UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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Attorneys for Plaintiffs
DAIICHI SANKYO COMPANY, LIMITED
and DAIICHI SANKYO, INC.

DAIICHI SANKYO COMPANY, LIMITED, and DAIICHI SANKYO, INC.	:	Civil Action No. _____
Plaintiffs,	:	COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2
v.	:	
MATRIX LABORATORIES, LTD. and MYLAN INC.,	:	
Defendants.	:	

Plaintiffs Daiichi Sankyo Company, Limited and Daiichi Sankyo, Inc. (hereinafter "Plaintiffs"), for their Complaint against Defendants Matrix Laboratories, Limited and Mylan Incorporated, allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Daiichi Sankyo Company, Limited ("Daiichi Sankyo Japan") is a corporation organized and existing under the laws of Japan, having a place of business at 5-1, Nihonbashi Honcho 3-chome, Chuo-ku, Tokyo 103-8426, Japan.

3. Plaintiff Daiichi Sankyo, Inc. ("Daiichi Sankyo U.S.") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

4. On information and belief, Matrix Laboratories, Ltd. ("Matrix Laboratories") is a corporation organized and existing under the laws of India, having a place of business at 1-1-151/1, Sai Ram Towers, Secunderabad, India 500003.

5. On information and belief, Mylan Inc. ("Mylan") is a corporation organized under the laws of the State of Pennsylvania, having a place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

6. On information and belief, Mylan owns a controlling interested (71.5%) in Matrix Laboratories, and the acts of Matrix Laboratories complained of herein were aided and abetted by and done with the cooperation, participation, and assistance of Mylan. On information and belief, Matrix Laboratories and Mylan have officers or directors in common.

7. Matrix Laboratories and Mylan are hereinafter collectively referred to as "Matrix."

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, Matrix is registered to do business in New Jersey and has a registered agent in New Jersey. In addition, Matrix sells various products and does business throughout the United States, including within this judicial district. Upon information and belief, Matrix has submitted to the jurisdiction of the United States District Court for the District of New Jersey. This Court has personal jurisdiction over Matrix by virtue of, *inter alia*, the above-mentioned facts.

10. Upon information and belief, Matrix has consented to personal jurisdiction of the United States District Court for the District of New Jersey.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF - PATENT INFRINGEMENT

12. Plaintiff Daiichi Sankyo U.S. holds an approved new drug application ("NDA") No. 22-100 for AZOR® tablets (5 mg/20 mg, 5 mg/40 mg, 10 mg/20 mg, and 10 mg/40 mg), which tablets contain the active ingredients amlodipine besylate and olmesartan medoxomil. AZOR® tablets were approved by the United States Food and Drug Administration ("FDA") on September 26, 2007, for the treatment of hypertension. Olmesartan medoxomil is an angiotensin II receptor antagonist.

13. Daiichi Sankyo Japan is the owner of United States Letters Patent No. 5,616,599 ("the '599 patent"). The '599 patent was duly and legally issued on April 1, 1997. A true copy of the '599 patent is attached hereto as Exhibit A.

14. The '599 patent claims various chemical compounds including olmesartan medoxomil specifically, as well as pharmaceutical compositions containing these compounds, and a method for the treatment or prophylaxis of hypertension administering these compounds.

15. The '599 patent was assigned by the inventors to Sankyo Co., Ltd. As Sankyo Co., Ltd., was merged into Daiichi Sankyo Japan on April 1, 2007, its rights in the '599 patent were succeeded by Daiichi Sankyo Japan.

16. Daiichi Sankyo U.S. is a licensee under the '599 patent and is marketing and selling in the United States the AZOR® tablets manufactured by Daiichi Sankyo Japan and its subsidiary.

17. Matrix submitted to the FDA an abbreviated new drug application ("ANDA"), ANDA No. 90-398, under the provisions of 21 U.S.C. §355(j), seeking approval to engage in the commercial manufacture, use, offer to sell, or sell generic amlodipine besylate and olmesartan medoxomil 5 mg/20 mg, 5 mg/40 mg, 10 mg/20 mg, and 10 mg/40 mg tablets (hereinafter referred to as "Matrix's ANDA Products") within the United States, and/or import into the United States Matrix's ANDA Products.

18. Matrix submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sell within the United States and/or import into the United States, of Matrix's ANDA Products before the expiration of the '599 patent.

19. By filing the ANDA under 21 U.S.C. §355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sell within the United States and/or import into the United States, of Matrix's ANDA Products before the expiration of the '599 patent, Matrix has committed an act of infringement under 35 U.S.C. §271(e)(2). Further, the commercial manufacture, use, offer to sell, or sell within the United States and/or import into the United States, of Matrix's ANDA Products for which Matrix seeks approval in its ANDA will also infringe one or more claims of the '599 patent.

20. Plaintiffs are entitled to the relief provided by 35 U.S.C. §271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Matrix's ANDA Products be a date which is not earlier than April 25, 2016, the expiration of the '599 patent, or any later date of exclusivity to which Plaintiffs become entitled. Further, Plaintiffs are entitled to an award of damages for any commercial manufacture, use, offer to sell, or sell within the United States and/or import into the United States, of Matrix's ANDA Products, and any act committed by Matrix with respect to the subject matter claimed in the '599 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

21. On information and belief, when Matrix filed its ANDA, it was aware of the '599 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '599 patent was an act of infringement of this patent.

22. Matrix made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '599 patent is invalid.

23. The relevant statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) requires that a notice of the Paragraph IV certification ("Notice Letter") "include a detailed statement of the

factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

24. On or about April 18, 2008, Matrix sent a Notice Letter, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and its subparagraph and the FDA regulations relating thereto, to Plaintiffs. The Notice Letter, as sent by Matrix, was received by Daiichi Sankyo U.S. on April 21, 2008 and by Daiichi Sankyo Japan on April 21, 2008.

25. In the Notice Letter, Matrix failed to comply with the statutory provisions set forth in paragraph 22, above. The Notice Letter does not present a *prima facie* case of invalidity of the claims of the '599 patent. Matrix's Notice Letter does not allege that the '599 patent is unenforceable. Other than the allegation of invalidity, Matrix's Notice Letter does not provide an independent allegation of noninfringement. On information and belief, Matrix lacked a good faith basis for alleging invalidity when the ANDA was filed. Matrix's ANDA and certification filing is a wholly unjustified infringement of the '599 patent.

26. Matrix has violated its duty of due care to avoid the known patent right of the '599 patent.

27. This is an exceptional case and Plaintiffs are entitled to an award of reasonable attorneys fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Matrix has infringed one or more claims of the '599 patent by filing the aforesaid ANDA relating to Matrix's ANDA Products;

B. Judgment that manufacture, use, sell, or offer to sell within the United States, and/or import into the United States, of Matrix's ANDA Products will infringe the '599 patent;

C. A permanent injunction restraining and enjoining Matrix and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sell within the United States, and/or import into the United States, of Matrix's ANDA Products as claimed in the '599 patent;

D. An Order that the effective date of any approval of the aforementioned ANDA relating to Matrix's ANDA Products be a date which is not earlier than the expiration of the right of exclusivity under the '599 patent, or any later date of exclusivity to which Plaintiffs become entitled;

E. Judgment that this is an exceptional case under 35 U.S.C. § 285, and Plaintiffs are entitled to the costs and reasonable attorneys fees in this action; and

F. Such other and further relief as the Court may deem just and proper.

Respectfully Submitted,

Dated: June 3, 2008

s/ William J. Heller
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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 one other action: *DAIICHI SANKYO COMPANY, LIMITED and DAIICHI SANKYO, INC. v. MYLAN LABORATORIES, INC. and MYLAN PHARMACEUTICALS, INC.*, 2:06-cv-03462-WJM-MF (D.N.J.).

Dated: June 3, 2008

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