Liza M. Walsh
Tricia B. O'Reilly
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068-1765
(973) 535-0500

Attorneys for Plaintiffs
Merck, Sharp & Dohme Corp.
Bristol-Myers Squibb Company, and
Bristol-Myers Squibb Pharma Co.

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

MERCK, SHARP & DOHME CORP., BRISTOL-MYERS SQUIBB COMPANY, and BRISTOL-MYERS SQUIBB PHARMA CO.	)	
Plaintiffs,	)	Civil Action No. _____
v.	)	
AUROBINDO PHARMA LTD., and AUROBINDO PHARMA USA, INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck, Sharp & Dohme Corp. ("Merck") and Bristol-Myers Squibb Company and Bristol-Myers Squibb Pharma Co. (collectively, "BMS"), by their undersigned attorneys and for their Complaint against Aurobindo Pharma Ltd. ("Aurobindo Ltd.") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (collectively, "Defendants"), allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 205322, which

Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to market a generic version of BMS's successful Sustiva® tablets that are sold in the United States, including this District.

The Parties

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at One Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889-0100.

3. Plaintiff Bristol-Myers Squibb Company is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 345 Park Avenue, New York, NY 10154.

4. Plaintiff Bristol-Myers Squibb Pharma Co., an indirect wholly-owned subsidiary of Bristol-Myers Squibb Co., is a general partnership organized and existing under the laws of the State of Delaware, having its principal place of business at Route 206 and Province Line Road, Lawrenceville, New Jersey 08540.

5. On information and belief, Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 Route 130 North, Dayton, NJ 08810.

6. On information and belief, Aurobindo Ltd. is an Indian corporation, having a principal place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad - 500 038, Andhra Pradesh, India.

7. On information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo Ltd. On information and belief, Aurobindo Ltd., directly or through its wholly-owned subsidiary, Aurobindo USA, sells and markets pharmaceutical products throughout the United States, including in the Judicial District.

8. On information and belief, the acts of Aurobindo Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of, and at least in part for the benefit of, Aurobindo USA.

9. On information and belief, the acts of Aurobindo USA complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of, and at least in part for the benefit of, Aurobindo Ltd.

Jurisdiction and Venue

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202.

11. This Court has personal jurisdiction over Aurobindo USA by virtue of, *inter alia*, Aurobindo USA's presence in New Jersey, its continuous and systematic contacts with New Jersey, and its course of conduct that is designed to cause the performance of acts that will result in foreseeable harm in New Jersey.

12. This Court has personal jurisdiction over Aurobindo Ltd. by virtue of, *inter alia*, Aurobindo Ltd.'s continuous and systematic contacts with New Jersey, and its course of conduct that is designed to cause the performance of acts that will result in foreseeable harm in New Jersey.

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

THE PATENTS

14. United States Patent No. 6,639,071 ("the '071 Patent"), entitled "Crystal Forms of (-)-6-Chloro-4-Cyclopropylethynyl-4-Trifluoromethyl-1,4-Dihydro-2H-3,1-Benzoxazin-2-One," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 28, 2003 to inventors Louis S. Crocker, Joseph L. Kukura, II, Andrew S. Thompson,

Christine Stelmach, and Steven D. Young. The '071 Patent was assigned to Merck & Co., Inc., which subsequently changed the name for the assignee to Merck Sharp & Dohme Corp. At all times from the issuance of the '071 Patent to the present, Merck or one of its predecessors in interest has been the owner of the '071 Patent. Pursuant to an agreement entered into between Merck and The DuPont Merck Pharmaceutical Company ("DPMC"), whereas DPMC was ultimately acquired by BMS, BMS has substantial rights to the '071 Patent, including but not limited to, rights associated with being a licensee of the '071 Patent, and the right to sue for infringement of the '071 Patent. The '071 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("FDA Orange Book") for Sustiva®. A true and correct copy of the '071 Patent is attached as Exhibit A.

15. United States Patent No. 6,939,964 ("the '964 Patent"), entitled "Crystal Forms of (-)-6-Chloro-4-Cyclopropylethynyl-4-Trifluoromethyl-1,4-Dihydro-2H-3,1-Benzoxazin-2-One," was duly and legally issued by the USPTO on September 6, 2005 to inventors Louis S. Crocker, Joseph L. Kukura, II, Andrew S. Thompson, Christine Stelmach, and Steven D. Young. The '964 Patent claims priority to the '071 Patent and the applications leading thereto. The '964 Patent was assigned to Merck & Co., Inc., which subsequently changed the name for the assignee to Merck Sharp & Dohme Corp. At all times from the issuance of the '964 Patent to the present, Merck or one of its predecessors in interest has been the owner of the '964 Patent. Pursuant to an agreement entered into between Merck and DPMC, whereas DPMC was ultimately acquired by BMS, BMS has substantial rights to the '964 Patent, including but not limited to, rights associated with being a licensee of the '964 Patent, and the right to sue for infringement of the '964 Patent. The '964 Patent is also listed in the FDA Orange Book for Sustiva®. A true and correct copy of the '964 Patent is attached as Exhibit B.

16. United States Patent No. 6,673,372 ("the '372 Patent"), entitled "Crystalline Efavirenz," was duly and legally issued by the USPTO on January 6, 2004 to inventors Lilian A. Radesca, Michael B. Maurin, Shelley R. Rabel, and James R. Moore. The '372 Patent was originally assigned to DuPont Pharmaceuticals Company, which subsequently became part of BMS and the name of the assignee was changed to Bristol-Myers Squibb Pharma Company. At all times from the issuance of the '372 Patent to the present, BMS or one of its predecessors in interest has been the owner of the '372 Patent. The '372 Patent claims particular crystalline forms of efavirenz, but is not listed in the FDA Orange Book for Sustiva®. A true and correct copy of the '372 Patent, including two Certificates of Correction, is attached as Exhibit C.

ACTS GIVING RISE TO THIS ACTION

17. By letter dated July 30, 2013, purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) ("Notice Letter"), Defendants notified BMS and Merck (collectively, "Plaintiffs") that Defendants had submitted ANDA No. 205322 to the FDA under section 505(j) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, importation, use, and sale of 600 mg efavirenz tablets ("Defendants' ANDA product") as a generic version of BMS's Sustiva® drug product.

18. Defendants' ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, importation, use, sale, and/or importation of Defendants' ANDA product prior to the expiration of the '071, '964, and '372 Patents. The '071 and '964 Patents are listed in the FDA Orange Book as being applicable to BMS's Sustiva® drug product.

19. On information and belief, Defendants intend to engage in the commercial manufacture, importation, use, and sale of Defendants' ANDA product promptly upon receiving FDA approval to do so.

20. In the Notice Letter, Defendants notified Plaintiffs that their ANDA contained a "paragraph IV" certification that, in Defendants' opinion, the '071and '964 Patents will not be infringed by the commercial manufacture, use, sale, offer to sale or importation of Defendants' ANDA product. The Notice Letter did not provide any statement regarding the '372 Patent.

21. The Notice Letter also included an Offer of Confidential Access, pursuant to 21 U.S.C. § 355(j)(5)(C), to certain information from ANDA No. 205322 for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought by Plaintiffs. The parties were unable to timely resolve issues involving restrictions and limitations on the use of the information contained within ANDA No. 205322, and therefore Defendants did not provide Plaintiffs access to ANDA No. 205322.

22. On information and belief, based in part on Defendants' Notice Letter, Defendants have filed ANDA 205322 with the FDA for the purpose of obtaining approval under 21 U.S.C. § 355(j) to engage in the commercial manufacture, use, or sale of Defendants' ANDA before the expiration of the '071 and '964 Patents.

23. Moreover, on information and belief, based in part on the information contained in the Notice Letter, Defendants have filed ANDA 205322 with the FDA for the purpose of obtaining approval under 21 U.S.C. § 355(j) to engage in the commercial manufacture, use, or sale of Defendants' ANDA before the expiration of the '372 Patent.

COUNT 1
Infringement of U.S. Patent No. 6,639,071

24. Plaintiffs repeat and re-allege paragraphs 1-23 above as if set forth herein.

25. By filing ANDA No. 205322 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product prior to the expiration date of the '071 Patent, Defendants have

committed an act of infringement of the '071 Patent under 35 U.S.C. § 271(e)(2) and such infringement will cause Plaintiffs irreparable harm unless enjoined by this Court.

26. On information and belief, Defendants' ANDA is a wholly unjustified infringement of the '071 Patent.

27. On information and belief, the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product by Defendants will infringe, induce infringement, and/or contributorily infringe one or more claims of the '071 Patent literally or under the doctrine of equivalents.

COUNT 2
Infringement of U.S. Patent No. 6,939,964

28. Plaintiffs repeat and re-allege paragraphs 1-27 above as if set forth herein.

29. By filing ANDA No. 205322 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product prior to the expiration date of the '964 Patent, Defendants have committed an act of infringement of the '964 Patent under 35 U.S.C. § 271(e)(2) and such infringement will cause Plaintiffs irreparable harm unless enjoined by this Court.

30. On information and belief, Defendants' ANDA is a wholly unjustified infringement of the '964 Patent.

31. On information and belief, the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product by Defendants will infringe, induce infringement, and/or contributorily infringe one or more claims of the '964 Patent literally or under the doctrine of equivalents.

COUNT 3
Infringement of U.S. Patent No. 6,673,372

32. Plaintiffs repeat and re-allege paragraphs 1-31 above as if set forth herein.

33. By filing ANDA No. 205322 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product prior to the expiration date of the '372 Patent, Defendants have committed an act of infringement of the '372 Patent under 35 U.S.C. § 271(e)(2) and such infringement will cause Plaintiffs irreparable harm unless enjoined by this Court.

34. On information and belief, Defendants' ANDA is a wholly unjustified infringement of the '372 Patent.

35. On information and belief, the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product by Defendants will infringe, induce infringement, and/or contributorily infringe one or more claims of the '372 Patent literally or under the doctrine of equivalents.

Relief Requested

WHEREFORE, Plaintiffs respectfully pray for the following relief:

(a) A judgment that Defendants have infringed one or more claims of the '071, '964, and '372 Patents by the filing of ANDA No. 205322;

(b) A judgment ordering that the effective date of any approval of Defendants' ANDA No. 205322 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.§ 355(j)) be a date that is not earlier than the latest expiration date of the '071, '964, and '372 Patents, or any later date of exclusivity to which BMS or Merck are or become entitled;

(c) A declaration and adjudication that Defendants will infringe the '071, '964, and '372 Patents by their threatened acts of manufacture, importation, sale, offer for sale, and/or use of products covered by said patent prior to expiration date of said patent;

(d) A permanent injunction enjoining Defendants and their officers, agents, servants, employees, and privies from infringing the '071, 964 and '372 Patents;

(e) Damages under 35 U.S.C. § 271(e)(4)(C), which this Court should treble pursuant to 35 U.S.C. § 284, if Defendants infringe the '071, '964 and '372 Patents by engaging in the commercial manufacture, importation, use, sale, offer to sell, or import its ANDA product in/into the United States prior to the expiration of the '071, 964, or '372 Patents or the expiration of any other exclusivity to which BMS or Merck become entitled;

(f) A judgment that this is an exceptional case and that Plaintiffs are entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

(g) Costs and expenses in this action; and

(h) Such other relief as this Court may deem just and proper.

Dated: September 11, 2013

Respectfully submitted,

By: *s/Liza M. Walsh*

Liza M. Walsh
Tricia B. O'Reilly
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068-1765
(973) 535-0500

Attorneys for Plaintiffs
Merck, Sharp & Dohme Corp.
Bristol-Myers Squibb Company, and
Bristol-Myers Squibb Pharma Co.

OF COUNSEL:
Paul H. Berghoff
James C. Gumina
Sean M. Sullivan
Andrew W. Williams
Kurt W. Rhode
Sydney R. Kokjohn
John M. Schafer
McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following pending actions:

BRISTOL-MYERS SQUIBB COMPANY; and BRISTOL-MYERS SQUIBB PHARMA CO. v. MYLAN PHARMACEUTICALS INC.; and MATRIX LABORATORIES LTD. v. MERCK & CO., INC.; and MERCK SHARP & DOHME CORP., C.A. No. 09-651 (LPS) (*District of Delaware*).

MERCK, SHARP & DOHME CORP.; BRISTOL-MYERS SQUIBB COMPANY; and BRISTOL-MYERS SQUIBB PHARMA CO. v. HETERO USA INC. and HETERO LABS LIMITED UNIT-III, Civil Action No. 13-cv-01402 (JBS)(AMD) (*District of New Jersey*).

MERCK, SHARP & DOHME CORP.; and BRISTOL-MYERS SQUIBB COMPANY v. CIPLA USA INC. and CIPLA LIMITED, Civil Action No. 13-cv-04017 (JBS)(AMD) (*District of New Jersey*).

DATED: September 11, 2013

CONNELL FOLEY LLP

By: *s/Liza M. Walsh*
Liza M. Walsh