IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB CO., and BRISTOL-MYERS SQUIBB PHARMA CO.,	)	
Plaintiffs/Counterclaim-Defendants,	)	C.A. No. 09-651 (LPS)
v.	)	
MYLAN PHARMACEUTICALS INC., and MATRIX LABORATORIES LTD.	)	
Defendants/Counterclaim-Plaintiffs,	)	
v.	)	
MERCK & CO., INC. and MERCK SHARP & DOHME CORP.,	)	
Counterclaim-Defendants.	)	

AMENDED AND SUPPLEMENTAL
COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bristol-Myers Squibb Co. and Bristol-Myers Squibb Pharma Co. (collectively "BMS") by their undersigned attorneys, and for their Complaint against Mylan Pharmaceuticals Inc. ("Mylan Pharms.") and Matrix Laboratories Ltd. ("Matrix Ltd.") (collectively "Defendants") allege as follows:

The Parties

1. Bristol-Myers Squibb Co. 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.

2. 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.

3. On information and belief, Defendant Mylan Pharms. is a corporation organized and existing under the laws of the state of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharms. is wholly-owned or controlled by Mylan Laboratories, Inc. ("Mylan Labs."), which is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Pharms. is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in and throughout the United States including the State of Delaware.

4. On information and belief, Defendant Matrix Ltd. is wholly-owned or controlled by Mylan Labs, and is a corporation operating and existing under the laws of India with its principal place of business at 1-1-151/1, 4th Floor, Sai Ram Towers, Alexander Road, Secunderabad – 500 003, Andhra, Pradesh, India.

5. On information and belief, Defendants collaborate to manufacture, import, distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) in the United States generally, and the State of Delaware specifically.

Nature of the Action

6. This is an action for patent infringement of United States Patent Number 6,673,372 B1 ("the '372 patent") 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. 91-471, which Matrix Ltd. 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.

Jurisdiction and Venue

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

8. Defendants sell various prescription products and conduct business throughout the United States, including this District.

9. Defendants manufacture bulk pharmaceuticals and pharmaceutical products that are regularly sold and used throughout the United States, including this District. Defendants sell their products in the United States, including this District, through retail drug store chains, wholesalers, distributors, health care organizations and governmental concerns.

10. This Court has personal jurisdiction over each Defendant by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to BMS, a Delaware corporation. This court has personal jurisdiction over each of the Defendants for the additional reasons set forth below.

11. This Court has personal jurisdiction over Mylan Pharms. by virtue of, *inter alia*, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. In addition, it sells various products and does business throughout the United States, including specifically in the State of Delaware.

12. On information and belief, Mylan Pharms. has previously availed itself of this forum for purposes of litigating its patent disputes. For example, in 2002, Mylan Pharms. filed a patent infringement lawsuit styled *Mylan Pharms. Inc. v. Kremers Urban Development Co. et al.*, C.A. No. 02-1628 (D. Del.). Mylan Pharms. also has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Mylan Pharms. admitted jurisdiction (for purposes of the litigation) and filed counterclaims in *AstraZeneca LP v. Mylan Pharms., Inc.*, C.A. No. 08-453 (D. Del.); *AstraZeneca Pharms. LP v. Mylan Pharms., Inc.*, C.A. No. 07-805 (D. Del.); *Sciele Pharma Inc. v. Mylan Pharms., Inc.*, C.A. No. 07-644 (D. Del.); *Boehringer Ingelheim Int'l GMBH v. Mylan Pharms., Inc.*, C.A. No. 05-854 (D. Del.); and *Janssen Pharmaceutica N.V. v. Mylan Pharms., Inc.*, C.A. No. 05-371 (D. Del.).

13. This Court has personal jurisdiction over Matrix Ltd. by virtue of, *inter alia*, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. In addition, it sells various products and do business throughout the United States, including specifically in the State of Delaware.

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

The Patents-In-Suit

15. The '372 patent was duly and legally issued by the United States Patent and Trademark Office on January 6, 2004. Bristol-Myers Squibb Pharma Co. is the owner by assignment of the '372 patent and has the right to sue for infringement thereof. A true and correct copy of the '372 patent is attached as Exhibit A.

16. A Certificate of Correction for the '372 patent was issued by the U.S. Patent & Trademark Office on April 17, 2012. A copy of the '372 patent's Certificate of Correction is appended hereto as Exhibit B.

17. BMS produced the '372 patent's Certificate of Correction to Defendants on April 23, 2012.

The Infringing Conduct by Defendants

18. Bristol-Myers Squibb Co. is the holder of approved New Drug Application ("NDA") No. 21-360 for efavirenz tablets, which BMS markets and sells under the trademark Sustiva®. BMS manufactures and sells a 600 mg dosage strength of Sustiva® tablets in the United States under NDA No. 21-360.

19. On information and belief, Defendants filed with the FDA ANDA No. 91-471 under 21 U.S.C. § 355(j)(2)(B), seeking to obtain approval to commercially manufacture, use, offer for sale and sell, before the expiration of the '372 patent, a generic version of Sustiva® for the treatment of human immunodeficiency virus type 1 infection.

20. On or about July 16, 2009, BMS received a letter ("Defendants' Notice Letter") dated July 16, 2009, from Defendants stating that Matrix Ltd. had filed Defendants' ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of Sustiva® efavirenz tablets before the expiration of U.S. Patent Nos. 6,639,071 and 6,939,964, owned by

Merck & Co., Inc. by assignment. Defendants' Notice Letter provides a detailed statement of the factual and legal basis for Defendants' paragraph IV certification regarding U.S. Patent Nos. 6,639,071 and 6,939,964, owned by Merck & Co., Inc. by assignment. Defendants' Notice Letter did not provide a detailed statement of the factual and legal basis for any claim of noninfringement of any claim of the '372 patent.

21. Defendants' Notice Letter contained an X-ray powder diffraction ("XRPD") analysis related to generic efavirenz tablets that are the subject of ANDA No. 91-471. Defendants' Notice Letter contained, *inter alia*, two figures that purported to be the XRPD pattern of efavirenz form-ß (dry) and the XRPD pattern of efavirenz form-ß (wet). Defendants' Notice Letter also contained, *inter alia*, two tables that purported to be the XRPD data for efavirenz form-ß (dry) and the XRPD data of efavirenz form-ß (wet).

22. At least ten (10) of the D-spacings for both the efavirenz form-ß (dry) and efavirenz form-ß (wet) as reported in Defendants' Notice Letter correspond to the 2θ values for Form 5 efavirenz as taught and claimed in the '372 patent and the '372 patent as corrected by the Certificate of Correction that issued on April 17, 2012. Form 5 of crystalline efavirenz in the '372 patent is characterized by the presence of at least four (4) 2θ values from the group of 10.2±0.2, 11.4±0.2, 11.6±0.2, 12.6±0.2, 19.1±0.2, 20.6±0.2, 21.3±0.2, 22.8±0.2, 24.8±0.2, 27.4±0.2, 28.2±0.2, and 31.6±0.2. Form 5 of crystalline efavirenz in the '372 patent as corrected by the Certificate of Correction that issued on April 17, 2012 is characterized by the presence of at least six (6) 2θ values from the group of 10.2±0.2, 11.4±0.2, 11.6±0.2, 19.1±0.2, 20.6±0.2, 21.3±0.2, 22.8±0.2, 24.8±0.2, 27.4±0.2, 28.2±0.2, and 31.6±0.2. The characteristics of the Defendants' efavirenz form-ß (dry) and efavirenz form-ß (wet) as reported in Defendants' Notice Letter indicate the presence of more than six of the required values.

23. Therefore, based on the information provided in Defendants' Notice Letter, efavirenz form-ß, as described in ANDA No. 91-471, infringes claims 17-23 of the '372 patent and the '372 patent as corrected by the Certificate of Correction that issued on April 17, 2012.

COUNT I
PATENT INFRINGEMENT OF THE '372 PATENT

24. BMS re-alleges and incorporates by reference paragraphs 1-23 as if fully recited herein.

25. Through the filing of ANDA No. 91-471, Defendants have infringed claims 17-23 of the '372 patent covering efavirenz and uses thereof under 35 U.S.C. § 271(e)(2), and such infringement will cause BMS irreparable harm unless enjoined by this Court.

COUNT II
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT OF THE '372 PATENT

26. BMS re-alleges and incorporates by reference paragraphs 1-23 as if fully recited herein.

27. 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 sale in the United States of Defendants' efavirenz product before the expiration date of the '372 patent. There is a real and actual controversy between the parties with respect to Defendants' activities and infringement of the '372 patent.

28. The manufacture and sale by Defendants of their efavirenz tablets during the term of the '372 patent will constitute patent infringement of claims 17-23 of the '372 Patent under 35 U.S.C. § 271(a).

29. On information and belief, by seeking FDA approval for the efavirenz product as described in Defendants' Notice Letter, Defendants intend to import into the United States and/or offer to sell, sell or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), the efavirenz product that is the subject of ANDA No. 91-471, which would infringe, and the use of which would infringe, claims 17-23 of the '372 patent.

30. BMS will be irreparably harmed if Defendants are not enjoined from infringing the '372 patent.

COUNT III
PATENT INFRINGEMENT OF THE '372 PATENT AS CORRECTED BY THE CERTIFICATE OF CORRECTION THAT ISSUED ON APRIL 17, 2012

31. BMS re-alleges and incorporates by reference paragraphs 1-23 as if fully recited herein.

32. Through the act of filing and maintaining ANDA No. 91-471, Defendants have infringed and continue to infringe claims 17-23 of the '372 patent as corrected by the Certificate of Correction that issued on April 17, 2012 covering efavirenz and uses thereof under 35 U.S.C. § 271(e)(2), and such infringement will cause BMS irreparable harm unless enjoined by this Court.

COUNT IV
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT OF THE '372 PATENT AS CORRECTED BY THE CERTIFICATE OF CORRECTION THAT ISSUED ON APRIL 17, 2012

33. BMS re-alleges and incorporates by reference paragraphs 1-23 as if fully recited herein.

34. 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 sale in the United States of Defendants' efavirenz product before the expiration date of the '372 patent. There is a real and actual controversy between the parties with respect to Defendants' activities and infringement of the '372 patent as corrected by the Certificate of Correction that issued on April 17, 2012.

35. The manufacture and sale by Defendants of their efavirenz tablets during the term of the '372 patent will constitute patent infringement of claims 17-23 of the '372 Patent as corrected by the Certificate of Correction that issued on April 17, 2012 under 35 U.S.C. § 271(a).

36. On information and belief, by seeking FDA approval for the efavirenz product as described in Defendants' Notice Letter, Defendants intend to import into the United States and/or offer to sell, sell or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), the efavirenz product that is the subject of ANDA No. 91-471, which would infringe, and the use of which would infringe, claims 17-23 of the '372 patent as corrected by the Certificate of Correction that issued on April 17, 2012.

37. BMS will be irreparably harmed if Defendants are not enjoined from infringing the '372 patent as corrected by the Certificate of Correction that issued on April 17, 2012.

Relief Requested

WHEREFORE, the Plaintiffs respectfully pray for judgment:

(a) That Defendants have infringed claims 17-23 of United States Patent No. 6,673,372 (as originally issued and as corrected) by the filing of ANDA No. 91-471;

(b) Declaring and adjudging that Defendants will infringe claims 17-23 of United States Patent No. 6,673,372 (as originally issued and as corrected) by its threatened acts

of manufacture, importation, sale, offer for sale and/or use of products covered by said patent prior to expiration of said patent;

(c) Ordering that the effective date of any approval of Defendants' application for efavirenz tablets and their use be not earlier than the expiration date of United States Patent No. 6,673,372;

(d) Awarding the Plaintiffs preliminary and final injunctions enjoining defendants and its officers, agents, servants, employees and privies from continued infringement of United States Patent No. 6,673,372;

(e) Declaring this case exceptional under 35 U.S.C. § 285 and granting the Plaintiffs their attorneys' fees; and

(f) Granting such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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