IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., MERCK KGaA and MERCK PATENT GESELLSCHAFT MIT BESCHRÄNKTER HAFTUNG,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ACCORD HEALTHCARE INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd. (collectively, "Forest"), and Merck KGaA and Merck Patent Gesellschaft mit beschränkter Haftung ("Merck Patent GmbH") (collectively, "Merck"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendant Accord Healthcare Inc. ("Accord") of Abbreviated New Drug Application ("ANDA") No. 208209 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Forest's Viibryd® product prior to the expiration of U.S. Patent Nos. 7,834,020; 8,193,195; 8,236,804; and 8,673,921.

PARTIES

2. Plaintiff Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Cumberland House, 1 Victoria Street, Hamilton HM11, Bermuda.

4. Plaintiff Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt Hessen, Germany.

5. Plaintiff Merck Patent GmbH is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt Hessen, Germany.

6. On information and belief, Defendant Accord is a corporation organized and existing under the laws of the State of North Carolina, with its principal place of business at 1009 Slater Road, Suite 210 B, Durham, North Carolina, 27703.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, and 1338(a).

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

9. This Court has personal jurisdiction over Accord because it has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in Delaware, and deriving substantial revenue from such activities.

10. On information and belief, Accord is in the business of formulating, developing, manufacturing, marketing, and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, including in the State of Delaware.

11. On information and belief, Accord has purposefully conducted business in the State of Delaware, continues to conduct business in Delaware, and Delaware is a likely

destination of Accord's products, including its proposed generic version of Viibryd® that is at issue in this action.

12. On information and belief, upon approval of Accord's Abbreviated New Drug Application ("ANDA") No. 208209, Accord will market and sell vilazodone (10, 20, and 40 mg) tablets (the "Accord ANDA Product") in Delaware and throughout the United States and will derive substantial revenue therefrom.

13. On information and belief, upon approval of Accord's ANDA No. 208202, Accord will place the Accord ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in Delaware and throughout the United States.

14. On information and belief, as a result of its submission of ANDA No. 208209, Accord has committed a tortious act of patent infringement 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiff Forest Laboratories, LLC, a Delaware company.

15. Accord has previously availed itself of this forum, for example, by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Acorda Therapeutics Inc. v. Accord Healthcare Inc.*, No. 14-932-LPS (D. Del.); *Cephalon, Inc. v. Accord Healthcare Inc.*, C.A. No. 13-2095-GMS (D. Del); *UCB Inc.. v. Accord Healthcare Inc.*, C.A. No. 13-1206-LPS (D. Del); *Millennium Pharmaceuticals Inc. v. Accord Healthcare Inc.*, C.A. No. 12-1490-GMS (D. Del). On information and belief, Accord has been a defendant in at least fourteen ANDA suits in the District of Delaware, and it has not challenged this Court's exercise of personal jurisdiction over it in any of those prior actions.

16. Concurrently with this Complaint, Plaintiffs are filing infringement actions in this judicial district against three other generic drug companies that have sought FDA approval to market and sell generic versions of Viibryd®. Plaintiffs would therefore be substantially burdened if forced to pursue parallel litigation in different districts.

17. This Court has personal jurisdiction over Accord by virtue of, *inter alia*, the above-mentioned facts.

BACKGROUND

18. United States Patent No. 7,834,020 ("the '020 patent"), entitled "Polymorphic Forms of 1-'4-(5-Cyanoindol-3-YL)Butyl-4-(2-Carbamoylbenzofuran-5-YL) Piperazine Hydrochloride" (attached as Exhibit A), was duly and legally issued on November 16, 2010.

19. United States Patent No. 8,193,195 ("the '195 patent"), entitled "Polymorphic Forms of 1-'4-(5-Cyanoindol-3-YL)Butyl-4-(2-Carbamoylbenzofuran-5-YL) Piperazine Hydrochloride" (attached as Exhibit B), was duly and legally issued on June 5, 2012.

20. United States Patent No. 8,236,804 ("the '804 patent"), entitled "Polymorphic Forms of 1-'4-(5-Cyanoindol-3-YL)Butyl-4-(2-Carbamoylbenzofuran-5-YL) Piperazine Hydrochloride" (attached as Exhibit C), was duly and legally issued on August 7, 2012.

21. United States Patent No. 8,673,921 ("the '921 patent"), entitled "Polymorphic Forms of 1-[4-(5-Cyanoindol-3-YL)Butyl]-4-(2-Carbamoylbenzofuran-5-YL) Piperazine Hydrochloride" (attached as Exhibit D), was duly and legally issued on March 18, 2014.

22. The '020, '195, '804, and '921 patents, are owned by Merck Patent GmbH, a wholly owned subsidiary of Plaintiff Merck KGaA. Forest is the exclusive licensee of the'020, '195, '804, and '921 patents with respect to commercializing pharmaceutical products containing vilazodone in the United States.

23. Viibryd® (vilazodone HCl) is approved by the FDA for the treatment of major depressive disorder, and it is available in 10, 20, and 40 mg tablets for oral use.

24. Forest Laboratories, Inc. (n/k/a Forest Laboratories, LLC) holds New Drug Application ("NDA") No. 022567, which was approved on January 21, 2011.

25. The '020, '195, '804, and '921 patents are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book," for Viibryd®.

26. By letters dated February 19, 2015 and February 20, 2015 (collectively, the "Notice Letter"), Accord notified Forest that it had submitted to the FDA ANDA No. 208209 seeking approval to market and sell the Accord ANDA Product in the United States prior to the expiration of the '020, '195, '804, and '921 patents.

27. In the Notice Letter, Accord stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) with respect to the '020, '195, '804, and '921 patents, and alleged that these patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Accord ANDA Product in the United States.

28. Accord's Notice Letter contained an offer of confidential access, the terms of which the parties have been negotiating in good faith in an effort to reach a mutually-acceptable agreement, and under which Accord's ANDA would be provided to Plaintiffs. The parties have been unable to reach agreement. Plaintiffs require discovery from Accord.

29. This action is being commenced before the expiration of forty-five days from the date of Forest's receipt of the Notice Letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,834,020

30. Plaintiffs incorporate each of the preceding paragraphs 1-29 as if fully set forth herein.

31. Accord's submission of ANDA No. 208209 for the purpose of obtaining approval to engage in the commercial import, manufacture, use, offer for sale, and/or sale of the Accord ANDA Product in the United States before the expiration of the '020 patent was an act of infringement of the '020 patent under 35 U.S.C. § 271(e)(2).

32. The commercial manufacture, use, offer for sale, sale and/or importation of the Accord ANDA Product in the United States would infringe one for more claims of the '020 patent under 35 U.S.C. § 217(a), (b) and/or (c).

33. Accord had knowledge of the '020 patent prior to submitting its ANDA to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation with respect to the '020 patent.

34. On information and belief, use of the Accord ANDA Product in accordance with and as directed by Accord's proposed labeling for that product would infringe one or more claims of the '020 patent.

35. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product with its proposed labeling upon approval of ANDA No. 208209.

36. On information and belief, Accord will infringe and will actively induce or contribute to the infringement of the '020 patent when ANDA No. 208209 is approved, and plans and intends to, and will do so upon approval.

37. On information and belief, Accord acted without a reasonable basis for believing that it would not be liable for infringing the '020 patent and/or actively inducing infringement of the '020 patent.

38. Unless Accord is enjoined from infringing the '020 patent and/or actively inducing or contributing to the infringement of the '020 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 8,193,195

39. Plaintiffs incorporate each of the preceding paragraphs 1-38 as if fully set forth herein.

40. Accord's submission of ANDA No. 208209 for the purpose of obtaining approval to engage in the commercial import, manufacture, use, offer for sale, and/or sale of the Accord ANDA Product in the United States before the expiration of the '195 patent was an act of infringement of the '195 patent under 35 U.S.C. § 271(e)(2).

41. The commercial manufacture, use, offer for sale, sale and/or importation of the Accord ANDA Product in the United States would infringe one for more claims of the '195 patent under 35 U.S.C. § 217(a), (b) and/or (c).

42. Accord had knowledge of the '195 patent prior to submitting its ANDA to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation with respect to the '195 patent.

43. On information and belief, use of the Accord ANDA Product in accordance with and as directed by Accord's proposed labeling for that product would infringe one or more claims of the '195 patent.

44. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product with its proposed labeling upon approval of ANDA No. 208209.

45. On information and belief, Accord will infringe and will actively induce or contribute to the infringement of the '195 patent when ANDA No. 208209 is approved, and plans and intends to, and will do so upon approval.

46. On information and belief, Accord acted without a reasonable basis for believing that it would not be liable for infringing the '195 patent and/or actively inducing infringement of the '195 patent.

47. Unless Accord is enjoined from infringing the '195 patent and/or actively inducing or contributing to the infringement of the '195 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 8,236,804

48. Plaintiffs incorporate each of the preceding paragraphs 1-47 as if fully set forth herein.

49. Accord's submission of ANDA No. 208209 for the purpose of obtaining approval to engage in the commercial import, manufacture, use, offer for sale, and/or sale of the Accord ANDA Product in the United States before the expiration of the '804 patent was an act of infringement of the '804 patent under 35 U.S.C. § 271(e)(2).

50. The commercial manufacture, use, offer for sale, sale and/or importation of the Accord ANDA Product in the United States would infringe one for more claims of the '804 patent under 35 U.S.C. § 217(a), (b) and/or (c).

51. Accord had knowledge of the '804 patent before submitting its ANDA to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation with respect to the '804 patent.

52. On information and belief, use of the Accord ANDA Product in accordance with and as directed by Accord's proposed labeling for that product would infringe one or more claims of the '804 patent.

53. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product with its proposed labeling upon approval of ANDA No. 208209.

54. On information and belief, Accord will infringe and will actively induce or contribute to the infringement of the '804 patent when ANDA No. 208209 is approved, and plans and intends to, and will do so upon approval.

55. On information and belief, Accord acted without a reasonable basis for believing that it would not be liable for infringing the '804 patent and/or actively inducing infringement of the '804 patent.

56. Unless Accord is enjoined from infringing the '804 patent and/or actively inducing or contributing to the infringement of the '804 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 8,673,921

57. Plaintiffs incorporate each of the preceding paragraphs 1-56 as if fully set forth herein.

58. Accord's submission of ANDA No. 208209 for the purpose of obtaining approval to engage in the commercial import, manufacture, use, offer for sale, and/or sale of the Accord

ANDA Product in the United States before the expiration of the '921 patent was an act of infringement of the '921 patent under 35 U.S.C. § 271(e)(2).

59. The commercial manufacture, use, offer for sale, sale and/or importation of the Accord ANDA Product in the United States would infringe one for more claims of the '921 patent under 35 U.S.C. § 217(a), (b) and/or (c).

60. Accord had knowledge of the '921 patent prior to submitting its ANDA to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation with respect to the '921 patent.

61. On information and belief, use of the Accord ANDA Product in accordance with and as directed by Accord's proposed labeling for that product would infringe one or more claims of the '921 patent.

62. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product with its proposed labeling upon approval of ANDA No. 208209.

63. On information and belief, Accord will infringe and will actively induce or contribute to the infringement of the '921 patent when ANDA No. 208209 is approved, and plans and intends to, and will do so upon approval.

64. On information and belief, Accord acted without a reasonable basis for believing that it would not be liable for infringing the '921 patent and/or actively inducing infringement of the '921 patent.

65. Unless Accord is enjoined from infringing the '921 patent and/or actively inducing or contributing to the infringement of the '921 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays that this Court grant the following relief:

(a) A judgment that Accord's submission of ANDA No. 208209 was an act of infringement of one or more claims of the '020, '195, '804, and '921 patents, and that Accord's manufacture, use, offer to sell, sale, or importation of the Accord ANDA Product in or into the United States prior to the expiration of the '020, '195, '804, and '921 patents, will infringe and/or actively induce or contribute to the infringement of one or more claims the '020, '195, '804, and '921 patents;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Accord' ANDA No. 208209, shall not be earlier than the latest expiration date of the '020, '195, '804, and '921 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(c) An Order permanently enjoining Accord, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, or importing in or into the United States the Accord ANDA Product, or any product or compound that infringes the '020, '195, '804, and '921 patents, or inducing the infringement of the '020, '195, '804, and '921 patents until after the latest expiration date of the '020, '195, '804, and '921 patents, including any extension and/or additional periods of exclusivity to which Forest is or becomes entitled.

(d) A declaration that this is an exceptional case and an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. §§ 285 and 271(e)(4), together with reasonable costs; and

(e) Such further and other relief as this Court deems proper and just.

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