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Sepracor Inc. and  
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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

SEPRACOR INC. and UNIVERSITY OF MASSACHUSETTS,	)	
	)	
Plaintiffs,	)	Civil Action No.:
	)	
v.	)	
	)	<b>COMPLAINT FOR PATENT</b>
GLENMARK PHARMACEUTICALS, LTD. and GLENMARK PHARMACEUTICALS INC., USA,	)	<b>INFRINGEMENT</b>
	)	
Defendants.	)	<b>(Filed Electronically)</b>

Plaintiffs Sepracor Inc. (“Sepracor”) and University of Massachusetts (“UMass”), by their attorneys, for their Complaint against Defendants Glenmark Pharmaceuticals, Ltd. (“Glenmark Ltd.”) and Glenmark Pharmaceuticals Inc., USA (“Glenmark USA”), 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 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 the United States Patent No. 7,214,683 (“the ‘683 patent”) and the 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, Defendant Glenmark Ltd. is a corporation organized and existing under the laws of India, having a place of business at Glenmark House, HDO-Corporate Building, Wing -A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai 400099, India. Upon information and belief, Defendant Glenmark Ltd. has appointed Dr. Vijay Soni, Executive Vice President – IP of Defendant Glenmark USA as its agent in New Jersey for the receipt of any service of process in this action.

5. Upon information and belief, Defendant Glenmark USA is a corporation organized and existing under the laws of the State of Delaware and a wholly owned subsidiary, agent and alter-ego of Defendant Glenmark Ltd., having a place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

**Jurisdiction and Venue**

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

7. This Court has personal jurisdiction over Defendant Glenmark Ltd. by virtue of, *inter alia*: (1) its presence in New Jersey through its appointed agent and its subsidiary, agent and alter-ego, Defendant Glenmark USA; and (2) its systematic and continuous contacts with New Jersey, including through its subsidiary, agent and alter-ego, Defendant Glenmark USA.

8. This Court has personal jurisdiction over Defendant Glenmark USA by virtue of, *inter alia*: (1) its presence in New Jersey; and (2) its systematic and continuous contacts with New Jersey.

9. Upon information and belief, the acts of Glenmark USA complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least for the benefit of Glenmark Ltd.

10. This Court has personal jurisdiction over both Defendants for the additional reasons set forth below.

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<sup>®</sup> 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<sup>®</sup>, and those patents cover an approved use of commercial Clarinex<sup>®</sup>. Further, the '683 patent covers certain approved Clarinex<sup>®</sup> products.

**Acts Giving Rise to this Action**

15. Plaintiff Sepracor received a letter from Defendants, dated June 8, 2007 ("the Notification Letter"), notifying them that Defendants had filed with the FDA an ANDA (No. 78-362) 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<sup>®</sup> brand desloratadine per tablet ("Glenmark'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 Glenmark's Proposed Products promptly upon receiving FDA approval to do so.

17. The Notification Letter states that ANDA No. 78-362 contains a "Paragraph IV Certification" that, in Defendants' opinion, the '683 and '684 patents are invalid.

18. The Notification Letter does not allege that the '683 and '684 patents are unenforceable, or that the marketing of Glenmark's Proposed Products will not infringe claims 1-5, 7, and 9-10 of the '683 patent, or any claim of the '684 patent.

19. The Notification Letter states that the Glenmark formulation components are desloratadine, corn starch, mannitol, pregeletinized starch and magnesium stearate.

20. Upon information and belief, ANDA No. 78-362 contains information showing that Glenmark's Proposed Products (a) are bioequivalent to a patented Clarinex<sup>®</sup> 5 milligram tablet product, (b) have the same active ingredient as a patented Clarinex<sup>®</sup> 5 milligram product, (c) have the same route of administration and strength as a patented Clarinex<sup>®</sup> 5 milligram product, and (d) have the same, or substantially the same, proposed labeling, and the same indication and usage as a patented Clarinex<sup>®</sup> product.

21. 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 Letter.

**Count I – Infringement of the '683 Patent by Defendants**

22. Plaintiffs repeat and reallege the allegations of paragraphs 1-21 as though fully set forth herein.

23. Defendants' submission of an ANDA including its § 505(j)(2)(A)(vii)(IV) allegation to obtain approval to engage in the commercial manufacture, importation, use, offer

for sale or sale of Glenmark'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).

24. Unless enjoined by this Court, Defendants, upon FDA approval of ANDA No. 78-362, will infringe the '683 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Glenmark's Proposed Products in the United States.

25. Glenmark Ltd.'s subsidiary, agent and alter-ego Defendant Glenmark USA is jointly and severally liable for any infringement of the '683 patent. This is so because, upon information and belief, Glenmark USA participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 78-362 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA. Additionally, upon information and belief, Glenmark USA will, without authority, market and/or distribute Glenmark's Proposed Products in the United States if ANDA No. 78-362 is approved by the FDA.

26. Glenmark USA's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 78-362 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '683 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Glenmark USA commercially manufactures, imports, uses, offers for sale or sells Glenmark's Proposed Products in the United States, or induces or contributes to any such conduct, it would further infringe the '683 patent under 35 U.S.C. § 271(a), (b) and/or (c).

27. Defendants had notice of the '683 patent prior to undertaking their acts of infringement. Defendants' infringement of the '683 patent has been, and continues to be, willful and deliberate.

28. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' infringement of the '683 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

**Count II – Infringement of the '684 Patent by Defendants**

29. Plaintiffs repeat and reallege the allegations of paragraphs 1-28 as though fully set forth herein.

30. Defendants' submission of an ANDA including its § 505(j)(2)(A)(vii)(IV) allegation to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Glenmark'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).

31. Unless enjoined by this Court, Defendants, upon FDA approval of ANDA No. 78-362, will infringe the '684 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Glenmark's Proposed Products in the United States.

32. Glenmark Ltd.'s subsidiary, agent and alter-ego Defendant Glenmark USA is jointly and severally liable for any infringement of the '684 patent. This is so because, upon information and belief, Glenmark USA participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 78-362 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA. Additionally, upon information and belief, Glenmark USA will, without authority, market and/or distribute Glenmark's Proposed Products in the United States if ANDA No. 78-362 is approved by the FDA.

33. Glenmark USA's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 78-362 and its § 505(j)(2)(A)(vii)(IV) allegation to

the FDA constitutes infringement of the '684 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Glenmark USA commercially manufactures, uses, imports, offers for sale or sells Glenmark's Proposed Products in the United States, or induces or contributes to any such conduct, it would further infringe the '684 patent under 35 U.S.C. § 271(a), (b) and/or (c).

34. Defendants had notice of the '684 patent prior to undertaking their acts of infringement. Defendants' infringement of the '684 patent has been, and continues to be, willful and deliberate.

35. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' infringement of the '684 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

**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 ANDA No. 78-362 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 ANDA No. 78-362 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 Glenmark'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 Glenmark'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 Glenmark'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 Glenmark'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 Glenmark'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 Glenmark'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. § 285;

L. Costs and expenses in this action; and

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

Dated: July 20, 2007

Respectfully submitted,

*s/ Charles M. Lizza*

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