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Pharmaceuticals, Inc. (N/K/A Watson
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Pharmaceuticals, L.L.C., Andrx Laboratories (NJ),
Inc., Andrx EU Ltd., and Andrx Labs, L.L.C.*

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

SHIONOGI 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.)

NOSTRUM LABORATORIES, INC. AND)
NOSTRUM PHARMACEUTICALS LLC,)

Defendants.)

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

For their complaint herein, Plaintiffs allege as follows:

1. Shionogi Inc. (“Shionogi”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

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. 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 a subsidiary of Andrx Corp., having a place of business at 8151 Peters Road, 4th Floor, Plantation, Florida 33324. Andrx EU Limited 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 Nostrum Laboratories, Inc. (“Nostrum Labs.”) is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 1800 N Topping Ave., Kansas City, MO 64120. Upon information and belief, Defendant Nostrum Labs. manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Nostrum Pharmaceuticals, LLC (“Nostrum Pharma”) is a corporation organized and existing under the laws of Delaware, with a

principal place of business at 11D Jules Lane, New Brunswick, NJ 08901. Upon information and belief, Defendant Nostrum Pharma, itself and through its wholly-owned subsidiary and agent Defendant Nostrum Labs. (collectively “Nostrum”), manufactures 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).

6. This Court has personal jurisdiction over Defendant Nostrum Pharma by virtue of, *inter alia*, its systematic and continuous contacts with New Jersey and because it has a principal place of business in New Jersey.

7. Upon information and belief, Nostrum Pharma has also previously submitted itself to the jurisdiction of this Court, by initiating suit in this Court. *See, e.g., Nostrum Pharms. LLC v. F.D.A.*, Civ. Action No. 11-3111 (JAP/TJB) (D.N.J.) (complaint filed on May 27, 2011).

8. This Court has personal jurisdiction over Defendant Nostrum Labs. by virtue of, *inter alia*, its systematic and continuous contacts with New Jersey and because it has submitted itself to the jurisdiction of courts in New Jersey by virtue of its incorporation under New Jersey law.

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

PATENTS IN SUIT

10. 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.

11. 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

12. Andrx Labs is the holder of New Drug Application (“NDA”) No. 21-574, by which the United States Food and Drug Administration (“FDA”) 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[®].”

13. Upon information and belief, Nostrum submitted to the FDA Abbreviated New Drug Application (“ANDA”) No. 203-832, 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 products”) prior to the expiration of those patents.

14. Upon information and belief, Nostrum Pharma participated in studies and clinical research that was reported in ANDA No. 203-832. Further, upon information and belief, Nostrum Pharma directed the activities of Nostrum Labs. complained of herein, including the filing of ANDA No. 203-832.

15. On or about May 24, 2012, Nostrum Labs. sent a letter (“Notice Letter”) to Shionogi, Pharmaceuticals, Inc., Andrx Pharmaceuticals, LLC and Andrx Laboratories, LLC in which it represented that it had filed an ANDA for the ANDA products, 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.

16. This action is being commenced within forty-five days from the date of the receipt of the Notice Letter by Shionogi, May 30, 2012.

**FIRST COUNT FOR INFRINGEMENT
OF UNITED STATES PATENT NO. 6,099,859**

17. Plaintiffs reallege paragraphs 1-16 as if fully set forth herein.

18. Nostrum's ANDA Product is covered by one or more claims of the '859 patent.

19. Nostrum's submission of ANDA No. 203-832 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Nostrum's ANDA Product before the expiration of the '859 patent is an act of infringement of the '859 patent.

20. The commercial manufacture, use, offer for sale, sale and/or importation of Nostrum's ANDA Product would infringe one or more claims of the '859 patent.

21. Unless Nostrum is enjoined from infringing the '859 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**SECOND COUNT FOR INFRINGEMENT
OF UNITED STATES PATENT NO. 6,866,866**

22. Plaintiffs reallege paragraphs 1-21 as if fully set forth herein.

23. Nostrum's ANDA Product is covered by one or more claims of the '866 patent.

24. Nostrum's submission of ANDA No. 203-832 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Nostrum's

ANDA Product before the expiration of the '866 patent is an act of infringement of the '866 patent.

25. The commercial manufacture, use, offer for sale, sale and/or importation of Nostrum's ANDA Product would infringe one or more claims of the '866 patent.

26. Unless Nostrum is enjoined from infringing the '866 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

27. Wherefore, Plaintiffs request that:

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

b. Judgment be entered that the making, using, selling, offering for sale, or import of Nostrum's ANDA product would infringe the '859 and '866 patents;

c. 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;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 203-832 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;

e. Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorney fees pursuant to 35 U.S.C. § 285; and

f. They be granted such other and further relief as the Court may deem just and proper under the circumstances.

Dated: July 13, 2012

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