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. and Bristol-Myers Squibb Company

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

MERCK, SHARP & DOHME CORP., and BRISTOL-MYERS SQUIBB COMPANY Plaintiffs, v. CIPLA USA, INC., and CIPLA LIMITED Defendants.	Civil Action No._____

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 Cipla USA, Inc.("Cipla USA") and Cipla Limited (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. 204766, 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. On information and belief, Cipla USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9100 S. Dadeland Blvd., Suite 1500, Miami, FL 33156.

5. On information and belief, Cipla Limited is an Indian corporation, having a principal place of business at Mumbai Central, Mumbai – 400 008, India.

6. On information and belief, Cipla USA acts as the agent of Cipla Limited.

Jurisdiction and Venue

7. 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.

8. This Court has personal jurisdiction over Cipla Limited by virtue of, *inter alia*, Cipla Limited'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.

9. This Court has personal jurisdiction over Cipla USA by virtue of, *inter alia*, Cipla 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.

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

THE PATENTS

11. 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.

12. 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. 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.

ACTS GIVING RISE TO THIS ACTION

13. By letter dated May 17,2013, 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. 204766 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.

14. 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 and '964 Patents. The '071 and '964 Patents are listed in the FDA Orange Book as being applicable to BMS's Sustiva® drug product.

15. 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.

16. In the Notice Letter, Defendants notified Plaintiffs that their ANDA contained a "paragraph IV" certification that, in Defendants' opinion, the '071and '964 Patents are invalid and/or will not be infringed by the commercial manufacture, use, sale, offer to sale or importation of Defendants' ANDA product.

17. 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. 204766 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. Plaintiffs accepted this Offer of Confidential Access on or around June 7, 2013.

18. On information and belief, based in part on the information from ANDA No. 204766 received pursuant to the Office of Confidential Access, Defendants' ANDA product infringes one or more claims of the '071 and '964 Patents.

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

19. Plaintiffs repeat and re-allege paragraphs 1-18 above as if set forth herein.

20. By filing ANDA No. 204766 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.

21. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement when ANDA No. 204766 was filed and when the paragraph IV certification was made. Defendants' ANDA is a wholly unjustified infringement of the '071 Patent.

22. 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

23. Plaintiffs repeat and re-allege paragraphs 1-18 above as if set forth herein.

24. By filing ANDA No. 204766 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.

25. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement when ANDA No. 204766 was filed and when the paragraph IV certification was made. Defendants' ANDA is a wholly unjustified infringement of the '964 Patent.

26. 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
Declaratory Judgment of Patent Infringement of U.S. Patent No. 6,639,071

27. Plaintiffs repeat and re-allege paragraphs 1-18 above as if set forth herein.

28. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, based upon an actual controversy between the parties. Defendants have taken immediate and active steps to obtain FDA permission to sell in the United States and, after obtaining FDA permission, to commence the sale in the United States of Defendants' ANDA product before the expiration date of the '071 Patent. There is a real and actual controversy between the parties with respect to Defendants' activities and infringement of the '071 Patent.

29. The manufacture and/or sale of Defendants' ANDA product by Defendants during the term of the '071 Patent will constitute patent infringement of the '071 Patent under 35 U.S.C. § 271(a) and/or (b).

30. On information and belief, by seeking FDA approval for Defendants' ANDA product as described in ANDA No. 204766, Defendants intend to import into the United States and/or sell, offer to sell, and/or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), Defendants' ANDA product, which would infringe the '071 Patent.

31. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '071 Patent.

COUNT 4
Declaratory Judgment of Patent Infringement of U.S. Patent No. 6,939,964

32. Plaintiffs repeat and re-allege paragraphs 1-18 above as if set forth herein.

33. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, based upon an actual controversy between the parties. Defendants have taken immediate and active steps to obtain FDA permission to sell in the United States and, after obtaining FDA

permission, to commence the sale in the United States of Defendants' ANDA product prior to the expiration date of the '964 Patent. There is a real and actual controversy between the parties with respect to Defendants' activities and infringement of the '964 Patent.

34. The manufacture and sale of Defendants' ANDA product by Defendants during the term of the '964 Patent will constitute patent infringement of the '964 Patent under 35 U.S.C. § 271(a) and/or (b).

35. On information and belief, by seeking FDA approval for Defendants' ANDA product as described in ANDA No. 204766, Defendants intend to import into the United States and/or sell, offer to sell, and/or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), Defendants' ANDA product, which would infringe the '964 Patent.

36. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '964 Patent.

Relief Requested

WHEREFORE, Plaintiffs respectfully pray for the following relief:

(a) A judgment that Defendants have infringed one or more claims of the '071 and '964 Patents by the filing of ANDA No. 204766;

(b) A judgment ordering that the effective date of any approval of Defendants' ANDA No. 204766 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 expiration date of the '071 and '964Patents, 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 and '964 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 and '964 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 and '964 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 or '964 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.

RESPECTFULLY SUBMITTED,

Dated: June 27, 2013

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. and Bristol-Myers Squibb Company

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