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ATTORNEYS FOR PLAINTIFF  
SCHERING CORPORATION

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

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SCHERING CORPORATION,

Plaintiff,

vs.

CARACO PHARMACEUTICAL  
LABORATORIES, LTD. and SUN  
PHARMACEUTICAL INDUSTRIES LTD.,

Defendants.

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Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiff Schering Corporation ("Schering"), for its Complaint against Defendants Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") and Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), hereby alleges as follows.

### **Parties**

1.A. Plaintiff Schering is a New Jersey corporation having places of business throughout New Jersey, including a place of business at 3070 Route 22 West, Branchburg, New Jersey 08876.

1.B. Upon information and belief, Defendant Caraco is a Michigan corporation having a place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202. Upon information and belief, Caraco manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

1.C. Upon information and belief, Defendant Sun Ltd. is an Indian corporation having a place of business at Acme Plaza, Andheri - Kurla Rd, Andheri (E), Mumbai - 400 059. Upon information and belief, Defendant Sun Ltd., including through its agent and alter ego Defendant Caraco, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

### **Nature of the Action**

2. This is a civil action for the infringement of United States Patent No. 7,405,223 ("the '223 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §1 *et seq.*

### **Jurisdiction and Venue**

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

4. This Court has personal jurisdiction over Defendant Caraco by virtue of, *inter alia*: (1) its systematic and continuous contacts with New Jersey; and (2) the fact that Caraco has committed, and/or aided, abetted, contributed to and/or participated in the

commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to a New Jersey corporation, Plaintiff Schering, in New Jersey.

5. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its systematic and continuous contacts with New Jersey, including through its agents, operating entities and alter egos; (3) its placement of goods into the stream of commerce for distribution throughout the United States, including New Jersey; (4) its ownership and operation of a manufacturing facility in Cranbury, New Jersey through its wholly owned subsidiary, agent and alter ego, Sun Pharmaceutical Industries Inc.; (5) the fact that Sun Ltd. has committed, and/or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to a New Jersey corporation, Plaintiff Schering, in New Jersey; and (6) its consent to jurisdiction in New Jersey, and its availment of the jurisdiction of this Court through the assertion of counterclaims, in numerous civil actions in this jurisdiction including: (a) *Orion Corp. v. Sun Pharm. Indus., Inc. and Sun Pharm. Indus. Ltd.*, No. 3:07-CV-05436 (D.N.J.); (b) *Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus. Ltd.*, No. 3:07-CV-01516 (D.N.J.); (c) *Altana Pharma AG, et al. v. Sun Pharm. Indus. Ltd. et al.*, No. 2:05-CV-01966 (D.N.J.); and (d) *PDL Biopharma, Inc. v. Sun Pharm. Indus. Ltd.*, No. 2:07-CV-01788 (D.N.J.).

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and/or (d) and 1400(b).

### **The Patent**

7. On July 29, 2008, the '223 patent, titled "Treating Allergic And Inflammatory Conditions," was duly and legally issued to Schering as assignee. Since that time, Schering has been, and continues to be, the sole owner of the '223 patent and the sole owner of

the right to sue and to recover for any infringement of that patent. A copy of the '223 patent is attached hereto as Exhibit A.

**Acts Giving Rise to this Action**

8. Upon information and belief, on or after June 21, 2006, Defendant Sun Ltd. submitted ANDA 78-359 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 78-359 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of generic tablets containing 5 milligrams of desloratadine per tablet. Upon information and belief, ANDA 78-359 was recently amended to specifically seek FDA approval to market these proposed generic tablets as an AB-rated generic substitution for Schering's Clarinex® brand 5 milligram desloratadine tablet product prior to the expiration of the '223 patent.

9. ANDA 78-359 now alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '223 patent are either invalid or not infringed by the manufacture, use or sale of its proposed generic version of Schering's Clarinex® brand 5 milligram desloratadine tablet product. Upon information and belief, Schering received written notification of ANDA 78-359 and its new § 505(j)(2)(A)(vii)(IV) allegations against the '223 patent on October 2, 2008.

10. Sun Ltd.'s submission of ANDA 78-359 to the FDA, including its new § 505(j)(2)(A)(vii)(IV) allegation regarding the '223 patent, constitutes infringement of the '223 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Sun Ltd. commercially uses, offers for sale or sells the proposed generic version of Schering's Clarinex® brand 5 milligram desloratadine tablet product, or induces or contributes to such conduct, it would further infringe the '223 patent under 35 U.S.C. § 271(a), (b) and/or (c).

11. Defendant Caraco is jointly and severally liable for any infringement of the '223 patent. This is so because, upon information and belief, Caraco participated in, contributed to, aided, abetted and/or induced the submission of ANDA 78-359 and its new § 505(j)(2)(A)(vii)(IV) allegation regarding the '223 patent to the FDA. Additionally, upon information and belief, Caraco will, without authority, market and/or distribute the proposed generic version of Schering's Clarinex® brand 5 milligram desloratadine tablet product in the United States and this judicial district if ANDA 78-359 is approved by the FDA.

12. Caraco's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 78-359 and its new § 505(j)(2)(A)(vii)(IV) allegation regarding the '223 patent to the FDA constitutes infringement of the '223 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Caraco commercially uses, offers for sale or sells the proposed generic version of Schering's Clarinex® brand 5 milligram desloratadine tablet product within the United States, or induces or contributes to any such conduct, it would further infringe the '274 patent under 35 U.S.C. § 271(a), (b) and/or (c).

13. Schering will be irreparably harmed by Defendant Sun Ltd.'s and Defendant Caraco's infringing activities unless those activities are enjoined by this Court. Schering does not have an adequate remedy at law. The balance of hardships and public interest also favor an injunction.

**Prayer for Relief**

**WHEREFORE**, Schering prays for judgment as follows:

A. That Defendants Caraco and Sun Ltd. have infringed the '223 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA 78-359 shall not be earlier than the expiration date of the '223 patent, including any extensions;

C. That Defendants Caraco and Sun Ltd., their officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially using, offering for sale or selling the proposed generic product defined by ANDA 78-359, and any other product that infringes or induces or contributes to the infringement of the '223 patent, prior to the expiration of the '223 patent, including any extensions;

D. That Schering be awarded monetary relief if Defendant Caraco and/or Defendant Sun Ltd. commercially uses, offers for sale or sells the proposed generic product defined by ANDA 78-359, or any other product that infringes or induces or contributes to the infringement of the '223 patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Schering with prejudgment interest;

E. That Schering be awarded the attorney fees, costs and expenses that it incurs prosecuting this action; and

F. That Schering be awarded such other and further relief as this Court deems just and proper.

Dated: November 14, 2008

Respectfully submitted,

s/ William J. O'Shaughnessy

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