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Orchid Chemicals & Pharmaceuticals Ltd. and
Orgenus Pharma, Inc.

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

IN RE: DESLORATADINE
PATENT LITIGATION

MDL No.: 1851

Case No. 3:07-CV-3930 (MLC)(TJB)

CIVIL ACTION

ELECTRONICALLY FILED

SCHERING CORPORATION,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS, USA, INC.,
et al.,

Defendants.

Case No. 3:06-CV-4715 (MLC)(TJB)

CIVIL ACTION

**ORCHID CHEMICALS &
PHARMACEUTICALS LTD.'S AMENDED
ANSWER AND COUNTERCLAIMS**

STATEMENT PURSUANT TO L. CIV. R. 10.1

Defendant Corporation Orchid Chemicals & Pharmaceuticals, Ltd. is an Indian corporation, with its principal place of business located at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai - 600 034, Tamil Nadu, India.

AMENDED ANSWER

Defendants Orchid Chemicals & Pharmaceuticals, Ltd. and Orgenus Pharma, Inc. (collectively “Orchid”) hereby answer the Amended Complaint of plaintiff Schering Corporation (“Schering”) and counterclaim as follows:

THE PARTIES

1.A. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 1.A.

1.B. – 1.D. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 1.B. – 1.D., which pertain solely to other Defendants.

1.E. Orchid admits that Defendant Orgenus is a New Jersey corporation and wholly-owned subsidiary of Defendant Orchid Ltd. having a place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540. Orchid denies the remaining allegations of paragraph 1E.

1.F. Orchid admits the allegations of paragraph 1.F.

1.G. – 1.V. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 1.G. – 1.V., which pertain solely to other Defendants.

NATURE OF ACTION

2. In responding to paragraph 2, Orchid admits that Schering purports to bring this action under Title 35, United States Code § 1 *et. seq.*, but Orchid expressly denies liability thereunder.

JURISDICTION AND VENUE

3. In responding to paragraph 3, Orchid admits that, with respect to the claims against it, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), but Orchid expressly denies liability thereunder.

4. – 26. Orchid states that the allegations in paragraphs 4 – 26 are conclusions of law as to which no response is required.

THE PATENTS

27. Orchid admits that United States Patent No. 6,100,274 (“the ’274 patent”) states on its face that it was issued to Schering by the United States Patent and Trademark Office. Orchid denies that the ’274 patent was “duly and legally issued” by the United States Patent and Trademark Office. Orchid lacks sufficient information as to the remaining allegations in paragraph 27, and, on that basis, denies each and every remaining allegation.

28. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 28, which pertain solely to other Defendants. U.S. Pat. No. 6,979,463 has not been asserted against Orchid.

Count I – Alleged Infringement of the ’274 Patent by All Defendants

29. Orchid admits that it submitted Abbreviated New Drug Applications (“ANDAs”) 78-356 and 78-357 for approval to engage in the commercial manufacture, use, and sale of generic versions of certain Schering Clarinex[®] brand desloratadine products before the expiration of the ’274 patent. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 29, which pertain solely to other Defendants.

30. Orchid admits that in a letter dated August 25, 2006, it notified plaintiff that Orchid had filed ANDAs No. 78-356 and 78-357 pursuant to section 505(j), Title 21 of the Federal Food, Drug & Cosmetic Act (“the Act”) in order to obtain approval to engage in the commercial manufacture, use, or sale of generic versions of Schering’s Clarinex[®] brand products. Orchid refers to the letter for its contents. Orchid admits that its ANDAs 78-356 and 78-357 assert that the claims of the ’274 patent are either invalid or not infringed by the generic drug products set forth in those ANDAs. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 30, which pertain solely to other Defendants.

31. Orchid denies the allegations of paragraph 31 as to ANDAs 78-356 and 78-357. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 31, which pertain solely to other Defendants.

32. Orchid denies the allegations of paragraph 32 as to Orchid. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 32, which pertain solely to other Defendants.

Count II – Alleged Infringement of the ’274 Patent by Defendant Zydus

33. – 36. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 33 - 36, which pertain solely to another Defendant.

Count III – Alleged Infringement of the '274 Patent by Defendant Sandoz

37. – 40. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 37 - 40, which pertain solely to another Defendant.

Count IV – Alleged Infringement of the '274 Patent by Defendant Mylan

41. – 44. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 41 - 44, which pertain solely to another Defendant.

Count V – Alleged Infringement of the '274 Patent by Defendants Orgenus and Orchid Ltd.

45. Orchid denies the allegations of paragraph 45.

46. Orchid admits that ANDAs 78-356 and 78-357 allege under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '274 patent are either invalid or not infringed by the manufacture, use, or sale of the proposed generic versions of Schering's Clarinex[®] brand products. Orchid admits that it provided written notification to Schering of ANDAs 78-356 and 78-357 and its 505(j)(2)(A)(vii)(IV) allegations in letters dated August 25, 2006.

47. Orchid denies the allegations of paragraph 47.

48. Orchid denies the allegations of paragraph 48.

49. Orchid denies the allegations of paragraph 49.

50. Orchid denies the allegations of paragraph 50.

**Count VI – Alleged Infringement of the '274 Patent by
Defendants L. Perrigo and Perrigo Co.**

51. – 56. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 51 - 56, which pertain solely to other Defendants.

**Count VII – Alleged Infringement of the '274 Patent by
Defendants Glenmark USA and Glenmark Ltd.**

57. – 62. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 57 - 62, which pertain solely to other Defendants.

**Count VIII – Alleged Infringement of the '274 Patent by
Defendants GeoPharma and Belcher**

63. – 68. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 63 - 68, which pertain solely to other Defendants.

**Count IX – Alleged Infringement of the '274 Patent by
Defendants Lupin Pharmaceuticals and Lupin Ltd.**

69. – 74. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 69 - 74, which pertain solely to other Defendants.

**Count X – Alleged Infringement of the '274 Patent by
Defendants Ranbaxy Inc. and Ranbaxy Ltd.**

75. – 80. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 75 – 80, which pertain solely to other Defendants.

**Count XI – Alleged Infringement of the '274 Patent by
Defendants DRLI and DRLL**

81. – 86. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 81 - 86, which pertain solely to other Defendants.

**Count XII – Alleged Infringement of the '463 Patent by
Defendants DRLI and DRLL**

87. – 92. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 87 - 92, which pertain solely to other Defendants.

**Count XIII – Alleged Infringement of the '274 Patent by
Defendants Caraco and Sun Ltd.**

93. – 98. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 93 - 98, which pertain solely to other Defendants.

**Count XIV – Alleged Infringement of the '274 Patent by
Defendants Watson Pharmaceuticals and Watson Laboratories**

99. – 104. Orchid is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 99 - 104, which pertain solely to other Defendants.

Response to Prayer for Relief

Orchid denies that Schering is entitled to any of the relief that it seeks in the prayer. Further answering Schering's Amended Complaint, Orchid alleges as follows:

AFFIRMATIVE DEFENSES

First Affirmative Defense

Orchid has not infringed, is not infringing, and will not infringe (directly, indirectly, contributorily or by inducement) any valid claim of the '274 patent.

Second Affirmative Defense

By reason of the prior art and/or statements and representations made to the United States Patent and Trademark Office during the prosecution of the application that led to the issuance of the '274 patent, the patent is so limited that no claim can be construed as covering any Orchid activity.

Third Affirmative Defense

Each and every asserted claim of the '274 patent placed in issue herein is invalid and void for failure to meet the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, and/or for double patenting.

Fourth Affirmative Defense

Plaintiff's case is not exceptional under 35 U.S.C. § 285.

Fifth Affirmative Defense

Each of Plaintiff's Counts alleging infringement of the '274 patent under § 271(a), (b), and/or (c) fail to state a claim upon which relief can be granted.

COUNTERCLAIMS

Defendants and Counterclaimants Orchid Chemicals & Pharmaceuticals, Ltd. and Orgenus Pharma, Inc. (collectively "Orchid") brings the following Counterclaims against Plaintiff and Counterdefendant Schering Corporation ("Schering").

Jurisdiction and Venue

1. This action arises under the Patent Laws of the United States, Title 35, United States Code, and the Food and Drug laws of the United States, Title 21, United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1338(a), 2201, and 2202.

2. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

3. In its Amended Complaint filed on or about December 18, 2006 in this Court, plaintiff Schering has charged Orchid with infringement of the '274 patent. There is, therefore, a substantial, actual, and continuing controversy between Defendant and Counterclaimant Orchid and Plaintiff and Counterdefendant Schering with respect to the infringement and validity of the '274 patent.

Parties

4. Orchid Chemicals & Pharmaceuticals, Ltd. is an Indian corporation, having a principal place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai - 600 034, Tamil Nadu, India.

5. Orgenus Pharma, Inc. is a New Jersey corporation and wholly-owned subsidiary of Defendant Orchid Ltd. having a place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540.

6. Defendant and Counterclaimant Orchid is informed and believes that Plaintiff and Counterdefendant 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.

First Counterclaim – Declaration of Non-Infringement

7. Defendant and Counterclaimant Orchid repeats and realleges the allegations in Counterclaim paragraphs 1 through 6 hereof as though fully set forth herein.

8. Orchid does not infringe, has not infringed, and will not infringe (directly, indirectly, contributorily, or by inducement) any valid claim of United States Patent No. 6,100,274 (“the ’274 patent”).

Second Counterclaim – Declaration of Invalidity

9. Defendant and Counterclaimant Orchid repeats and realleges the allegations in Counterclaim paragraphs 1 through 8 hereof as though fully set forth herein.

10. Each and every claim of the ’274 patent is invalid for failure to meet the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103 and 112.

Third Counterclaim – Delisting of the ’274 Patent

11. Defendant and Counterclaimant Orchid repeats and realleges the allegations in Counterclaim paragraphs 1 through 10 hereof as though fully set forth herein.

12. This is a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii) for an order requiring Plaintiff and Counterdefendant Schering to delete the ’274 patent from the Orange Book with respect to NDA 21-312 on the ground that the ’274 patent does not claim either (i) the drug for which the application was approved, or (ii) an approved method of using the drug.

13. An applicants that submits a New Drug Application (NDA) is required to disclose to FDA “any patent which claims the drug for which the applicant submitted the application ... and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(B)(1). The statute directs FDA to list the disclosed patents, which FDA

does in a publication entitled “Approved Drug Products With Therapeutic Equivalence Evaluations,” more commonly known as the “Orange Book.”

14. An applicant that submits a Abbreviated New Drug Application (ANDA) for a generic drug referencing an NDA must make one of four certifications as to each patent listed in the Orange Book that purportedly claims the drug approved in the NDA. 21 U.S.C. § 355(j)(2)(A)(vii). When an ANDA applicant certifies that an Orange Book-listed patent is invalid or will not be infringed (a so-called “paragraph IV certification”), it must provide notice to the patentee and the holder of the approved NDA that it has submitted such a certification. *Id.* § 355(j)(2)(B)(i).

15. Once the patent holder receives notice that an ANDA applicant has filed a paragraph IV certification with respect to an approved drug, the patent holder has 45 days within which to file a patent infringement action. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee files an infringement action within the designated 45-day period, subject to certain exceptions, the FDA generally may not approve the ANDA until 30 months have passed. 21 U.S.C. § 355(j)(5)(B)(iii).

16. Plaintiff and Counterdefendant Schering has approved New Drug Applications (or “NDAs”) for a variety of dosage forms of its CLARINEX® products. For example, NDA No. 021-165 relates to CLARINEX® 5 mg tablets, while NDA No. 021-312 relates to CLARINEX® 2.5 and 5 mg orally disintegrating tablets (marketed as “CLARINEX® RediTabs”).

17. Schering caused the '274 patent to be listed on the Orange Book for both NDA No. 021-165 and NDA No. 021-312. Thus, any ANDA applicant seeking to market a generic version of desloratadine orally disintegrating tablets, for instance, has to submit a

certification relating to the '274 patent. Possible certifications include a statement that the ANDA applicant will not market its proposed generic product until the expiration of the '274 patent (which is slated to expire in 2020) or that the patent is invalid or will not be infringed.

18. Defendant Orchid filed an ANDA for desloratadine orally disintegrating tablets (No. 78-356), which referenced Plaintiff Schering's CLARINEX® RediTabs NDA, and included a paragraph IV certification for the '274 patent listed in the Orange Book. Orchid provided notice to Schering of the certification, Schering sued within the required 45-days, and now FDA presumptively is prevented from approving Orchid's ANDA for 30-months, or until about March 2009, absent prior action by this Court.

19. Schering improperly caused the FDA to list the '274 patent with regard to NDA No. 021-312 because the '274 patent does not cover CLARINEX® RediTabs. The '274 patent discloses and claims desloratadine compositions containing a basic salt. However, as the FDA-approved label for CLARINEX® RediTabs confirms, Schering's orally disintegrating formulation does not contain a basic salt. *June 26, 2002 Final Draft Labeling* at 1.

20. Orchid is in a position to enter the market for generic desloratadine orally disintegrating tablets but for the presumptive 30-month stay associated with Schering's filing of the instant lawsuit relating to Orchid ANDA No. 78-356. Thus, as Schering is aware, Orchid has fully and finally resolved a separate lawsuit with another pharmaceutical company involving another patent listed in the Orange Book for NDA No. 21-312 and another listed patent has expired. Orchid expects to obtain tentative approval to market its generic desloratadine orally disintegrating tablets in the near future. In short, the 30-month stay is the only remaining barrier to the availability of generic desloratadine orally disintegrating tablets to the public.

21. Concerned that pharmaceutical companies might improperly list patents in the Orange Book to thwart potential generic entry, Congress has specifically authorized courts to issue an order that the NDA holder “correct or delete the patent information submitted by the holder . . . on the ground that the patent does not claim either—(aa) the drug for which the application was approved; or (bb) the approved method of using the drug.” 21 U.S.C. § 355(j)(5)(C)(ii).

22. Orchid is entitled to an order that Schering be ordered to delete the ’274 patent from the Orange Book with respect to NDA No. 21-312 on the grounds that the ’274 patent neither claims the drug for which NDA No. 21-312 was approved nor an approved method of using the drug.

Fourth Counterclaim – Declaration of Exceptional Case

23. Defendant and Counterclaimant Orchid repeats and realleges the allegations in Counterclaim paragraphs 1 through 23 hereof as though fully set forth herein.

24. This case is exceptional under 35 U.S.C. § 285.

Prayer for Judgment

WHEREFORE, Orchid prays for the following relief:

A. That all claims against Defendant/Counterclaimant Orchid be dismissed with prejudice and that all relief requested by Plaintiff/Counterdefendant Schering be denied;

B. That a judgment be entered declaring that Defendant/Counterclaimant Orchid does not infringe, has not infringed, and will not infringe any valid claim of United States Patent No. 6,100,274, and that Orchid has a lawful right to continue with ANDA Nos. 78-356 and 78-357 for desloratadine tablets, and further that Defendant/Counterclaimant Orchid has a lawful right to manufacture, market, and/or sell their desloratadine tablets once approved by the FDA;

C. That a judgment be entered declaring that the claims of United States Patent No. 6,100,274 is invalid;

D. That an order be entered requiring Schering to delete United States Patent No. 6,100,274 patent from the Orange Book with respect to NDA 21-312;

E. That an order be entered that ANDA No. 78-356 is not subject to a stay of approval pursuant to 35 U.S.C. § 355(j)(5)(B)(iii) based on U.S. Patent No. 6,100,274.

F. Finding this case to be exceptional pursuant to 35 U.S.C. § 285 and imposing sanctions for the entire costs, attorney fees and expenses that Orchid incurs in this action;

G. That a judgment be entered that this action is an exceptional case pursuant to 35 U.S.C. § 285 and that Defendant/Counterclaimant Orchid is therefore entitled to a recovery of its reasonable attorneys fees upon prevailing in this action;

H. That Defendant/Counterclaimant Orchid be awarded costs, attorneys fees and other relief, both legal and equitable, to which it may be justly entitled; and

I. That Defendant/Counterclaimant Orchid be awarded such other and further relief as this Court deems just and proper.

Dated: April 16, 2008

s/ R. Christopher Owens
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Pharmaceuticals, Ltd. and Orgenus Pharma, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that to the best of my knowledge the specific matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. However, Defendants Orchid Chemicals & Pharmaceuticals, Ltd. and Orgenus, Inc. hereby provide notice of pendency in this District of an action related to this case. Specifically, the action entitled *Sepracor Inc. v. Orchid Chemicals & Pharmaceutical, Ltd.*, 07-CV-04623-MLC-TJB, currently pending before this Court, is related to this action under L.Civ. Rule 40.1(c). Both this case and *Sepracor Inc. v. Orchid Chemicals & Pharmaceuticals, Ltd.* relate to patent infringement claims arising out of the filing by Orchid Chemicals & Pharmaceuticals Ltd. of ANDA Nos. 78-356 and 78-357.

Dated: April 16, 2008

s/ R. Christopher Owens
R. Christopher Owens