IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIONOGI PHARMA, INC. and CIMA LABS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN INC. and MYLAN PHARMACEUTICALS INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Shionogi Pharma, Inc. and CIMA LABS INC. (collectively, "Plaintiffs"), for their Complaint against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Defendants" or "Mylan") hereby allege as follows:

1. Shionogi Pharma, Inc. ("Shionogi Pharma") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Five Concourse Parkway, Suite 1800, Atlanta, Georgia 30328.

2. CIMA LABS INC. ("CIMA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 7325 Aspen Lane, Brooklyn Park, Minnesota 55428.

3. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharma") is a West Virginia corporation, and a wholly-owned subsidiary and agent of Defendant Mylan Inc., having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Defendant Mylan Pharma manufactures numerous generic drugs for sale and use throughout the United States, including in

this judicial district. Mylan Pharma has qualified to do business in Delaware and appointed a registered agent for service of process.

4. Upon information and belief, Defendant Mylan Inc. ("Mylan Inc.") 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. Upon information and belief, Defendant Mylan Inc., itself and through its wholly-owned subsidiary and agent Defendant Mylan Pharma, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for infringement of U.S. Patent No. 6,740,341 B1 ("the '341 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over each Defendant by virtue of the fact, *inter alia*, that 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 Plaintiffs, all of whom are Delaware corporations.

8. Upon information and belief, Defendants are in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Defendant Mylan Inc. conducts its North American operations, in part, through Defendant Mylan Pharma. Together, they collaborate in developing, manufacturing, marketing, and selling generic drugs throughout the United States, including in this judicial district.

9. This Court has personal jurisdiction over Defendant Mylan Pharma by virtue of, *inter alia*, its systematic and continuous contacts with Delaware and because it has appointed a registered agent for service of process in Delaware.

10. This Court has personal jurisdiction over Defendant Mylan Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

11. Defendants have previously submitted to the jurisdiction of this Court. Defendant Mylan Pharma has, *inter alia*, initiated suit in this Court and asserted claims arising under the Patent Laws of the United States in this Court. *See, e.g.*, *Mylan Pharmaceuticals Inc. v. Ethypharm S.A., et al.*, C.A. No. 10-1064-UNA; *Mylan Pharmaceuticals Inc. v. Galderma Laboratories, Inc., et al.*, C.A. No. 10-892-LPS. Defendants have also previously availed themselves of this Court by asserting counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this jurisdiction. *See, e.g.*, *Forest Laboratories, Inc. v. Dr. Reddy's Laboratories, Inc., et al.*, C.A. No. 08-52-GMS; *Shionogi Pharma, Inc. v. Mylan Inc., et al.*, C.A. No. 10-135-RBK.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

THE PATENT-IN-SUIT

13. On May 25, 2004, the '341 patent, titled "Taste Masking Rapid Release Coating System," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff CIMA has been, and continues to be, owner by assignment of the '341 patent, and Plaintiff Shionogi Pharma is an exclusive licensee of the '341 patent in the United States with regard to orally disintegrating tablets containing prednisolone sodium phosphate, prednisolone or any salt or base thereof.

14. Shionogi Pharma holds New Drug Application ("NDA") No. 021959 for 10 mg, 15 mg, and 30 mg prednisolone sodium phosphate orally disintegrating tablets. Shionogi

Pharma markets these tablets in the United States under the trade name "Orapred ODT®." The '341 patent is listed in the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Orapred ODT®.

ACTS GIVING RISE TO THIS ACTION

CLAIM – INFRINGEMENT OF THE '341 PATENT

15. Upon information and belief, Defendant Mylan Pharma, on behalf of itself and as agent for Defendant Mylan Inc., submitted ANDA No. 202-179 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, and sale of 10 mg, 15 mg, and 30 mg prednisolone sodium phosphate orally disintegrating tablets ("Mylan's ANDA Products"). ANDA No. 202-179 specifically seeks FDA approval to market Mylan's ANDA Products prior to the expiration of the '341 patent.

16. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Mylan Pharma certified in ANDA No. 202-179 that the claims of the '341 patent will not be infringed by the manufacture, use, or sale of Mylan's ANDA Products. Defendants provided written notification of ANDA No. 202-179 and its § 505(j)(2)(A)(vii)(IV) certification by sending Plaintiffs a letter bearing a date of October 25, 2010.

17. Mylan Pharma's submission of ANDA No. 202-179 to the FDA constitutes infringement of the '341 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the Mylan ANDA Products, or induces or contributes to any such conduct, it would further infringe the '341 patent under 35 U.S.C. §271(a), (b), and/or (c).

18. Mylan Inc. is jointly and severally liable for Mylan Pharma's infringement of the '341 patent. Upon information and belief, Mylan Inc. participated in, contributed to,

aided, abetted, and/or induced Mylan Pharma's submission of ANDA No. 202-179 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA. Mylan Inc.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 202-179 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA constitutes infringement of the '341 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Inc. commercially manufactures, uses, offers to sell, sells, or imports any of Mylan's ANDA Products, or induces or contributes to any such conduct, it would further infringe the '341 patent under 35 U.S.C. §271(a), (b), and/or (c).

19. Defendants Mylan Inc. and Mylan Pharma were aware of the existence of the '341 patent prior to filing ANDA No. 202-179.

20. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '341 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202-179 shall not be earlier than the expiration date of the '341 patent, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, Mylan's ANDA products identified in this Complaint, and any other products that infringes the '341 patent, prior to the expiration of the '341 patent, including any extensions;

D. That Plaintiffs be awarded the attorneys fees, costs, and expenses that they incur in prosecuting this action; and

E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Bruce M. Wexler
Joseph M. O'Malley, Jr.
Melanie R. Rupert
Christopher Hurd
PAUL, HASTINGS, JANOFSKY & WALKER LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

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