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

William J. Heller
McCARTER & ENGLISH
Four Gateway Center
100 Mulberry St.
Newark, New Jersey 07102
Phone: (973) 622-4444
Facsimile: (973) 624-7070

Of Counsel:
Robert L. Baechtold
Lisa B. Pensabene
Dominick A. Conde
Joshua I. Rothman
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112
Phone: (212) 218-2100
Facsimile: (212) 218-2200

Attorneys for Plaintiffs
Daiichi Sankyo Company, Limited
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.	:	
MYLAN PHARMACEUTICALS INC. and MYLAN LABORATORIES INC.,	:	
Defendants.	:	

Plaintiffs Daiichi Sankyo Company, Limited and Daiichi Sankyo, Inc. (hereinafter "Plaintiffs"), for their Complaint against Defendants Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc., 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 3-5-1, Nihonbashi Honcho, 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, Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

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

6. On information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Laboratories, and the acts of Mylan Pharmaceuticals complained of herein were aided and abetted by and done with the cooperation, participation, and assistance of Mylan Laboratories. On information and belief, Mylan Pharmaceuticals and Mylan Laboratories have officers or directors in common.

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

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

10. 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

11. Plaintiff Daiichi Sankyo U.S. holds an approved new drug application ("NDA") No. 21-532 for Benicar HCT® tablets (40/12.5 mg, 40/25 mg, and 20/12.5 mg), which tablets contain the active ingredients Olmesartan Medoxomil and Hydrochlorothiazide. Benicar HCT® tablets were approved by the United States Food and Drug Administration ("FDA") on June 5, 2003, for the treatment of hypertension. Olmesartan Medoxomil is an angiotensin II receptor antagonist.

12. 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.

13. 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.

14. 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.

15. Daiichi Sankyo U.S. is a licensee under the '599 patent and is marketing and selling Benicar HCT® tablets in the United States.

16. Mylan Pharmaceuticals submitted to the FDA an abbreviated new drug application ("ANDA"), ANDA No. 78-827, under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic Olmesartan Medoxomil and Hydrochlorothiazide tablets 40/12.5 mg, 40/25 mg, and 20/12.5 mg (hereinafter referred to as "Mylan's ANDA Products").

17. Mylan submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's ANDA Products before the expiration of the '599 patent.

18. 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 for sale, sale and/or importation of Mylan's ANDA Products before the expiration of the '599 patent, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or

importation of Mylan's ANDA Products for which Mylan seeks approval in its ANDA will also infringe one or more claims of the '599 patent.

19. 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 Mylan'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 for sale, sale and/or importation of Mylan's ANDA Products, and any act committed by Mylan 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).

20. On information and belief, when Mylan 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.

21. Mylan 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.

22. 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."

23. On or about May 10, 2007, Mylan sent a Notice Letter, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and the FDA regulations relating thereto, to Plaintiffs. The Notice Letter, as sent by Mylan, was received by Daiichi Sankyo U.S. on May 11, 2007 and by Daiichi Sankyo Japan on May 14, 2007.

24. In the Notice Letter, Mylan 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. Mylan's Notice Letter does not allege that the '599 patent is unenforceable. Other than the allegation of invalidity, Mylan's Notice Letter does not provide an independent allegation of noninfringement. On information and belief, Mylan lacked a good faith basis for alleging invalidity when the ANDA was filed. Mylan's ANDA and certification filing is a wholly unjustified infringement of the '599 patent.

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

26. 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 Mylan has infringed one or more claims of the '599 patent by filing the aforesaid ANDA relating to Mylan's ANDA Products;

B. Judgment that manufacture, use, sale or offer for sale of Mylan's ANDA Products will infringe the '599 patent;

C. A permanent injunction restraining and enjoining Mylan 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, sale within the United States, or importation into the United States, of Mylan'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 Mylan'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.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the within action is not the subject of any other action pending in any Court, or of any pending arbitration or administrative proceeding.

Dated: June 22, 2007

s/ William J. Heller
William J. Heller
McCARTER & ENGLISH
Four Gateway Center
100 Mulberry St.
Newark, New Jersey 07102
Phone: (973) 622-4444
Facsimile: (973) 624-7070

Attorneys for Plaintiffs
Daiichi Sankyo Company, Limited
Daiichi Sankyo, Inc.

Of Counsel:
Robert L. Baechtold
Lisa B. Pensabene
Dominick A. Conde
Joshua I. Rothman
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112-3801
Phone: (212) 218-2100
Facsimile: (212) 218-2200