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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

AUROBINDO PHARMA USA INC.,)	
AUROBINDO PHARMA LTD., and)	Civil Action No.
AUROMEDICS PHARMA LLC,)	
)	JURY TRIAL DEMANDED
Plaintiffs,)	
)	
v.)	<i>Filed Electronically</i>
)	
APICORE US LLC and)	
MYLAN INSTITUTIONAL LLC,)	
)	
Defendants.)	

COMPLAINT FOR DECLARATORY JUDGMENT AND DEMAND FOR JURY TRIAL

Plaintiffs Aurobindo Pharma USA Inc. (“Aurobindo USA”), Aurobindo Pharma Ltd. (“Aurobindo Ltd.”), and AuroMedics Pharma LLC (“AuroMedics”) (together, “Aurobindo”) for their Complaint against Apicore US LLC (“Apicore”) and Mylan Institutional LLC (“Mylan”) (together, “Defendants”) allege as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of non-infringement and invalidity under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of

the United States, Title 35, United States Code, in response to accusations of infringement by Defendants, regarding Aurobindo's Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"), to manufacture and sell an isosulfan blue for injection product prior to the expiration of U.S. Patent No. 7,662,992 ("the '992 patent"), 8,969,616 ("the '616 patent") and 9,353,050 ("the '050 patent").

THE PARTIES

2. Aurobindo USA is a Delaware corporation having a place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

3. Aurobindo Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India.

4. AuroMedics is a Delaware corporation having a place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

5. On information and belief, Apicore is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 49 Napoleon Court, Somerset, New Jersey 08873.

6. On information and belief, Apicore is a pharmaceutical company in the field of active pharmaceutical ingredient manufacturing.

7. On information and belief, Mylan is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 1718 Northrock Court, Rockford, Illinois 61103.

8. On information and belief, Mylan is a pharmaceutical company that develops and commercializes injectable pharmaceutical products.

9. On information and belief, Apicore owns or has asserted ownership of the '992 patent, entitled "Process for Preparation of Isosulfan Blue," a copy of which is attached hereto as Exhibit A.

10. On information and belief, Apicore owns or has asserted ownership of the '616 patent, entitled "Process for Preparation of Isosulfan Blue," a copy of which is attached hereto as Exhibit B.

11. On information and belief, Apicore owns or has asserted ownership of the '050 patent, entitled "Process for Preparation of Isosulfan Blue," a copy of which is attached hereto as Exhibit C.

JURISDICTION AND VENUE

12. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code.

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 et seq.

14. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction which seeks a declaratory judgment that the '992, '616 and '050 patents are invalid and/or are not infringed.

15. The Court has personal jurisdiction over Mylan because of its continuous and systematic contacts with the state of New Jersey, including its conducting of substantial and regular business therein through the marketing and sales of its pharmaceutical products in New Jersey.

16. The Court has personal jurisdiction over Apicore because of its continuous and systematic contacts with the state of New Jersey, including its conducting of substantial and regular business therein through the marketing and sales of its pharmaceutical products in New Jersey, and through Apicore having a principle place of business at 49 Napoleon Court, Somerset, NJ 08873.

17. Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b), (c), and (d).

PATENTS-IN-SUIT

18. On its face, the '992 patent issued from Application No. 12/180,057 on February 16, 2010, with assignee "Apicore, LLC," naming Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial as inventors. The '992 patent claims processes for preparing compounds purporting to include isosulfan blue.

19. On its face, the '616 patent issued from Application No. 13/951,034 on March 3, 2015, with assignee "Apicore US LLC," naming Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial as inventors. The '616 patent claims processes for preparing compounds purporting to include isosulfan blue.

20. On its face, the '050 patent issued from Application No. 13/310,019 on May 31, 2016, with assignee "Apicore US LLC," naming Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial as inventors. The '050 patent claims compounds purporting to include isosulfan blue with purity of at least 99.0% by HPLC.

BACKGROUND

21. Aurobindo has submitted Abbreviated New Drug Application (“ANDA”) No. 206831 for 1% strength isosulfan blue for injection. This ANDA sought approval to market Aurobindo’s isosulfan blue for injection product in the United States.

22. On February 2, 2016, the FDA approved Aurobindo’s ANDA No. 206831.

23. On information and belief, Mylan, by itself or through affiliated entities, also markets a 1% isosulfan blue for injection product in the United States, purportedly pursuant to ANDA No. 90,874. ANDA No. 90,874 was approved July 20, 2010.

24. ANDA No. 90,874 was originally held by Synerx.

25. Upon information and belief, Mylan acquired Synerx on or around January, 2011.

26. Upon information and belief, Apicore has entered into an exclusive arrangement with Mylan to commercialize isosulfan blue products purportedly manufactured according to the claims of the ‘992, ‘616 and ‘050 patents.

27. On March 2, 2016, Defendants sent a letter to Aurobindo Ltd. and Aurobindo USA, alleging that Aurobindo Ltd. and/or Aurobindo USA infringe one or more claims of the ‘992 and ‘616 patents through Aurobindo’s ANDA No. 206831.

28. On March 3, 2016, Defendants sent a letter to AuroMedics alleging that Aurobindo Ltd. and/or Aurobindo USA infringe one or more claims of the ‘992 and ‘616 patents.

29. On March 7, 2016, Aurobindo sent a letter to Defendants stating that Aurobindo does not believe it infringes the ‘992 patent and the ‘616 patent.

30. On March 8, 2016, Defendants sent Aurobindo a letter requesting information regarding Aurobindo’s isosulfan blue process and a sample of Aurobindo’s isosulfan blue product.

31. On March 14, 2016, Aurobindo and Defendants entered into a non-disclosure agreement prior to additional information being exchanged.

32. On March 14, 2016, and March 18, 2016, Aurobindo supplied Defendants with additional information for the sole purpose of Defendants' infringement analysis, for outside counsel and experts' eyes only.

33. Subsequent letters were exchanged on March 28, 2016, March 29, 2016, and April 1, 2016, concerning Defendants' request for additional information.

34. On May 11, 2016, Defendants sued Aurobindo, alleging, *inter alia*, infringement of the '992 patent and the '616 patent, in *Mylan Inst. LLC, et al. v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 16-cv-491, in the United States District Court for the Eastern District of Texas against Aurobindo (the "Texas Action").

35. On May 31, 2016, prior to answer by Aurobindo, Defendants filed a First Amended Complaint in the Texas Action, alleging, *inter alia*, infringement of the '050 patent by Aurobindo.

36. In the Texas action, Mylan asserted that it is an exclusive licensee of the '992, '616, and '050 patents.

CONTROVERSY

37. There is an actual, substantial, continuing and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '992, '616, and '050 patents.

38. In the Texas Action and prior, Defendants have alleged that Aurobindo infringes the '992, '616, and '050 patents.

39. Aurobindo and Defendants have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the '992, '616 and '050 patents.

40. Defendants' claims of infringement of the '992, '616 and '050 patents create a case or controversy as to Aurobindo's non-infringement of the '992, '616 and '050 patents through its preparation and marketing of isosulfan blue for injection products made pursuant to ANDA No. 206831, and as to the invalidity of the '992, '616 and '050 patents.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '992 PATENT

41. Aurobindo repeats and incorporates by reference the foregoing paragraphs of its Complaint as if fully set forth herein.

42. This declaratory judgment claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '992 patent will be infringed by the manufacture, use, sale, offer for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831.

43. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will infringe any valid and enforceable claim of the '992 patent.

44. Aurobindo is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will not infringe, directly or indirectly, any valid claim of the '992 patent.

COUNT II
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '616 PATENT

45. Aurobindo repeats and incorporates by reference the foregoing paragraphs of its Complaint as if fully set forth herein.

46. This declaratory judgment claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '616 patent will be infringed by the manufacture, use, sale, offer for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831.

47. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will infringe any valid and enforceable claim of the '616 patent.

48. Aurobindo is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will not infringe, directly or indirectly, any valid claim of the '616 patent.

COUNT III
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '050 PATENT

49. Aurobindo repeats and incorporates by reference the foregoing paragraphs of its Complaint as if fully set forth herein.

50. This declaratory judgment claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '050 patent will be infringed by the manufacture,

use, sale, offer for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831.

51. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will infringe any valid and enforceable claim of the '050 patent.

52. Aurobindo is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will not infringe, directly or indirectly, any valid claim of the '050 patent.

COUNT IV
DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '992 PATENT

53. Aurobindo repeats and incorporates by reference the foregoing paragraphs of its Complaint as if fully set forth herein.

54. This declaratory judgment claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '992 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

55. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will infringe any valid and enforceable claim of the '992 patent.

56. Aurobindo is entitled to a judicial declaration that the claims of the '992 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

COUNT V
DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '616 PATENT

57. Aurobindo repeats and incorporates by reference the foregoing paragraphs of its Complaint as if fully set forth herein.

58. This declaratory judgment claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '616 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

59. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will infringe any valid and enforceable claim of the '616 patent.

60. Aurobindo is entitled to a judicial declaration that the claims of the '616 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

COUNT VI
DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '050 PATENT

61. Aurobindo repeats and incorporates by reference the foregoing paragraphs of its Complaint as if fully set forth herein.

62. This declaratory judgment claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '050 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

63. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 206831 will infringe any valid and enforceable claim of the '050 patent.

64. Aurobindo is entitled to a judicial declaration that the claims of the '050 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo respectfully requests that the Court enter a Judgment and Order in their favor and against Defendants as follows:

(a) For a declaration that the manufacture, use, offer to sell, sale, and/or importation into the United States of the isosulfan blue for injection product that is the subject of ANDA No.

206831 does not, and will not, infringe any valid and enforceable claim of the '992, '616 and '050 patents;

- (b) For a declaration that the claims of the '992, '616 and '050 patents are invalid;
- (c) For a declaration that this case is exceptional in favor of Aurobindo and awarding attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;
- (d) For an award of costs and expenses; and
- (e) For such other relief as the Court determines to be just and proper.

DEMAND FOR TRIAL BY JURY

Aurobindo hereby demands trial by jury as to all issues so triable.

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Dated: June 9, 2016

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Aurobindo, by and through the undersigned, hereby certifies that to the best of their knowledge the specific matters in controversy herein are the subject of Civil Action No. 16-cv-00491 pending in the United States District Court for the Eastern District of Texas, and no other related actions.

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

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