

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SHIONOGI PHARMA, INC., ANDRX )  
CORPORATION, ANDRX )  
PHARMACEUTICALS, INC. (N/K/A )  
WATSON LABORATORIES, INC.- )  
FLORIDA), ANDRX PHARMACEUTICALS, )  
L.L.C., ANDRX LABORATORIES (NJ), INC., )  
ANDRX EU LTD., AND ANDRX LABS, )  
L.L.C., )  
Plaintiffs, )  
v. )  
MYLAN INC., and MYLAN )  
PHARMACEUTICALS INC., )  
Defendants. )

C.A. No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

For their complaint herein, Plaintiffs allege as follows:

1. Shionogi Pharma, Inc. (“Shionogi”) (formerly Sciele Pharma, Inc.) 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. Andrx Corporation (“Andrx Corp.”) is a Delaware corporation and subsidiary of Watson Pharmaceuticals, Inc., having a place of business at 4955 Orange Drive, Davie, Florida 33314. Andrx Pharmaceuticals, Inc. (“Andrx Pharmaceuticals”) is a Florida corporation and subsidiary of Andrx Corp., now known as Watson Laboratories, Inc.-Florida, having a place of business at 4955 Orange Drive, Davie, Florida 33314. Andrx Pharmaceuticals, L.L.C. and Andrx Labs, L.L.C. (“Andrx Labs”) are Delaware limited liability companies and subsidiaries of Andrx Corp., having a place of business at 4955 Orange Drive, Davie, Florida 33314. Andrx Laboratories (NJ), Inc. is a Delaware corporation and subsidiary of Andrx Corp., having a place of business at 8151 Peters Road, 4th floor, Plantation, Florida 33324. Andrx EU

Ltd. is a UK corporation and subsidiary of Andrx Corp., having a place of business at 8151 Peters Road, 4th floor, Plantation, Florida 33324. The Andrx companies are hereinafter referred to collectively as “Andrx.”

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, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Mylan Inc. (“Mylan”) 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, 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.

#### **JURISDICTION AND VENUE**

5. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

6. This Court has personal jurisdiction over each of the Defendants by virtue of the facts that, *inter alia*, that each of the Defendants, Mylan and Mylan Pharma, 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. This Court

has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

7. Upon information and belief, Defendant Mylan participated in the preparation and filing of Mylan Pharma's ANDA No. 200690 in its own capacity.

8. Upon information and belief, Defendant Mylan and Defendant Mylan Pharma are in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Defendant Mylan 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 by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including being registered to do business in the State of Delaware.

10. Mylan states in its 2007 Annual Report that “[Mylan Pharma], Mylan’s flagship generic subsidiary, once again ranked as one of the nation’s leading provider of pharmaceutical providers overall, and pharmacists filled over 257 million prescriptions with products from Mylan.” On information and belief, a proportionate number of these prescriptions were filled in Delaware.

11. Mylan further states in its 2008 Annual Report that Mylan Pharma is its “primary U.S. pharmaceutical research, development, manufacturing, marketing, and distribution subsidiary.” Upon information and belief, Mylan Pharma has marketed and distributed numerous generic products throughout Delaware.

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

13. In addition, Defendant Mylan and Defendant Mylan Pharma have previously submitted to the jurisdiction of this Court by, *inter alia*, Defendant Mylan Pharma having initiated suit in this Court and having asserted claims in this Court, and have further previously availed themselves of this Court by Defendant Mylan and Defendant Mylan Pharma having asserted counterclaims in other civil actions initiated in this jurisdiction.

#### **PATENTS IN SUIT**

14. Andrx is the owner of United States Patent No. 6,099,859 (“the ’859 patent”), which was duly and legally issued on August 8, 2000, and is titled “Controlled Release Oral Tablet Having A Unitary Core.” Shionogi has an exclusive license under the ’859 patent in the United States. A copy of the ’859 patent is attached as Exhibit A.

15. Andrx is the owner of United States Patent No. 6,866,866 (“the ’866 patent”), which was duly and legally issued on March 15, 2005, and is titled “Controlled Release Metformin Compositions.” Shionogi has an exclusive license under the ’866 patent in the United States. A copy of the ’866 patent is attached as Exhibit B.

#### **ACTS GIVING RISE TO THIS ACTION**

16. Andrx Labs is the holder of New Drug Application (“NDA”) No. 21-574, by which the United States Food and Drug Administration (“FDA”) first granted approval for 500 mg and 1000 mg extended-release metformin hydrochloride tablets. The metformin hydrochloride tablets described in Andrx’s NDA are indicated as an adjunct to diet and exercise to lower blood glucose to improve glycemic control in adults with Type 2 diabetes mellitus. Shionogi markets these tablets in the United States under the tradename “Fortamet<sup>®</sup>.”

17. Upon information and belief, Defendant Mylan Pharma submitted to the FDA Abbreviated New Drug Application (“ANDA”) No. 200690, which included a certification with respect to the ’859 and ’866 patents under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to manufacture, use, and sell 500 mg and 1000 mg extended-release metformin hydrochloride tablets (“the ANDA product”) prior to the expiration of those patents.

18. On or about January 4, 2010, Defendant Mylan Pharma sent a letter (“Notice Letter”) to Watson Pharmaceuticals, Inc. and Andrx in which Defendant Mylan Pharma represented that it had filed an ANDA for the ANDA product, including certifications with respect to the ’859 and ’866 patents, and that it sought approval of its ANDA prior to the expiration of those patents.

**FIRST COUNT FOR INFRINGEMENT BY DEFENDANTS MYLAN  
AND MYLAN PHARMA OF UNITED STATES PATENT NO. 6,099,859**

19. Plaintiffs reallege paragraphs 1-18 as if fully set forth herein.

20. Because Defendant Mylan and Defendant Mylan Pharma seek approval of their ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the ’859 patent before its expiration, Defendant Mylan and Defendant Mylan Pharma have infringed the ’859 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

21. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Mylan products that are the subject of ANDA No. 200690 will infringe the ’859 patent. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 200690 be a date that is not earlier than the expiration date of the ’859 patent, or any later expiration of exclusivity for the ’859 patent to which Plaintiffs are or become entitled.

22. Upon information and belief, Defendant Mylan and Defendant Mylan Pharma were aware of the existence of the '859 patent and were aware that the submission of the ANDA and certification with respect to the '859 patent constituted an act of infringement of that patent.

**SECOND COUNT FOR INFRINGEMENT BY DEFENDANTS MYLAN AND MYLAN PHARMA OF UNITED STATES PATENT NO. 6,866,866**

23. Plaintiffs reallege paragraphs 1-22 as if fully set forth herein.

24. Because Defendant Mylan and Defendant Mylan Pharma seek approval of their ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '866 patent before its expiration, Defendant Mylan and Defendant Mylan Pharma have infringed the '866 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Mylan products that are the subject of ANDA No. 200690 will infringe the '866 patent. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 200690 be a date that is not earlier than the expiration date of the '866 patent, or any later expiration of exclusivity for the '866 patent to which Plaintiffs are or become entitled.

26. Upon information and belief, Defendant Mylan and Defendant Mylan Pharma were aware of the existence of the '866 patent and were aware that the submission of the ANDA and certification with respect to the '866 patent constituted an act of infringement of that patent.

**THIRD COUNT FOR INFRINGEMENT BY DEFENDANT MYLAN**

27. Plaintiffs reallege paragraphs 1-26 as if fully set forth herein.

28. Upon information and belief, Defendant Mylan has actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 200690 to the FDA. On information and belief, Defendant Mylan and Mylan Pharma were aware of the '859 and '866 patents when it engaged in these knowing and purposeful activities referred to above.

29. Under 35 U.S.C. §271(b) and 271(e)(2)(A), Defendant Mylan induced the infringement of the '859 and '866 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 200690. The filing of the ANDA by Defendant Mylan and Defendant Mylan Pharma constitutes a direct act of infringement under 35 U.S.C. §271(e). Defendant Mylan's active and knowing aiding and abetting Defendant Mylan Pharma in the filing of ANDA No. 200690 constitutes induced infringement.

**PRAYER FOR RELIEF**

30. Plaintiffs request that:

a. Judgment be entered that Defendants have infringed the '859 and '866 patents by submitting the aforesaid ANDA;

b. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '859 and '866 patents.

c. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 200690 be a date that is not earlier than the expiration date of the '859 and '866 patents, or any later expiration of exclusivity for the '859 and '866 patents to which Plaintiffs are or become entitled; and

d. The Court grant such other and further relief as it deems just and proper under the circumstances.

RICHARDS, LAYTON & FINGER P.A

*/s/ Frederick L. Cottrell*

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Frederick L. Cottrell, III (#2555)  
Steven J. Fineman (#4025)  
One Rodney Square  
P.O. Box 551  
Wilmington, DE 19899  
(302) 651-7700  
cottrell@rlf.com  
fineman@rlf.com

*Attorneys for Plaintiffs Andrx*

OF COUNSEL:

Gary E. Hood  
Paul S. Tully  
MCDONNELL BOEHNEN HULBERT  
& BERGHOFF LLP  
300 S. Wacker Drive, Suite 3100  
Chicago, IL 60606  
(312) 913-0001

February 18, 2010

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Karen Jacobs Louden*

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Jack B. Blumenfeld (#1014)  
Karen Jacobs Louden (#2881)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899-1347  
(302) 658-9200  
jblumenfeld@mnat.com  
klouden@mnat.com

*Attorneys for Plaintiff Shionogi Pharma, Inc.*

OF COUNSEL:

Bruce M. Wexler  
Joseph M. O'Malley, Jr.  
Preston K. Ratliff, II  
PAUL, HASTINGS, JANOFSKY & WALKER LLP  
75 East 55th Street  
New York, NY 10022  
(212) 318-6000