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Sepracor Inc. and
University of Massachusetts*

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

SEPRACOR INC. and UNIVERSITY OF MASSACHUSETTS,)	
)	Civil Action No.:
Plaintiffs,)	
)	COMPLAINT FOR PATENT INFRINGEMENT
v.)	
)	
ORCHID CHEMICALS & PHARMACEUTICALS LTD., ORCHID HEALTHCARE, and ORGENUS PHARMA, INC.)	(Filed Electronically)
)	
Defendants.)	
)	

Plaintiffs Sepracor Inc. (“Sepracor”) and University of Massachusetts (“UMass”), by their attorneys, for their Complaint against Defendants Orchid Chemicals & Pharmaceuticals Ltd. (“Orchid Ltd.”), Orchid Healthcare, and Orgenus Pharma, Inc. (“Orgenus”) hereby allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, arising from Defendants’ filing of Abbreviated New

Drug Applications (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of the patented Clarinex[®] drug products prior to the expiration of United States Patent Nos. 7,211,582 (“the ‘582 patent”), 7,214,683 (“the ‘683 patent”) and 7,214,684 (“the ‘684 patent”), which are owned by Sepracor and UMass.

The Parties

2. Plaintiff Sepracor is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

3. Plaintiff UMass is a public institution of higher education of the Commonwealth of Massachusetts, having a place of business at 55 Lake Avenue North, Worcester, Massachusetts 01655.

4. Upon information and belief, Orchid Ltd. is a corporation organized and existing under the laws of India, 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, Orchid Ltd. is registered to do business in New Jersey and maintains a registered agent in New Jersey for the receipt of service of process.

5. Upon information and belief, Orchid Healthcare is a division and an agent and alter-ego of Orchid Ltd., having a place of business at #313, Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034, India and/or Plot No. B3-B6 & B11-B14, Sipcot Industrial Park, Irungattukottai, Sriperumbudur (TK) – 602 105, Kancheepuram District, Tamil Nadu, India.

6. Upon information and belief, Orgenus is a New Jersey corporation and a wholly owned subsidiary, agent and alter-ego of Orchid Ltd., having a place of business at 116 Village Boulevard, Suite 200, Princeton, New Jersey 08540.

7. Orchid Ltd. and Orchid Healthcare are referred to hereinafter, collectively, as “Orchid.”

8. Upon information and belief, Orchid is in the business of manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

9. Upon information and belief, Orchid, with the participation of Orgenus, prepared, assembled and caused to be filed with the FDA, pursuant to 21 U.S.C. § 355(j), ANDA No. 78-356 concerning generic versions of orally disintegrating tablets containing 2.5 and 5 milligrams of Clarinex[®] brand desloratadine per tablet and ANDA No. 78-357 concerning generic versions of tablets containing 5 milligrams of Clarinex[®] brand desloratadine per tablet (these generic tablets are collectively referred to herein as “Orchid’s Proposed Products”).

10. Upon information and belief, if either ANDA No. 78-356 or ANDA No. 78-357 or both are approved, it is the intention of Orchid to distribute Orchid’s Proposed Products in the United States.

Jurisdiction and Venue

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

12. This court has personal jurisdiction over Orgenus because Orgenus is a New Jersey corporation.

13. This court has personal jurisdiction over Orchid by virtue of, *inter alia*: (1) its registration to do business in New Jersey; (2) its presence in New Jersey through its subsidiary, agent and alter-ego, Orgenus; and (3) its systematic and continuous contacts with New Jersey, including through its subsidiary, agent and alter-ego, Orgenus, and through Orchid Healthcare as agent and alter-ego. Further, upon information and belief, Orchid is in the business of manufacturing, marketing, importing into the United States and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Orchid directly, or through its divisions, subsidiaries, agents and/or alter-egos, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Orchid purposefully has conducted and continues to conduct business, directly, and/or through its divisions, subsidiaries, agents and/or alter-egos in this judicial district, and this judicial district is a likely destination of Orchid's Proposed Products.

14. This Court also has personal jurisdiction over Orchid because Orchid has previously submitted to the jurisdiction of this Court. For example, in *Schering Corporation v. Zydus Pharmaceuticals, USA, Inc. et al.*, D.N.J., Civil Action No. 3:06-4715 (MLC) (TJB), Orchid consented to jurisdiction in New Jersey and filed certain counterclaims, thus availing itself of this Court's jurisdiction in connection with causes of action involving the same ANDAs at issue here, *i.e.*, Nos. 78-356 and 78-357.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents In Suit and the Clarinex[®] Drug Products

16. On May 1, 2007, the '582 patent, entitled "Methods for Treating Urticaria Using Descarboethoxyloratadine," was duly and legally issued. Sepracor and UMass are

assignees of the entire right, title and interest in the '582 patent. A copy of the '582 patent is attached hereto as Exhibit A.

17. On May 8, 2007, the '683 patent, entitled "Compositions of Descarboethoxyloratadine," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '683 patent. A copy of the '683 patent is attached hereto as Exhibit B.

18. On May 8, 2007, the '684 patent, entitled "Methods for the Treatment of Allergic Rhinitis," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '684 patent. A copy of the '684 patent is attached hereto as Exhibit C.

19. The '582, '683 and '684 patents are identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" in association with 5 milligram desloratadine tablets, which are sold as a commercial product under the trade name Clarinex[®], and 2.5 and 5 milligram desloratadine orally disintegrating tablets, which are sold as a commercial product under the trade name Clarinex[®] RediTabs[®]. These patents cover approved uses of commercial Clarinex[®] and approved Clarinex[®] products.

Acts Giving Rise to this Action

20. Plaintiffs Sepracor and UMass received a letter from Orchid, dated August 13, 2007, notifying them that Orchid had filed with the FDA an ANDA (No. 78-356) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale or sale of generic orally disintegrating tablets containing 2.5 and 5 milligrams of Clarinex[®] brand desloratadine per tablet.

21. Plaintiffs Sepracor and UMass received a second letter from Orchid, dated August 13, 2007 (collectively, these letters are referred to as “the Notification Letters”), notifying them that Orchid had filed with the FDA an ANDA (No. 78-357) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale or sale of generic tablets containing 5 milligrams of Clarinex[®] brand desloratadine per tablet.

22. Upon information and belief, Orchid intends to engage and will engage in the commercial manufacture, importation, use, offer for sale or sale of Orchid’s Proposed Products promptly upon receiving FDA approval to do so.

23. The Notification Letters state that ANDA Nos. 78-356 and 78-357 contain a “Paragraph IV Certification” that, in Orchid’s opinion, the ‘582, ‘683 and ‘684 patents are invalid and/or not infringed.

24. The Notification Letters do not provide a detailed basis for why the ‘582, ‘683 and ‘684 patents will not be infringed by the manufacture, importation into the United States, use, offer for sale, or sale of Orchid’s Proposed Products.

25. Upon information and belief, ANDA Nos. 78-356 and 78-357 contain information showing that Orchid’s Proposed Products: (a) are the bioequivalent to a patented Clarinex[®] 5 milligram tablet product; (b) are the bioequivalent to a patented Clarinex[®] RediTabs[®] orally disintegrating 2.5 or 5 milligram tablet; (c) have the same active ingredient as a patented Clarinex[®] product; (d) have the same route of administration and strength as a patented Clarinex[®] product; and (e) have the same, or substantially the same, proposed labeling, and the same indication and usage as a patented Clarinex[®] product.

26. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) before the expiration of forty-five days from the date of receipt of the Notification Letters.

Count I – Infringement of the ‘582 Patent by Defendant

27. Plaintiffs repeat and reallege the allegations of paragraphs 1-26 as though fully set forth herein.

28. Orchid’s submission of ANDAs 78-356 and 78-357 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Orchid’s Proposed Products, prior to the expiration of the ‘582 patent, constitutes infringement of one or more of the claims of the ‘582 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Orchid and/or Orgenus commercially uses, offers for sale or sells any of Orchid’s Proposed Products, or induces or contributes to such conduct, it would further infringe one or more claims of the ‘582 patent under 35 U.S.C § 271(a), (b) and/or (c).

29. Orgenus is jointly and severally liable for any infringement of one or more claims of the ‘582 patent. This is so because, upon information and belief, Orgenus participated in, contributed to, aided, abetted and/or induced the submission of ANDAs 78-356 and 78-357 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

30. Unless enjoined by this Court, Orchid and Orgenus, upon FDA approval of ANDA No. 78-356 and/or ANDA No. 78-357, will infringe the ‘582 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Orchid’s Proposed Products in the United States.

31. Orchid and Orgenus had notice of the '582 patent prior to undertaking their acts of infringement. Orchid and Orgenus' infringement of the '582 patent has been, and continues to be, willful and deliberate.

32. Plaintiffs will be substantially harmed if Orchid's and Orgenus' infringement of the '582 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Count II – Infringement of the '683 Patent by Defendant

33. Plaintiffs repeat and reallege the allegations of paragraphs 1-32 as though fully set forth herein.

34. Orchid's submission of ANDAs 78-356 and 78-357 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Orchid's Proposed Products, prior to the expiration of the '683 patent, constitutes infringement of one or more of the claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Orchid and/or Orgenus commercially uses, offers for sale or sells any of Orchid's Proposed Products, or induces or contributes to such conduct, it would further infringe one or more claims of the '683 patent under 35 U.S.C § 271(a), (b) and/or (c).

35. Orgenus is jointly and severally liable for any infringement of one or more claims of the '683 patent. This is so because, upon information and belief, Orgenus participated in, contributed to, aided, abetted and/or induced the submission of ANDAs 78-356 and 78-357 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

36. Unless enjoined by this Court, Orchid and Orgenus, upon FDA approval of ANDA No. 78-356 and/or ANDA No. 78-357, will infringe the '683 patent under 35 U.S.C. §

271 by making, using, importing, offering to sell, or selling Orchid's Proposed Products in the United States.

37. Orchid and Orgenus had notice of the '683 patent prior to undertaking their acts of infringement. Orchid's and Orgenus' infringement of the '683 patent has been, and continues to be, willful and deliberate.

38. Plaintiffs will be substantially harmed if Orchid and Orgenus' infringement of the '683 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Count III – Infringement of the '684 Patent by Defendant

39. Plaintiffs repeat and reallege the allegations of paragraphs 1-38 as though fully set forth herein.

40. Orchid's submission of ANDAs 78-356 and 78-357 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Orchid's Proposed Products, prior to the expiration of the '684 patent, constitutes infringement of one or more of the claims of the '684 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Orchid and/or Orgenus commercially uses, offers for sale or sells any of Orchid's Proposed Products, or induces or contributes to such conduct, it would further infringe one or more claims of the '684 patent under 35 U.S.C § 271(a), (b) and/or (c).

41. Orgenus is jointly and severally liable for any infringement of one or more claims of the '684 patent. This is so because, upon information and belief, Orgenus participated in, contributed to, aided, abetted and/or induced the submission of ANDAs 78-356 and 78-357 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

42. Unless enjoined by this Court, Orchid and Orgenus, upon FDA approval of ANDA No. 78-356 and/or ANDA No. 78-357, will infringe the '684 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Orchid's Proposed Products in the United States.

43. Orchid and Orgenus had notice of the '684 patent prior to undertaking their acts of infringement. Orchid's and Orgenus' infringement of the '684 patent has been, and continues to be, willful and deliberate.

44. Plaintiffs will be substantially harmed if Orchid's and Orgenus' infringement of the '684 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Prayer for Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment declaring that Defendants have infringed one or more claims of the '582 patent;

B. A Judgment declaring that Defendants have infringed one or more claims of the '683 patent;

C. A Judgment declaring that Defendants have infringed one or more claims of the '684 patent;

D. An Order that the effective date of any FDA approval of ANDA No. 78-356 and/or ANDA No. 78-357 be no earlier than the date on which the '582 patent expires, including any regulatory or patent term extension;

E. An Order that the effective date of any FDA approval of ANDA No. 78-356 and/or ANDA No. 78-357 be no earlier than the date on which the '683 patent expires, including any regulatory or patent term extension;

F. An Order that the effective date of any FDA approval of ANDA No. 78-356 and/or ANDA No. 78-357 be no earlier than the date on which the '684 patent expires, including any regulatory or patent term extension;

G. Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, importing, offering to sell, or selling Orchid's Proposed Products until after the expiration of the '582 patent, including any regulatory or patent term extension;

H. Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, importing, offering to sell, or selling Orchid's Proposed Products until after the expiration of the '683 patent, including any regulatory or patent term extension;

I. Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, importing, offering to sell, or selling Orchid's Proposed Products until after the expiration of the '684 patent, including any regulatory or patent term extension;

J. A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Orchid's Proposed Products will directly infringe or induce and/or contribute to infringement of the '582 patent;

K. A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Orchid's Proposed Products will directly infringe or induce and/or contribute to infringement of the '683 patent;

L. A declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Orchid's Proposed Products will directly infringe or induce and/or contribute to infringement of the '684 patent;

M. If Defendants engage in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Orchid's Proposed Products prior to the expiration of the '582 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed based on the willfulness of the infringement, together with interest;

N. If Defendants engage in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Orchid's Proposed Products prior to the expiration of the '683 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed based on the willfulness of the infringement, together with interest;

O. If Defendants engage in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Orchid's Proposed Products prior to the expiration of the '684 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed based on the willfulness of the infringement, together with interest;

P. Attorneys' fees in this action based on willful infringement pursuant to 35 U.S.C. § 284 and/or as an exceptional case pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

Q. Costs and expenses in this action; and

R. Such further and other relief as this Court may deem just and proper.

Dated: September 26, 2007

Respectfully submitted,

s/ Charles M. Lizza

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LOCAL CIVIL RULE 11.2 & 40.1 CERTIFICATION

I hereby certify that the matters captioned: (1) *Schering Corporation v. Zydus Pharmaceuticals, USA, Inc., et al.*, Civil Action No. 06-4715 (MLC) (D.N.J.); (2) *Schering Corporation v. Caraco Pharmaceutical Laboratories Ltd., et al.*, Civil Action No. 06-14386 (E.D. Mich.); and (3) *Schering Corporation v. GeoPharma Inc., et al.*, Civil Action No. 06-1843 (M.D. Fla.), which have been consolidated before the Honorable Mary L. Cooper under the caption, *In Re: Desloratadine Patent Litigation*, MDL No. 1851 (MLC) (D.N.J.), are related patent infringement cases because the defendants in the matter in controversy are defendants in the previously identified matters, and the alleged acts causing the infringement in both cases are the same, *i.e.*, based upon the defendants' filing of the same ANDAs with the FDA. Also, the patents asserted in the current matter are related to the previously identified matters because all the patents are associated with Clarinex® products.

I also certify that the matters captioned, *Sepracor Inc., et al. v. Glenmark Pharmaceuticals, Ltd., et al.*, Civil Action No. 07-3385 (SRC) (D.N.J.) and *Sepracor Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 07-4213 (JAP) (D.N.J.), are related actions because they involve the same plaintiffs and the same patents as the matter in controversy.

In light of the number of related cases pending before different judges, I submitted a letter to the Honorable Garrett E. Brown, Chief Judge of this Court, on September 19, 2007, to request that the related cases, including the current matter, be reassigned to Judge Cooper, before whom the earlier filed, related cases are pending. As stated in my letter, reassigning these cases will avoid a situation where many different judges could be separately presiding over each one of

the several related cases, in turn, impacting judicial resources and possibly resulting in inconsistent rulings.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 26, 2007

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