IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER LLC, *Plaintiff*, **-v-** **AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA, INC.,** *Defendants*.	Civil Action No. _____

COMPLAINT

Plaintiff Reckitt Benckiser LLC ("Reckitt" or "Plaintiff"), by its attorneys, Young Conaway Stargatt & Taylor, LLP and Hiscock & Barclay, LLP, hereby alleges as follows:

NATURE OF THE ACTION

1. 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, arising from Aurobindo Pharma Limited's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Plaintiff Reckitt's MUCINEX® DM product prior to the expiration of United States Patent Nos. 6,372,252 ("the '252 patent"), 6,955,821 ("the '821 patent"), and 7,838,032 ("the '032 patent") (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff Reckitt is a corporation incorporated and existing under the laws of the State of Delaware, having a principal place of business at 399 Interpace Parkway, Parsippany, New Jersey 07054.

3. On information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and exiting under the laws of India, having a registered office at Plot no. 2, Maitrivihar, Ameerpet, Hyderabad – 500038, Telangana, India and a principal place of business at Water Mark Building, Plot no. 11, Survey no. 9, Kondapur, Hitech City, Hyderabad – 500 084, Telangana, India.

4. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and exiting under the laws of Delaware and has a principal place of business at 6 Wheeling Road, Dayton, New Jersey, 08810.

5. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Limited and is controlled by Aurobindo Pharma Limited.

6. Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. are hereinafter referred to collectively as "Aurobindo" or "Defendants."

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over the asserted claims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201, and 2202.

8. On information and belief, Aurobindo Pharma Limited is in the business of developing and manufacturing generic pharmaceutical products. On information and belief, Aurobindo Pharma USA, Inc. is the agent, affiliate, representative, alter ego of, and/or acts in concert with Aurobindo Pharma Limited for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including this judicial district.

9. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because it is incorporated and registered to do business in Delaware, and because it has purposely availed itself

of the privilege of doing business in this judicial district. Further, Aurobindo Pharma USA, Inc. maintains continuous and systematic contacts with the State of Delaware, including the sale of generic pharmaceutical drugs to Delaware residents, so as to reasonably allow jurisdiction to be exercised over it.

10. This Court has personal jurisdiction over Aurobindo Pharma Limited because it does substantial business in Delaware, derives substantial revenue from Delaware, and engages in persistent conduct with Delaware, with and through its agent Aurobindo Pharma USA, Inc., including, on information and belief, the preparation and submission of the ANDA No. 20-6941.

11. On information and belief, Aurobindo Pharma Limited has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has taken advantage of the rights and protections provided by this Court through the assertion of counterclaims, including in at least Civil Action No. 1:14-cv-00664-GMS (D. Del.).

12. On information and belief, Aurobindo Pharma Limited and/or Aurobindo Pharma USA, Inc. participated in the preparation and/or filing of ANDA No. 20-6941.

13. On information and belief, this Court has personal jurisdiction over Aurobindo by virtue of, inter alia, the facts alleged in paragraphs 8-12.

14. In the alternative, this Court has personal jurisdiction over Aurobindo Pharma Limited pursuant to Rule 4(k)(2) of the Federal Rules of Civil Procedure. This claim arises under federal law. Aurobindo Pharma Limited is headquartered in India and organized under the laws of India. Aurobindo Pharma Limited has purposely availed itself of the benefits and protections afforded by United States law by filing its ANDA No. 20-6941 with the FDA in order to market and sell generic Dextromethorphan Hydrobromide and Guaifenesin Extended-release Tablets, 30 mg/600 mg and 60 mg/1200 mg (OTC), within the United States. In addition,

on information and belief, Aurobindo Pharma Limited has filed other ANDAs in order to market and sell other generic products in the United States, and on information and belief has sold and continues to sell such products within the United States.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and/or 1400, because, upon information and belief, a substantial part of the events or omissions giving rise to the claims occurred in this judicial district.

THE PATENTS-IN-SUIT

16. Plaintiff Reckitt is the lawful owner of the ’252 patent. The ’252 patent, entitled “Guaifenesin Sustained Release Formulation and Tablets,” duly and legally issued on April 16, 2002, naming Ralph W. Blume, Robert D. Davis, and Donald Jeffrey Keyser as inventors. A true and correct copy of the ’252 patent is attached hereto as Exhibit A.

17. Plaintiff Reckitt is the lawful owner of the ’821 patent. The ’821 patent, entitled “Sustained Release Formulations of Guaifenesin and Additional Drug Ingredients,” duly and legally issued on October 18, 2005, naming Ralph W. Blume, Robert D. Davis, and Donald Jeffrey Keyser as inventors. A true and correct copy of the ’821 patent is attached hereto as Exhibit B.

18. Plaintiff Reckitt is the lawful owner of the ’032 patent. The ’032 patent, entitled “Sustained Release of Guaifenesin,” duly and legally issued on November 23, 2010, naming Ralph W. Blume, Robert D. Davis, and Donald Jeffrey Keyser as inventors. A true and correct copy of the ’032 patent is attached hereto as Exhibit C.

MUCINEX® DM

19. Plaintiff Reckitt is the holder of New Drug Application ("NDA") No. 021-620 for Guaifenesin 600 mg/Dextromethorphan Hydrobromide 30 mg and Guaifenesin 1200 mg/Dextromethorphan Hydrobromide 60 mg. These tablets are marketed by Reckitt in the United States under the tradename MUCINEX® DM, and are indicated to help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and to make coughs more productive.

20. On April 29, 2004, the FDA approved NDA No. 021-620 for the manufacture, marketing, and sale of MUCINEX® DM. Plaintiff Reckitt has manufactured, marketed, and sold MUCINEX® DM under NDA No. 021-620 since its approval.

21. The patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering MUCINEX® DM.

DEFENDANTS' ANDA

22. Plaintiff Reckitt received a letter from Aurobindo dated August 4, 2014 (the "Notification Letter"), stating that ANDA No. 20-6941 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA.

23. The Notification Letter further states that Aurobindo submitted ANDA No. 20-6941 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, or sale of Dextromethorphan Hydrobromide and Guaifenesin Extended-release Tablets, 30 mg/600 mg and 60 mg/1200 mg (OTC) ("Defendants' generic product") before the expiration of the patents-in-suit. On information and belief, ANDA No. 20-6941 refers to and relies on

Plaintiff Reckitt's NDA 021-620 for MUCINEX® DM and purports to contain data showing bioequivalence of Defendants' generic product with MUCINEX® DM.

24. Plaintiff Reckitt received a copy of Aurobindo's Notification Letter on or about August 5, 2014.

25. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Reckitt commenced this action within 45 days of receiving Aurobindo's Notification Letter on August 5, 2014.

COUNT I
(Infringement of the '252 Patent Under 35 U.S.C. § 271(e)(2)(A))

26. Plaintiff repeats and realleges all allegations contained in Paragraphs 1-25 above as if they were stated in full herein.

27. On information and belief, Defendants' generic product is covered by at least claim 24 of the '252 patent.

28. By filing ANDA No. 20-6941 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' generic product prior to the expiration of the '252 patent, Aurobindo has infringed at least claim 24 of the '252 patent under 35 U.S.C. § 271(e)(2)(A).

29. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-6941 to be a date which is not any earlier than the expiration date of the '252 patent.

COUNT II
(Declaratory Judgment of Infringement of the '252 Patent Under 35 U.S.C. § 271)

30. Plaintiff repeats and realleges all allegations contained in Paragraphs 1-29 above as if they were stated in full herein.

31. On information and belief, unless enjoined by this Court, Aurobindo plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product with its proposed labeling immediately following approval of ANDA No. 20-6941.

32. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic product before the expiration of the '252 patent would infringe at least claim 24 of the '252 patent under 35 U.S.C. § 271.

33. The acts of infringement by Defendants set forth above will cause Plaintiff irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

COUNT III
(Infringement of the '821 Patent Under 35 U.S.C. § 271(e)(2)(A))

34. Plaintiff repeats and realleges all allegations contained in Paragraphs 1-33 above as if they were stated in full herein.

35. On information and belief, Defendants' generic product is covered by at least claim 1 of the '821 patent.

36. By filing ANDA No. 20-6941 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' generic product prior to the expiration of the '821 patent, Aurobindo has infringed at least claim 1 of the '821 patent under 35 U.S.C. § 271(e)(2)(A).

37. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-6941 to be a date which is not any earlier than the expiration date of the '821 patent.

COUNT IV
(Declaratory Judgment of Infringement of the '821 Patent Under 35 U.S.C. § 271)

38. Plaintiff repeats and realleges all allegations contained in Paragraphs 1-37 above as if they were stated in full herein.

39. On information and belief, unless enjoined by this Court, Aurobindo plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product with its proposed labeling immediately following approval of ANDA No. 20-6941.

40. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic product before the expiration of the '821 patent would infringe at least claim 1 of the '821 patent under 35 U.S.C. § 271.

41. The acts of infringement by Defendants set forth above will cause Plaintiff irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

COUNT V
(Infringement of the '032 Patent Under 35 U.S.C. § 271(e)(2)(A))

42. Plaintiff repeats and realleges all allegations contained in Paragraphs 1-41 above as if they were stated in full herein.

43. On information and belief, Defendants' generic product is covered by at least claim 1 of the '032 patent.

44. By filing ANDA No. 20-6941 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants' generic product prior to the expiration of the '032 patent, Aurobindo has infringed at least claim 1 of the '032 patent under 35 U.S.C. § 271(e)(2)(A).

45. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-6941 to be a date which is not any earlier than the expiration date of the '032 patent.

COUNT VI
(Declaratory Judgment of Infringement of the '032 Patent Under 35 U.S.C. § 271)

46. Plaintiff repeats and realleges all allegations contained in Paragraphs 1-45 above as if they were stated in full herein.

47. On information and belief, unless enjoined by this Court, Aurobindo plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product with its proposed labeling immediately following approval of ANDA No. 20-6941.

48. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic product before the expiration of the '032 patent would infringe at least claim 1 of the '032 patent under 35 U.S.C. § 271.

49. The acts of infringement by Defendants set forth above will cause Plaintiff irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter:

A. A judgment that Aurobindo has infringed each of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting and maintaining ANDA No. 20-6941;

B. A declaratory judgment that Defendants' commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' generic product would infringe each of the patents-in-suit under 35 U.S.C. § 271;

C. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions as claimed in the patents-in-suit, including Defendants' generic product;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 20-6941 be a date that is not earlier than the expiration of the last to expire of the patents-in-suit, including any extensions thereof and any later expiration of exclusivity associated with those patents;

E. To the extent Aurobindo committed any acts with respect to the composition claims in the patents-in-suit, other than those expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiff be awarded damages for such acts;

F. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiff its reasonable attorneys' fees;

G. Any and all other relief as the Court deems just and proper.

Date: September 17, 2014

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