

**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.	)	
	)	

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**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 a patent related to Salix’s pharmaceutical product, Apriso<sup>®</sup> (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 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.).

10. This Court has personal jurisdiction over Novel because it has submitted to this Court's jurisdiction in a case involving the same parties. *See, e.g., Salix Pharms., Inc. et al. v. Novel Labs. Inc.*, No. 14-cv-213-GMS.

### **NATURE OF THIS ACTION**

11. 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<sup>®</sup> pharmaceutical product prior to the expiration of United States Patent Numbers 6,551,620 ("the '620 patent"), 8,337,886 ("the '886 patent"), 8,496,965 ("the '965 patent"), and 8,865,688 ("the '688 patent") (collectively, "the Orange Book-listed patents").

### **THE PATENT IN SUIT**

12. Falk is the owner by assignment of the '688 patent, entitled "Compositions and Methods For Treatment of Bowel Diseases With Granulated Mesalamine." The '688 patent was duly and legally issued by the USPTO on October 21, 2014. A true and correct copy of the '688 patent is attached as Exhibit D.

13. Salix is Falk's exclusive licensee of the '688 patent.

**APRISO® MESALAMINE CAPSULES**

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

15. 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.

16. In accordance with 21 C.F.R. § 314.53, Salix has listed the ’620, ’886, ’965, and ’688 patents in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) as covering Apriso®.

**NOVEL’S ANDA AND FIRST NOTICE LETTER**

17. Novel sent Salix a letter (“the First Notice Letter”), dated January 6, 2014, notifying Salix that Novel had filed ANDA No. 205841 (“Novel’s ANDA”) seeking approval for the commercial manufacture, importation, use or sale of 375 mg mesalamine oral extended release capsules (“Novel’s ANDA product”) prior to the expiration of the ’620, ’886, and ’965 patents and stating that Novel was providing information to Salix pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Salix received the First Notice Letter on or about January 7, 2014.

18. As stated in the First 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 ’620, ’886, and ’965 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.

19. The First Notice Letter did not include any statement on the ’688 patent, as that patent had not yet been issued by the USPTO or listed in the Orange Book.

20. 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.”

21. Plaintiffs brought suit against Novel in this Court on February 18, 2014, alleging infringement of the Orange Book-listed ’620, ’886, and ’965 patents (the “First ANDA Action”). The First ANDA Action was filed within forty-five (45) days of Plaintiffs’ receiving the First Notice Letter. The First ANDA Action was assigned Civil Action No. 14-cv-213-GMS (D. Del.).

### **NOVEL’S SECOND NOTICE LETTER**

22. After the ’688 patent issued on October 21, 2014, Plaintiffs duly listed the ’688 patent in the Orange Book.

23. On information and belief, on or about December 19, 2014, Novel amended ANDA No. 205841 to include a “Paragraph IV Certification” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that Orange Book-listed ’688 patent is “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.

24. Novel sent Salix a letter (“the ’688 Notice Letter”), dated December 19, 2014, notifying Salix that Novel had filed ANDA No. 205841 seeking approval for the commercial manufacture, importation, use or sale of Novel’s ANDA product prior to the expiration of the ’688 patent and stating that Novel was providing information to Salix pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Salix received the ’688 Notice Letter on or about December 30, 2014.

25. On information and belief and as stated in the ’688 Notice Letter, Novel filed its ANDA with the FDA under 21 U.S.C. § 355(j), seeking approval to market Novel’s ANDA product before the expiration of the Orange Book-listed ’688 patent.

26. On information and belief and as stated in the '688 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 '688 patent.

27. On information and belief and as stated in the '688 Notice Letter, Novel's ANDA contains bioavailability and/or bioequivalence data comparing Novel's ANDA product to Apriso<sup>®</sup>.

28. The '688 Notice Letter enclosed what was purportedly the "Detailed Factual and Legal Bases for NOVEL'S Certification That U.S. Patent No. 8,865,688 B2 Is Invalid and/or Will Not be Infringed."

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

30. 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<sup>®</sup> 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 '688 PATENT UNDER 35 U.S.C. § 271(e)(2)**

31. Plaintiffs reallege and incorporate by reference paragraphs 1-30.

32. On information and belief, Novel's ANDA product is covered by one or more claims of the '688 patent.

33. 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 '688 patent,

Novel has infringed, either literally or under the doctrine of equivalents, one or more claims of the '688 patent under 35 U.S.C. § 271(e)(2).

34. Upon FDA approval of Novel's ANDA No. 205841, Novel will infringe one or more claims of the '688 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Novel's ANDA product 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).

35. 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.

36. 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 '688 patent.

37. On information and belief, Novel has knowledge of the '688 patent and knows that it will aid and abet another's direct infringement of one or more claims of the '688 patent, either literally or under the doctrine of equivalents.

38. 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 '688 patent, either literally or under the doctrine of equivalents, immediately following approval of Novel's ANDA.

39. 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 '688 patent, and has no substantial noninfringing use.

40. On information and belief, Novel has knowledge of the '688 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 '688 patent.

41. 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 '688 patent, either literally or under the doctrine of equivalents.

42. As a result of Novel's infringement of the '688 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. 8,865,688 are valid and enforceable;

B. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Novel's amendment of ANDA No. 205841 to include a certification pursuant 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to United States Patent No. 8,865,688 and 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. 8,865,688 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 amendment of ANDA No. 205841 to include a certification pursuant 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to United States Patent No. 8,865,688 and 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. 8, 865,688 was an act of infringement;

D. A declaration that Novel would infringe one or more claims of United States Patent No. 8,865,688 under 35 U.S.C. §§ 271(a)-(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. 8,865,688 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. 8,865,688, 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. 8,865,688, 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: January 8, 2015

Respectfully submitted,

/s/ Mary W. Bourke

Mary W. Bourke (#2356)

Kristen Healey Cramer (#4512)

Dana K. Severance (#4869)

Daniel M. Attaway (#5130)

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

222 Delaware Avenue, Suite 1501

Wilmington, DE 19801

(302) 252-4333

mbourke@wcsr.com

kcramer@wcsr.com

deseverance@wcsr.com

dattaway@wcsr.com

*Attorney for Plaintiffs Salix Pharmaceuticals, Inc.  
and Dr. Falk Pharma GmbH*