

William J. O'Shaughnessy
Gita F. Rothschild
Richard Hernandez
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102

ATTORNEYS FOR PLAINTIFF
SCHERING CORPORATION

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

SCHERING CORPORATION,)
)
Plaintiff,)
)
vs.)
)
ORGENUS PHARMA INC. AND ORCHID)
CHEMICALS AND PHARMACEUTICALS)
LTD.,)
)
Defendants.)

Civil Action No. _____

COMPLAINT

Plaintiff Schering Corporation ("Schering"), for its Complaint against Defendants
Orgenus Pharma, Inc. ("Orgenus") and Orchid Chemicals and Pharmaceuticals Ltd. ("Orchid
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 Orgenus is a New Jersey corporation and wholly owned subsidiary, agent and alter-ego of Defendant Orchid Ltd. having places of business at 116 Village Boulevard, Princeton, New Jersey 08540, and 700 Alexander Park, Suite 104, Princeton, New Jersey 08540.

1.C. Upon information and belief, Defendant Orchid Ltd. is an Indian corporation having a place of business at Plot No. B3-B6 & B11-B14, Sipcot Industrial Park, Irungattukottai, Sriperumbudur (TK) - 602 105, Kancheepuram District, Tamil Nadu, India. Upon information and belief, Defendant Orchid Ltd. is registered to do business in New Jersey and has a place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540.

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 Orgenus by virtue of the fact that, *inter alia*, Orgenus is a New Jersey corporation.

5. This Court has personal jurisdiction over Defendant Orchid Ltd. by virtue of, *inter alia*: (1) its presence in New Jersey, including through its subsidiary, agent and alter-

ego; (2) its systematic and continuous contacts with New Jersey, including through its subsidiary, agent and alter-ego; and (3) its registration to do business in New Jersey.

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 Orchid Ltd. submitted ANDA 78-357 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 78-357 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 78-357 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 78-357 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 78-357 and its new § 505(j)(2)(A)(vii)(IV) allegations against the '223 patent on or about November 6, 2008.

10. Orchid Ltd.'s submission of ANDA 78-357 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 Orchid 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 Orgenus is jointly and severally liable for any infringement of the '223 patent. This is so because, upon information and belief, Orgenus participated in, contributed to, aided, abetted and/or induced the submission of ANDA 78-357 and its new § 505(j)(2)(A)(vii)(IV) allegation regarding the '223 patent to the FDA. Additionally, upon information and belief, Orgenus 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 78-357 is approved by the FDA.

12. Orgenus's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 78-357 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 Orgenus 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 '223 patent under 35 U.S.C. § 271(a), (b) and/or (c).

13. Schering will be irreparably harmed by Defendant Orchid Ltd.'s and Defendant Orgenus'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 Orchid Ltd. and Orgenus 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 78-357 shall not be earlier than the expiration date of the '223 patent, including any extensions;
- C. That Defendants Orchid Ltd. and Orgenus, their officers, agents, servants, employees and attorneys, 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 78-357, 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 Orchid Ltd. and/or Defendant Orgenus commercially manufactures, uses, offers for sale or sells the proposed generic product defined by ANDA 78-357, 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: December 12, 2008

Respectfully submitted,

s/ William J. O'Shaughnessy

William J. O'Shaughnessy

Gita F. Rothschild

Richard Hernandez

MCCARTER & ENGLISH, LLP

Four Gateway Center

100 Mulberry Street

Newark, NJ 07102

(973) 622-4444

*Attorneys for Plaintiff
Schering Corporation*

Of Counsel:

John M. Desmarais

Peter J. Armenio

Gerald J. Flattmann, Jr.

Anne S. Toker

KIRKLAND & ELLIS LLP

Citigroup Center

153 East 53rd Street

New York, New York 10022

(212) 446-4800