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Attorneys for Plaintiffs
Sepracor Inc. and
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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEPRACOR INC. and UNIVERSITY OF MASSACHUSETTS, **Plaintiffs,** **v.** **LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No.:** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Sepracor Inc. ("Sepracor") and University of Massachusetts ("UMass"), by their attorneys, for their Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. hereby allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, arising from Defendants' filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of the patented Clarinex® drug products prior

to the expiration of United States Patent No. 7,214,683 ("the '683 patent") and United States Patent No. 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, Lupin Limited ("Lupin Ltd.") is an Indian corporation having a place of business at 159 CST Road, Kalina, Santacruz (E), Mumbai 400098, India.

5. Upon information and belief, Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") is a corporation organized under the laws of the state of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202, and maintaining a registered agent in New Jersey.

6. Lupin Ltd. and Lupin Pharmaceuticals are hereinafter collectively referred to as "Lupin."

Jurisdiction and Venue

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

8. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals, directly or through related companies, conduct business in New Jersey, have availed themselves of the

rights and benefits of New Jersey law, have engaged in continuous and systematic contacts with New Jersey, and Lupin Pharmaceuticals maintains a registered agent in New Jersey.

9. Upon information and belief, the acts of Lupin Ltd. complained of herein were aided and abetted by and done with the cooperation, participation, and assistance of Lupin Pharmaceuticals.

10. Upon information and belief, Lupin has submitted to the jurisdiction of the United States District Court for the District of New Jersey. This Court has personal jurisdiction over Lupin by virtue of, *inter alia*, the above-mentioned facts.

11. 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

12. 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 A.

13. 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 B.

14. The '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 those patents cover an approved use of commercial Clarinex®.

Acts Giving Rise to this Action

15. Plaintiff Sepracor received a letter from Defendants, dated September 6, 2007 and received on September 10, 2007 ("the Notification Letter"), notifying them that Defendants had filed with the FDA an ANDA (No. 78-352) 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 desloratadine ("Lupin's Proposed Products").

16. Upon information and belief, Defendants intend to engage and will engage in the commercial manufacture, importation, use, offer for sale or sale of Lupin's Proposed Products promptly upon receiving FDA approval to do so.

17. The Notification Letter states that, in Defendants' opinion, the '683 and '684 patents are invalid and that the marketing or selling of Lupin's Proposed Products will not infringe claims of the '683 or '684 patent.

18. The Notification Letter does not allege that the '683 and '684 patents are unenforceable.

Count I – Infringement of the '683 Patent by Defendants

19. Plaintiffs repeat and reallege the allegations of paragraphs 1-18 as though fully set forth herein.

20. Defendants' submission of its ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Lupin'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).

21. Unless enjoined by this Court, upon FDA approval of ANDA No. 78-352, Lupin will infringe the '683 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Lupin's Proposed Products in the United States.

22. Defendants had notice of the '683 patent prior to undertaking their acts of infringement. Defendants' certification to the FDA that its proposed product will not infringe and/or that the '683 patent is invalid or unenforceable lacked a good faith basis. Defendants' filing of its ANDA constitutes a wholly unjustified infringement of the '683 patent, and makes this action exceptional under 35 U.S.C. § 285.

23. Plaintiffs will be substantially harmed if Lupin's infringement of the '683 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

Count II − Infringement of the '684 Patent by Defendants

24. Plaintiffs repeat and reallege the allegations of paragraphs 1-23 as though fully set forth herein.

25. Defendants' submission of its ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Lupin'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).

26. Unless enjoined by this Court, upon FDA approval of ANDA No. 78-352, Lupin will infringe the '684 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Lupin's Proposed Products in the United States.

27. Defendants had notice of the '684 patent prior to undertaking their acts of infringement. Defendants' certification to the FDA that its proposed product will not infringe and/or that the '684 patent is invalid or unenforceable lacked a good faith basis. Defendants'

filing of its ANDA constitutes a wholly unjustified infringement of the '684 patent, and makes this action exceptional under 35 U.S.C. § 285.

28. Plaintiffs will be substantially harmed if Lupin's 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 '683 patent;

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

C. An Order that the effective date of any FDA approval of Defendants' ANDA No. 78-352 be no earlier than the date on which the '683 patent expires, including any regulatory or patent term extension;

D. An Order that the effective date of any FDA approval of Defendants' ANDA No. 78-352 be no earlier than the date on which the '684 patent expires, including any regulatory or patent term extension;

E. 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 Lupin's Proposed Products until after the expiration of the '683 patent, including any regulatory or patent term extension;

F. 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 Lupin's Proposed Products until after the expiration of the '684 patent, including any regulatory or patent term extension;

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

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

I. If Defendants engage in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Lupin'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;

J. If Defendants engage in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Lupin'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;

K. 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 and 285;

L. Costs and expenses in this action; and

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

Dated: November 1, 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 matter, 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 matter because all the patents are associated with Clarinex® products.

I also certify that the matters captioned, *Sepracor Inc., et al. v. Orchid Chemicals & Pharmaceuticals Ltd., et al.,* Civil Action No. 07-4623 (MLC) (D.N.J.), *Sepracor Inc., et al. v. Glenmark Pharmaceuticals, Ltd., et al.*, Civil Action No. 07-3385 (MLC) (D.N.J.) (the "*Glenmark* case") and *Sepracor Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.,* Civil Action No. 07-4213 (MLC) (D.N.J.) (the "*Sun* case"), all assigned to Judge Cooper, are related actions because they involve the same plaintiffs and two of the same patents as the matter in controversy.

I also certify that the matters captioned, *Sepracor Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.,* Civil Action No. 07-5001 (FLW) (D.N.J.), *Sepracor Inc., et al. v. Mylan Pharmaceuticals, Inc., et al.,* Civil Action No. 07-5017 (JAP) (D.N.J.) and *Sepracor Inc., et al. v. Perrigo Research and Development Company, et al.,* Civil Action No. 07-5136 (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 assigned 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. Following this letter, the *Sun* and *Glenmark* cases were reassigned by Chief Judge Brown to Judge Cooper.

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: November 1, 2007

Respectfully submitted,

s/ Charles M. Lizza

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