

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

MYLAN INSTITUTIONAL LLC and)	
APICORE US LLC)	
)	Civil Action No.: 2:16-cv-491
Plaintiffs,)	
)	Jury Trial Demanded
v.)	
)	
AUROBINDO PHARMA LTD.,)	
AUROBINDO PHARMA USA INC., and)	
AUROMEDICS PHARMA LLC)	
)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Apicore US LLC (“Apicore”) and Mylan Institutional LLC (“Mylan”) (collectively, “Plaintiffs”) bring this Complaint for patent infringement against Aurobindo Pharma Ltd (“Aurobindo India”), Aurobindo Pharma USA Inc. (“Aurobindo USA”), and AuroMedics Pharma LLC (“AuroMedics”) (collectively, “Defendants”).

THE PARTIES

1. 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, NJ 08873.
2. Apicore is a pharmaceutical company that provides innovative solutions to the pharmaceutical industry in the field of active pharmaceutical ingredient manufacturing.
3. Apicore developed a process for the manufacture of a high purity isosulfan blue product that is vastly superior to other methods of isosulfan blue synthesis and has entered into an exclusive arrangement with Mylan to commercialize this innovation.

4. 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, IL 61103.

5. Mylan is a pharmaceutical company that develops and commercializes injectable pharmaceutical products.

6. On information and belief, Aurobindo India is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India.

7. On information and belief, Aurobindo India develops and manufactures certain pharmaceutical drug products for sale in the United States, including in Texas and in this district, and/or imports certain pharmaceutical drug products into the United States. In 2013, Aurobindo India commenced marketing injectables products in the United States through its subsidiary AuroMedics. In the past, Aurobindo India has designated Aurobindo USA as its U.S. agent before the FDA. In the past, Aurobindo India has designated AuroMedics as its U.S. agent before the FDA. On information and belief, AuroMedics and/or Aurobindo USA is the U.S. agent before the FDA for ANDA No. 206831.

8. On information and belief, Aurobindo USA is a Delaware corporation having a place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Aurobindo USA is a wholly-owned subsidiary and agent of Aurobindo India.

9. On information and belief, Aurobindo USA markets, offers to sell, manufactures, distributes, and sells certain pharmaceutical drug products in the United States, including in Texas and in this district, and/or imports certain pharmaceutical drug products into the United States.

10. On information and belief, AuroMedics is a Delaware corporation having a place of business at 6 Wheeling Road, Dayton, New Jersey 08810. AuroMedics is a wholly-owned subsidiary of Aurobindo India.

11. On information and belief, AuroMedics markets, manufactures, offers to sell, distributes, and sells certain pharmaceutical drug products in the United States, including in Texas and in this district, and/or imports certain pharmaceutical drug products into the United States.

12. On information and belief, Aurobindo India, Aurobindo USA, and AuroMedics operate and act in concert as an integrated, unitary business for purposes of manufacturing, marketing, offering to sell, selling, and distributing generic pharmaceutical products throughout the United States, including in Texas and in this district. For example, in several of Aurobindo India's Earnings Conference Calls, including the call on February 10, 2016, Mr. Robert Cunard – CEO, Aurobindo USA and Mr. Ronald Quadrel – CEO, AuroMedics, along with individuals at Aurobindo India, were stated as representing the senior management team.

NATURE OF THE ACTION

13. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 1 *et seq.*, involving United States Patent No. 7,662,992 (the "992 patent") and United States Patent No. 8,969,616 (the "616 patent") (collectively, the "Patents-in-Suit").

14. This action arises out of Defendants' offering to sell and selling in the United States and/or importing into the United States isosulfan blue, which is manufactured by the processes, or equivalents thereof, claimed in the Patents-in-Suit.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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

17. This Court has personal jurisdiction over Aurobindo India because, on information and belief, *inter alia*, Aurobindo India collaborated with Aurobindo USA and AuroMedics for the purpose of preparing and submitting ANDA No. 206831. Aurobindo India conducts business through and with Aurobindo USA and/or AuroMedics, its wholly-owned subsidiaries. On information and belief, Aurobindo India has affiliations with Texas and this district that are pervasive, continuous, and systematic. Aurobindo India directly or through its affiliates and agents develops, formulates, synthesizes, manufactures, markets, imports, offers to sell, and/or sells pharmaceutical drug products. On information and belief, Aurobindo India engages in direct marketing, offering to sell, distribution, and/or sale of pharmaceutical drug products, including isosulfan blue, within Texas and this district and to the residents of Texas and this district. On information and belief, Aurobindo India regularly conducts and/or solicits business, directly or through its subsidiaries Aurobindo USA and/or AuroMedics.

18. This Court has personal jurisdiction over Aurobindo USA because Aurobindo USA has affiliations with Texas and this district that are pervasive, continuous, and systematic. Furthermore, Aurobindo USA has a Texas Taxpayer Number, which is 32038681568. In addition, Aurobindo USA is licensed with the Texas Department of State Health Services under License Number 0103142 and engages in direct marketing, distribution, offering for sale, and/or sale of pharmaceutical drug products, including isosulfan blue, within Texas and this district and to the residents of this district.

19. This Court has personal jurisdiction over AuroMedics because AuroMedics has affiliations with Texas and this district that are pervasive, continuous, and systematic. Furthermore, AuroMedics is licensed with the Texas Department of State Health Services under License Number 1000855 and engages in direct marketing, distribution, offering for sale, and/or sale of pharmaceutical drug products, including isosulfan blue, within Texas and this district and to the residents of Texas and this district.

20. Moreover, because the acts giving rise to infringement by Aurobindo India, Aurobindo USA, and AuroMedics have occurred within Texas and this district, personal jurisdiction is proper within this district.

PATENTS-IN-SUIT

21. Apicore was formed in 2003. For several years, the entire company was devoted to the development of isosulfan blue, a small molecule active pharmaceutical ingredient (“API”). After years of extraordinary effort and significant expense, Apicore developed a vastly superior manufacturing process that allowed for the commercial synthesis of isosulfan blue at a purity level much greater than had been previously achieved by others. That superior process is the basis for the Patents-in-Suit.

22. The ’992 patent, entitled “Process for Preparation of Isosulfan Blue,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on February 16, 2010. The named inventors of the ’992 patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. A true and correct copy of the ’992 patent is attached hereto as Exhibit A.

23. The ’616 patent, entitled “Process for Preparation of Isosulfan Blue,” was duly and legally issued by the USPTO on March 3, 2015. The named inventors of the ’616 patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. A true and correct copy of the ’616 patent is attached hereto as Exhibit B.

24. The '616 Patent is a continuation of U.S. Application No. 13/310,019 (the "'019 App'n"). The '019 App'n, entitled "Process for Preparation of Isosulfan Blue," was filed on December 2, 2011. The '019 App'n was published on March 29, 2012 as U.S. Publication No. 2012/0078007 A1 (the "'007 Pub'n"). The named inventors of the '007 Pub'n are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. The pending claims of the '019 App'n were granted allowance and the issue fee was paid on April 11, 2016. The Issue Notification for the '019 App'n was mailed on May 11, 2016. The allowed claims of the '019 App'n are substantially identical to the claims published in the '007 Pub'n. A true and correct copy of the '007 Pub'n, a true and correct copy of the allowed claims of the '019 App'n, and a true and correct copy of the transaction history for the '019 App'n as of May 11, 2016, available from the USPTO Public Patent Application Information Retrieval ("PAIR") system website, are attached hereto as Exhibits C, D, and E respectively.

25. Apicore is the lawful owner of the Patents-in-Suit and the '019 App'n. and has all right, title and interest in and to the Patents-in-Suit and the '019 App'n.

26. Mylan, which now owns Synerx, is an exclusive licensee to the Patents-in-Suit and the '019 App'n.

27. Neither Apicore nor Mylan has authorized or licensed Defendants to use any of the inventions claimed in the Patents-in-Suit or the '019 App'n.

28. On information and belief, Defendants collaborate in the manufacture, marketing, offering for sale, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved abbreviated new drug application) within the United States generally, and in Texas and in this district specifically.

29. On information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

30. On information and belief, Defendants were aware of and reviewed the Patents-in-Suit and the '019 App'n prior to launching their isosulfan blue product.

31. On information and belief, Aurobindo India submitted to the FDA ANDA No. 206831 seeking approval to engage in the commercial manufacture, use, marketing, offer for sale and sale of isosulfan blue. On information and belief, AuroMedics and/or Aurobindo USA served as Aurobindo India's U.S. Agent before the FDA with respect to ANDA No. 206831.

32. On information and belief, Aurobindo India received approval of its ANDA No. 206831 on February 2, 2016. Aurobindo India announced publicly its intent to begin offering for sale and selling isosulfan blue in the United States in March 2016. The FDA approved label for Defendants' isosulfan blue product states that Aurobindo India is the manufacturer of the isosulfan blue product. A true and correct copy of Defendants' isosulfan blue label is attached as Exhibit F.

33. On or about March 1, 2016, Defendants began providing pricing information for Defendants' isosulfan blue to U.S. customers, including current customers of Plaintiffs.

34. Currently, on information and belief, major pharmaceutical wholesalers offer Defendants' isosulfan blue in the United States, including in Texas and in this district. Further, on information and belief, Defendants have approached and contracted with group purchasing organizations ("GPOs") to provide Defendants' isosulfan blue to their members throughout the United States, including in Texas and in this district

35. On March 2, 2016, Plaintiffs sent Aurobindo India and Aurobindo USA each a letter identifying the Patents-in-Suit and advising that Plaintiffs believe that to commercially

make isosulfan blue, Aurobindo India and/or Aurobindo USA likely infringe one or more claims of the Patents-in-Suit.

36. On March 3, 2016, Plaintiffs sent a similar letter to AuroMedics identifying the Patents-in-Suit and advising that Plaintiffs believe that to commercially make isosulfan blue, Aurobindo India and/or Aurobindo USA likely infringe one or more claims of the Patents-in-Suit.

37. On March 7, 2016, Defendants replied that they believed they did not infringe the Patents-in-Suit.

38. On March 8, 2016, Plaintiffs sent Defendants a letter seeking more information regarding Defendants' process steps and specifically requesting, among other things, "whether any silver-containing ingredients are utilized [and] what oxidizing agents are employed . . . in the oxidation step to yield Aurobindo's isosulfan blue product." Also, the letter requested a sample of Defendants' isosulfan blue product. Further, a copy of the '007 Pub'n was enclosed with the letter in which Plaintiffs informed Defendants of their belief that the claims of the '019 App'n in their current form would be allowed by the USPTO without additional amendments and that the current claims of the '019 App'n are substantially identical to the claims in the '007 Pub'n.

39. On March 14, 2016, Defendants, Mylan and Apicore entered into a non-disclosure agreement concerning the exchange of additional information from Defendants for outside counsel and expert eyes only, and for the sole purpose of Plaintiffs' infringement analyses. Following the agreement, Defendants replied on March 14, 2016, disclosing the oxidizing agent it used, but without any supporting documentation.

40. On March 17, 2016, Plaintiffs sent another letter to Defendants requesting additional information and supporting documentation for the purpose of Plaintiffs' infringement analyses.

41. On March 18, 2016, Defendants responded with a letter and a single-paged document that did not disclose the additional information requested by Plaintiffs.

42. On March 23, 2016, Plaintiffs sent a letter to Defendants detailing the specific information needed for analyses both under theories of literal infringement and under the doctrine of equivalents.

43. On March 28, 2016, Defendants replied asserting their position that they had disclosed sufficient information, and refusing to disclose further information without explanation from Plaintiffs concerning their theories of infringement under the doctrine of equivalents.

44. On March 29, 2016, Plaintiffs sent a final letter to Defendants reiterating their request for additional information and describing why the requested information was needed.

45. On April 1, 2016, Defendants sent a few additional documents that did not address the scope of Plaintiffs' prior requests for information or product samples.

ACTS GIVING RISE TO THIS ACTION

46. On information and belief, Defendants have directly, or through affiliates and subsidiaries, made and/or imported Defendants' isosulfan blue product into the United States.

47. On information and belief, Defendants have directly, or through affiliates and subsidiaries, provided notice to potential customers in the United States, that Defendants' isosulfan blue product is commercially available throughout the United States, including in Texas and in this district.

48. On information and belief, Defendants have directly, or through affiliates and subsidiaries, offered for sale and/or sold Defendants' isosulfan blue product in the United States, including in Texas and in this district.

49. On information and belief, Defendants have directly, or through affiliates and subsidiaries, offered to sell and/or sold Defendants' isosulfan blue product to Mylan's customers at a price significantly below Mylan's contract price with those customers.

COUNT 1
INFRINGEMENT OF THE '992 PATENT

50. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

51. Upon information and belief, Defendants' making, using, offering to sell and/or selling within the United States and/or importation into the United States of Defendants' isosulfan blue products without authorization infringes one or more claims of the '992 patent, including at least Claim 1, under 35 U.S.C. §§ 271(a), 271(b), and/or 271(g), literally and/or under the doctrine of equivalents.

52. On information and belief, Defendants infringe the '992 patent because Defendants' isosulfan blue product is prepared by the same process, or its equivalent, as claimed in the '992 patent.

53. On information and belief, Defendants' isosulfan blue product made by Plaintiffs' patented process is not materially changed by subsequent processes and is not a trivial and nonessential component of another product.

54. Defendant Aurobindo India cited the '992 patent in its Indian Patent application published as Publication Number IN3509/CHE/2012, which was filed on August 27, 2012.

55. Defendant Aurobindo India had knowledge of the '992 patent at least as early as August 23, 2013 and no later than the service of this Complaint.

56. Defendant Aurobindo USA had knowledge of the '992 patent at least as early as March 3, 2016, and no later than the service of this Complaint.

57. Defendant AuroMedics had knowledge of the '992 patent at least as early as March 4, 2016, and no later than the service of this Complaint.

58. Defendants have had constructive notice of the '992 patent as of its date of issuance on February 16, 2010.

59. Upon information and belief, Defendants were and are aware of the existence of the '992 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '992 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

60. Plaintiffs have and will continue to be substantially and irreparably damaged and harmed if Defendants' infringement of the '992 patent is not enjoined by this Court.

61. Defendants' infringement of the '992 patent has caused Plaintiffs substantial harm.

COUNT 2
INFRINGEMENT OF THE '616 PATENT

62. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

63. Upon information and belief, Defendants' making, using, offering to sell and/or selling within the United States and/or importation into the United States of Defendants' isosulfan blue products without authorization infringes one or more claims of the '616 patent, including at least Claim 1, under 35 U.S.C. §§ 271(a), 271(b), and/or 271(g), literally and/or under the doctrine of equivalents.

64. On information and belief, Defendants infringe the '616 patent because Defendants' isosulfan blue product is prepared by the same process, or its equivalent, as claimed in the '616 patent.

65. On information and belief, Defendants' isosulfan blue product made by Plaintiffs' patented process is not materially changed by subsequent processes and is not a trivial and nonessential component of another product.

66. Defendant Aurobindo India had knowledge of the '616 patent at least as early as March 7, 2016, and no later than the service of this Complaint.

67. Defendant Aurobindo USA had knowledge of the '616 patent at least as early as March 3, 2016, and no later than the service of this Complaint.

68. Defendant AuroMedics had knowledge of the '616 patent at least as early as March 4, 2016, and no later than the service of this Complaint.

69. Defendants have had constructive notice of the '616 patent as of its date of issuance on March 3, 2015.

70. Upon information and belief, Defendants were and are aware of the existence of the '616 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '616 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

71. Plaintiffs have and will continue to be substantially and irreparably damaged and harmed if Defendants' infringement of the '616 patent is not enjoined by this Court.

72. Defendants' infringement of the '616 patent has caused Plaintiffs substantial harm.

JURY DEMAND

73. Under Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs respectfully requests a trial by jury on all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

- A. A judgment that Defendants have infringed the Patents-in-Suit under 35 U.S.C. §§ 271(a), 271(b), and/or 271(g) by making, using, selling, offering to sell within the United States and/or importing into the United States Defendants' isosulfan blue products and/or by inducing others to infringe the Patents-in-Suit;
- B. An order preliminarily and/or permanently enjoining Defendants, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting or attempting to act in concert or privity with them, their successors, and assigns, or acting on their behalf, from infringing, contributorily infringing, or inducing others to infringe the Patents-in-Suit, and upon its issuance the '019 App'n, including engaging in the offer to sell and selling in the United States, and/or importation into the United States, of Defendants' isosulfan blue products that are the subject of ANDA No. 206831 until the expiration of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity to which Plaintiffs are or may become entitled;
- C. A judgment awarding Plaintiffs damages or other monetary relief under 35 U.S.C. § 281 as appropriate;
- D. A judgment ordering Defendants to pay damages to Plaintiffs to compensate for their infringement of each of the Patents-in-Suit, including supplemental damages for any

post-verdict infringement up until entry of the final judgment with an accounting as needed, together with pre-judgment and post-judgment interest on the damages awarded, with all of these damages to be enhanced in an amount up to treble the amount of the calculated compensatory damages as justified under 35 U.S.C. § 284;

E. A judgment declaring that Defendants' infringement of the Patents-in-Suit was willful, and awarding treble damages under 35 U.S.C. § 284;

F. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

G. Such further and other relief as this Court may deem just and proper.

Dated: May 11, 2016

Respectfully submitted,

Of Counsel
Nicole W. Stafford (*Lead Counsel*)
Aden M. Allen
Anna G. Phillips
Olin Ray Hebert, III
WILSON SONSINI GOODRICH & ROSATI
900 S. Capital of Texas Hwy
Las Cimas IV, Fifth Floor
Austin, TX 78732
Telephone: (512) 338-5400

/s/ Melissa R. Smith
Melissa R. Smith
GILLAM & SMITH, LLP
TX State Bar No. 24001351
melissa@gillamsmithlaw.com
303 S. Washington Ave.
Marshall, Texas 75670
Telephone: (903) 934-8450
Facsimile: (903) 934-9257

*Attorneys for Plaintiff Mylan Institutional
LLC*

H. Rajan Sharma
Neal DeYoung
Joanna Garelick Goldstein
David Galluzzo
Sharma & DeYoung
55 Fifth Avenue, 17th Floor
New York, NY 10017

Attorneys for Plaintiff Apicore US LLC