and drug laws and patent laws of the United States, Titles 21 and 35 of the United States Code, respectively. This action relates to Abbreviated New Drug Application ("ANDA") No. 205841, filed by Novel with the United States Food and Drug Administration ("FDA") for approval to manufacture, import, market, use, or sell a generic copy of Salix's Apriso® pharmaceutical product prior to the expiration of United States Patent Numbers 6,551,620 ("the '620 patent"), 8,337,886 ("the '886 patent"), and 8,496,965 ("the '965 patent") (collectively, "the Orange Book-listed patents").

THE PATENTS IN SUIT

11. Falk is the owner by assignment of 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 ("USPTO") on April 22, 2003. A true and correct copy of the '620 patent is attached as Exhibit A.

12. Salix is Falk's exclusive licensee of the '620 patent.

13. Falk is the owner by assignment of the '886 patent, entitled "Pellet Formulation for the Treatment of the Intestinal Tract." The '886 patent was duly and legally issued by the USPTO on December 25, 2012. A true and correct copy of the '886 patent is attached as Exhibit B.

14. Salix is Falk's exclusive licensee of the '886 patent.

15. Falk is the owner by assignment of the '965 patent, entitled "Pellet Formulation for the Treatment of the Intestinal Tract." The '965 patent was duly and legally issued by the USPTO on July 30, 2013. A true and correct copy of the '965 patent is attached as Exhibit C.

16. Salix is Falk's exclusive licensee of the '965 patent.

APRISO® MESALAMINE CAPSULES

17. Salix is the holder of approved New Drug Application ("NDA") No. 22-301 for Apriso® (mesalamine) Extended Release Capsules.

18. The FDA approved NDA No. 22-301 for the manufacture, marketing and sale of Apriso® in a 0.375g dosage strength with a single indication for the maintenance of remission of ulcerative colitis in adults. Salix has sold Apriso® under NDA No. 22-301 since its approval.

19. In accordance with 21 C.F.R. § 314.53, Salix listed the '620, '886, and '965 patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Apriso®.

NOVEL'S ANDA

20. Novel sent Salix a letter ("the Notice Letter"), dated January 6, 2014, notifying Salix that Novel had filed ANDA No. 205841 seeking approval to market Novel's ANDA product prior to the expiration of the Orange Book-listed patents and stating that Novel was providing information to Salix pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Salix received the Notice Letter on or about January 7, 2014.

21. On information and belief and as stated in the Notice Letter, Novel filed, or caused to be filed, ANDA No. 205841 ("Novel's ANDA") with the FDA.

22. On information and belief and as stated in the Notice Letter, Novel filed its ANDA with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial

manufacture, importation, use or sale of 375 mg mesalamine oral extended release capsules ("Novel's ANDA product") before the expiration of the Orange Book-listed patents.

23. On information and belief and as stated in the Notice Letter, Novel's ANDA seeks approval to engage in the commercial manufacture, importation, use or sale of Novel's ANDA product before the expiration of the Orange Book-listed patents.

24. On information and belief and as stated in the Notice Letter, Novel's ANDA contains bioavailability and/or bioequivalence data comparing Novel's ANDA product to Apriso®.

25. On information and belief and as stated in the Notice Letter, as part of its ANDA, Novel filed "Paragraph IV Certifications" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the Orange Book-listed patents are "invalid, unenforceable, and/or will not be infringed by the manufacture, importation, use or sale of" Novel's ANDA product that is the subject of Novel's ANDA."

26. The Notice Letter enclosed what was purportedly the "Detailed Factual and Legal Bases for NOVEL'S Certification That U.S. Patent Nos. 6,551,620 B2, 8,337,886 B2, and 8,496,965 B2 are Invalid and/or Will Not Be Infringed."

27. Plaintiffs commenced this action within forty-five (45) days of receiving the Notice Letter.

28. The FDA will require Novel's proposed product insert for Novel's ANDA product to contain the same prescribing, dosage and administration, and side effect information as found on the Apriso® product insert. *See* 21 C.F.R. § 314.94(8)(iv). Because of this requirement, the FDA-approved product insert for Novel's ANDA product will contain a single approved use for the maintenance of remission of ulcerative colitis in adults.

COUNT I

INFRINGEMENT OF THE '620 PATENT UNDER 35 U.S.C. § 271(e)(2)

29. Plaintiffs reallege and incorporate by reference paragraphs 1-28.

30. On information and belief, Novel's ANDA product is covered by one or more claims of the '620 patent.

31. By submitting its ANDA No. 205841 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 Novel's ANDA product before the expiration of the '620 patent, Novel has infringed, either literally or under the doctrine of equivalents, one or more claims of the '620 patent under 35 U.S.C. § 271(e)(2).

COUNT II

DELCARATORY JUDGMENT OF INFRINGEMENT OF THE '620 PATENT UNDER 35 U.S.C. § 271(b-c)

32. Plaintiffs reallege and incorporate by reference paragraphs 1-31.

33. Upon FDA approval of Novel's ANDA No. 205841, Novel will infringe one or more claims of the '620 patent, either literally or under the doctrine of equivalents, by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c).

34. On information and belief, Novel intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Novel's ANDA product with an FDA-approved product insert that will direct physicians and patients in the use of Novel's ANDA product.

35. On information and belief, by marketing its ANDA product with the FDA-approved product insert, Novel will actively and intentionally aid, abet, encourage, participate,

and induce others to perform acts that Novel knows will directly infringe one or more claims of the ’620 patent.

36. On information and belief, Novel has knowledge of the ’620 patent and knows that it will aid and abet another’s direct infringement of one or more claims of the ’620 patent, either literally or under the doctrine of equivalents.

37. On information and belief, Novel’s offer to sell, sale, and/or importation of Novel’s ANDA product for use in accordance with the FDA-approved product insert will actively induce infringement under 35 U.S.C. § 271(b) of one or more claims of the ’620 patent, either literally or under the doctrine of equivalents, immediately following approval of Novel’s ANDA.

38. On information and belief, Novel knows that its ANDA product with the FDA-approved product insert is especially made or adapted for the maintenance of remission of ulcerative colitis in adults, is a material part of the invention claimed in the ’620 patent, and has no substantial noninfringing use.

39. On information and belief, Novel has knowledge of the ’620 patent and knows that use of its ANDA product in accordance with the FDA-approved product insert will directly infringe one or more claims of the ’620 patent.

40. On information and belief, Novel’s offer to sell, sale, and/or importation of Novel’s ANDA product for use in accordance with the FDA-approved product insert will contributorily infringe under 35 U.S.C. § 271(c) one or more claims of the ’620 patent, either literally or under the doctrine of equivalents.

41. As a result of Novel'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 III

INFRINGEMENT OF THE '886 PATENT UNDER 35 U.S.C. § 271(e)(2)

42. Salix realleges and incorporates by reference paragraphs 1-41.

43. On information and belief, Novel's ANDA product is covered by one or more claims of the '886 patent.

44. By submitting its ANDA No. 205841 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 Novel's ANDA product before the expiration of the '886 patent, Novel has infringed, either literally or under the doctrine of equivalents, one or more claims of the '886 patent under 35 U.S.C. § 271(e)(2).

COUNT IV

DELCARATORY JUDGMENT OF INFRINGEMENT OF THE '886 PATENT UNDER 35 U.S.C. § 271(b-c)

45. Plaintiffs reallege and incorporate by reference paragraphs 1-44.

46. Upon FDA approval of Novel's ANDA No. 205841, Novel will infringe one or more claims of the '886 patent, either literally or under the doctrine of equivalents, by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c).

47. On information and belief, Novel intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Novel's ANDA product with an FDA-approved product insert that will direct physicians and patients in the use of Novel's ANDA product.

48. On information and belief, by marketing its ANDA product with the FDA-approved product insert, Novel will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Novel knows will directly infringe one or more claims of the ’886 patent.

49. On information and belief, Novel has knowledge of the ’886 patent and knows that it will aid and abet another’s direct infringement of one or more claims of the ’886 patent, either literally or under the doctrine of equivalents.

50. On information and belief, Novel’s offer to sell, sale, and/or importation of Novel’s ANDA product for use in accordance with the FDA-approved product insert will actively induce infringement under 35 U.S.C. § 271(b) of one or more claims of the ’886 patent, either literally or under the doctrine of equivalents, immediately following approval of Novel’s ANDA.

51. On information and belief, Novel knows that its ANDA product with the FDA-approved product insert is especially made or adapted for the maintenance of remission of ulcerative colitis in adults, is a material part of the invention claimed in the ’886 patent, and has no substantial noninfringing use.

52. On information and belief, Novel has knowledge of the ’886 patent and knows that use of its ANDA product in accordance with the FDA-approved product insert will directly infringe one or more claims of the ’886 patent.

53. On information and belief, Novel’s offer to sell, sale, and/or importation of Novel’s ANDA product for use in accordance with the FDA-approved product insert will contributorily infringe under 35 U.S.C. § 271(c) one or more claims of the ’886 patent, either literally or under the doctrine of equivalents.

54. As a result of Novel'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 V

INFRINGEMENT OF THE '965 PATENT UNDER 35 U.S.C. § 271(e)(2)

55. Plaintiffs reallege and incorporate by reference paragraphs 1-54.

56. On information and belief, Novel's ANDA product is covered by one or more claims of the '965 patent.

57. By submitting its ANDA No. 205841 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 Novel's ANDA product before the expiration of the '965 patent, Novel has infringed, either literally or under the doctrine of equivalents, one or more claims of the '965 patent under 35 U.S.C. § 271(e)(2).

COUNT VI

DELCARATORY JUDGMENT OF INFRINGEMENT OF THE '965 PATENT UNDER 35 U.S.C. § 271(c)

58. Plaintiffs reallege and incorporate by reference paragraphs 1-57.

59. Upon FDA approval of Novel's ANDA No. 205841, Novel will infringe one or more claims of the '965 patent, either literally or under the doctrine of equivalents, by contributing to infringement by others under 35 U.S.C. §§ 271(c).

60. On information and belief, Novel intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Novel's ANDA product with an FDA-approved product insert that will direct physicians and patients in the use of Novel's ANDA product.

61. On information and belief, Novel knows that its ANDA product with the FDA-approved product insert is especially made or adapted for the maintenance of remission of ulcerative colitis in adults, is a material part of the invention claimed in the ’965 patent, and has no substantial noninfringing use.

62. On information and belief, Novel has knowledge of the ’965 patent and knows that use of its ANDA product in accordance with the FDA-approved product insert will directly infringe one or more claims of the ’965 patent.

63. On information and belief, Novel’s offer to sell, sale, and/or importation of Novel’s ANDA product for use in accordance with the FDA-approved product insert will contributorily infringe under 35 U.S.C. § 271(c) one or more claims of the ’965 patent, either literally or under the doctrine of equivalents.

64. As a result of Novel’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; 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), Novel’s submission to the FDA of ANDA No. 205841 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Novel’s ANDA product 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), Novel's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 205841 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Novel's ANDA product before the expiration of United States Patent No. 6,551,620 and United States Patent No. 8,337,886 were acts of infringement;

D. A declaration that Novel 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 35 U.S.C. §§ 271(c) by its manufacture, use, offering to sell, and sale in, and/or importation into the United States of Novel's ANDA product prior to expiration of the Orange Book-listed patents and any additional dates of exclusivity therefor;

E. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Novel, 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 United States Patent No. 6,551,620; United States Patent No. 8,337,886; and United States Patent No. 8,496,965 with Novel's ANDA product prior to the expiration date of the Orange Book-listed patents, and any additional dates of exclusivity;

F. A permanent injunction enjoining Novel and all persons acting in concert with Novel from seeking, obtaining, or maintaining approval of Novel's ANDA No. 205841 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;

G. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Novel's ANDA product 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.

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

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

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

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

Dated: February 18, 2014

Respectfully submitted,

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