

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, Mylan Pharmaceuticals, Inc. (“Mylan Pharmaceuticals”) is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. Upon information and belief, Mylan Laboratories, Inc. (“Mylan Laboratories”) is a corporation organized under the laws of the State of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

6. Upon information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Laboratories. Mylan Pharmaceuticals and Mylan Laboratories are hereinafter collectively referred to as “Mylan.”

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, Mylan Pharmaceuticals is registered to do business in New Jersey and has a registered agent in New Jersey.

9. Upon information and belief, the acts of Mylan Pharmaceuticals complained of herein were aided and abetted by and done with the cooperation, participation, and assistance of Mylan Laboratories. Upon information and belief, Mylan Pharmaceuticals and Mylan Laboratories have officers or directors in common, and Mylan Laboratories has a registered agent in New Jersey.

10. Upon information and belief, Mylan sells various products and does business throughout the United States, including within this judicial district. Upon information and belief, Mylan has submitted to the jurisdiction of the United States District Court for the District of New Jersey. This Court has personal jurisdiction over Mylan 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 5, 2007 ("the Notification Letter"), notifying them that Defendants had filed with the FDA an ANDA (No. 78-351) 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 ("Mylan'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 Mylan's Proposed Products promptly upon receiving FDA approval to do so.

17. The Notification Letter states that ANDA No. 78-351 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 or selling of Mylan's Proposed Products will not infringe claims of the '683 or '684 patent directly, by inducement or contributorily.

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 Mylan’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. 78-351, Mylan will infringe the ‘683 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Mylan’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 Mylan’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 Mylan’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. 78-351, Mylan will infringe the '684 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Mylan'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 Mylan'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. 78-351 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. 78-351 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 Mylan'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 Mylan'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 Mylan'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 Mylan'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 Mylan'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 Mylan'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: October 18, 2007

Respectfully submitted,

s/ Charles M. Lizza

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