UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

(Northern Division)

SCIELE PHARMA, INC.,
Five Concourse Parkway, Suite 1800,
Atlanta, Georgia 30328

and

ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., and ANDRX LABS, L.L.C.,
4955 Orange Drive,
Davie, Florida 33314

and

ANDRX LABORATORIES (NJ), INC.,
ANDRX EU LTD.,
8151 Peters Road, 4th Floor,
Plantation, Florida 33324

Plaintiffs,

v.

LUPIN LTD.,
Laxmi Towers "B" Wing, 5th Floor
Banda Kurla Complex
Mumbai 400 051
India

and

LUPIN PHARMACEUTICALS, INC.,
Harborplace Tower, 21st Floor
111 South Calvert Street
Baltimore, Maryland 21202,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

For their complaint herein, Plaintiffs allege as follows:

1. Sciele Pharma, Inc. ("Sciele") 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. 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 Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a Virginia corporation, and a wholly-owned subsidiary and agent of Defendant Lupin Ltd., having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, Defendant Lupin Pharma 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 Lupin, Ltd. ("Lupin") is a corporation organized and existing under the laws of India, having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Upon information and belief, Defendant Lupin, itself and through its wholly-owned subsidiary and agent Defendant Lupin Pharma, 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). 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*, each Lupin and Lupin 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. Defendants have also stated to Plaintiffs that they consent to personal jurisdiction in this district. In addition, 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, Lupin Pharma participated in the preparation and filing of Lupin's ANDA No. 90-692 as an agent of Lupin and/or in its own capacity.

8. Upon information and belief, Lupin is in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Lupin established Lupin Pharma for the purpose of distributing, marketing, and selling its generic drug products in the United States. Lupin maintains an Internet website at the URL www.lupinworld.com at which Lupin represents that it has a representative office at Harborplace

Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, the principal place of business of Lupin Pharma.

9. Upon information and belief, based in part on representations on their websites and Lupin's Annual Report, Lupin and Lupin Pharma hold themselves out as a unitary entity by representing to the public that the activities of Lupin and Lupin Pharma are directed, controlled, and carried out by a single entity, namely, Lupin, headquartered in India.

10. Upon information and belief, Lupin maintains and controls a broad distribution network in the United States for Lupin's products that results in the distribution and sale of hundreds of millions of dollars of Lupin's products. The distribution network includes its "direct to market team" and its "structure for marketing generic products", as well as several marketing alliances with other companies in the United States.

11. Upon information and belief, based in part on the representations on Lupin and Lupin Pharma's websites, Lupin and Lupin Pharma sell and ship Lupin drug products directly to Cardinal Health and Wal-Mart Pharmacy Warehouse, who then sell Lupin's drug products throughout the United States, including in this judicial district.

12. Upon information and belief, Lupin exercises considerable control over its wholly-owned subsidiary Lupin Pharma, including but not limited to, approving significant decisions of Lupin Pharma such as allowing Lupin Pharma to act as the agent for Lupin in connection with preparing and filing ANDA No. 90-692, and acting as Lupin's "representative office" and agent in the United States.

13. Upon information and belief, Lupin is currently the sole manufacturer of the "Suprax®" drug product in the United States, and Lupin Pharma distributes "Suprax®" for sale throughout the United States, including in this judicial district. Upon further information

and belief, the package insert for the "Suprax®" drug product manufactured by Lupin and sold throughout the United States, including in this judicial district, states that the "Suprax®" drug product is manufactured for Lupin Pharma.

14. Upon information and belief, Lupin has entered into a multi-year contract with Forest Laboratories, Inc. to promote the "AeroChamber Plus®" drug product, whereby Lupin Pharma has used its "50 person sales force to promote the product to pediatricians". Upon information and belief, Lupin Pharma distributes the "AeroChamber Plus®" drug product for sale throughout the United States, including in this judicial district.

15. This Court has personal jurisdiction over Defendant Lupin Pharma by virtue of, *inter alia,* its systematic and continuous contacts with Maryland.

16. This Court has personal jurisdiction over Defendant Lupin by virtue of, *inter alia,* its systematic and continuous contacts with Maryland.

PATENTS IN SUIT

17. 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." Sciele has an exclusive license under the '859 patent in the United States. A copy of the '859 patent is attached as Exhibit A.

18. 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." Sciele 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

19. 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. Sciele markets these tablets in the United States under the tradename "Fortamet®."

20. Upon information and belief, Lupin submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 90-692, 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.

21. On or about December 3, 2008, Lupin sent a letter ("Notice Letter") to Watson Pharmaceuticals, Inc., and Andrx in which Lupin 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.

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

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

23. Because Lupin and Lupin Pharma seek approval of ANDA No. 90-692 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '859 patent before its expiration, Lupin and Lupin Pharma have infringed the '859 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

24. Upon information and belief, the commercial manufacture, use, offer to sell, sale or import of the Lupin products that are the subject of its ANDA No. 90-692 would 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 Lupin’s ANDA 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.

25. Upon information and belief, Lupin was aware of the existence of the ’859 patent and was aware that the submission of its ANDA and certification with respect to the ’859 patent constituted an act of infringement of that patent.

26. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

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

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

28. Because Lupin and Lupin Pharma seek approval of ANDA No. 90-692 to engage in the commercial manufacture, use, or sale of a drug product claimed in the ’866 patent before its expiration, Lupin and Lupin Pharma have infringed the ’866 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, the commercial manufacture, use, offer to sell, sale or import of the Lupin products that are the subjects of its ANDA No. 90-692 would 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 Lupin’s ANDA 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.

30. Upon information and belief, Lupin and Lupin Pharma were aware of the existence of the ’866 patent and were aware that the filing of its ANDA and certification with respect to the ’866 patent constituted an act of infringement of that patent.

31. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

THIRD COUNT FOR INFRINGEMENT BY LUPIN PHARMA

32. Plaintiffs reallege paragraphs 1-31 as if fully set forth herein.

33. Upon information and belief, Lupin Pharma has actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 90-692 to the FDA. On information and belief, Lupin Pharma was aware of the ’859 and ’866 patents when it engaged in these knowing and purposeful activities referred to above.

34. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Lupin Pharma induced the infringement of the ’859 and ’866 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 90-692. The filing of the ANDA by Lupin and Lupin Pharma constitutes a direct act of infringement under 35 U.S.C. §271(e). Lupin Pharma’s active and knowing aiding and abetting Lupin in the filing of ANDA No. 90-692 constitutes induced infringement.

STATEMENT REGARDING PRIOR-FILED SUIT

35. This is not the first-filed action involving the named Plaintiffs and Defendants, the patents, and the counts of patent infringement set forth above. Plaintiffs have previously filed, on January 15, 2009, an identical action seeking to enjoin Lupin and Lupin Pharma from infringing the ’859 and ’866 patents in the District of Delaware, and that action has been assigned Civil Action No. 1:09-cv-00037. Defendants Lupin and Lupin Pharma have

previously consented to personal jurisdiction in the District of Delaware, and they are presently engaged in patent litigation as Defendants in that district. Judicial economy would be promoted, and Plaintiffs' choice of forum respected, if the claims related to Plaintiffs' action for infringement of the '859 and '866 patents are addressed in the District of Delaware.

36. Plaintiffs filed this action as a protective measure. Defendants have stated that they would not consent to personal jurisdiction in Delaware in this action, even though they have done so previously, but would consent to personal jurisdiction in this district. Given Defendants' present refusal to consent to personal jurisdiction in Delaware, although having consented to personal jurisdiction in that district previously, Plaintiffs were required to file this second action out of an abundance of caution. Plaintiffs expect that personal jurisdiction will be maintained in the District of Delaware and that the action will proceed in that forum, in which case this second action would be unnecessary and voluntarily dismissed.

PRAYER FOR RELIEF

37. 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. 90-692 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;

d. 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

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

KRAMON & GRAHAM P.A.

/s/

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January 16, 2009