

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, Defendant GeoPharma, Inc. (“GeoPharma”) is a Florida corporation, having a place of business at 6950 Bryan Dairy Road, Largo Florida 33777. Upon information and belief, GeoPharma manufactures numerous products for sale and use throughout the United States, including in this judicial district, and including through its subsidiaries, agents and alter-egos.

5. Upon information and belief, Defendant Belcher Pharmaceuticals, Inc. (“Belcher Pharmaceuticals”) is a Florida corporation and a subsidiary, agent and alter-ego of GeoPharma, having a place of business at 6950 Bryan Dairy Road, Largo Florida 33777. Upon information and belief, Belcher Pharmaceuticals manufactures numerous products for sale and use throughout the United States, including in this judicial district, and including through its parent, agents and alter-egos, including, GeoPharma.

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. The Court has jurisdiction over Defendant GeoPharma by virtue of, *inter alia*, its specific contacts with New Jersey in connection with this case and its continuous and systematic contacts with New Jersey, including through its subsidiaries, agents and alter-egos.

8. The Court has jurisdiction over Defendant Belcher Pharmaceuticals by virtue of, *inter alia*, its specific contacts with New Jersey in connection with this case and its continuous and systematic contacts with New Jersey, including through its parent, agents and alter-egos, including GeoPharma.

9. 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

10. 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.

11. 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.

12. 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

13. Plaintiffs received a letter from Belcher, dated January 30, 2008 (“the Notification Letter”), notifying them that Belcher had filed with the FDA an ANDA (No. 78-355) 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 5.0 milligrams desloratadine (“Belcher’s Proposed Products”).

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

15. The Notification Letter states that, in Belcher’s opinion, the ‘683 and ‘684 patents are invalid.

16. The Notification Letter does not allege that the ‘683 and ‘684 patents are unenforceable, or that the marketing of Belcher’s Proposed Products will not infringe claims of the ‘683 or the ‘684 patent.

Count I – Infringement of the ‘683 Patent by Belcher

17. Plaintiffs repeat and reallege the allegations of paragraphs 1-16 as though fully set forth herein.

18. Belcher’s submission of its ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Belcher’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).

19. Unless enjoined by this Court, upon FDA approval of ANDA No. 78-355, Belcher will infringe the ‘683 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Belcher’s Proposed Products in the United States.

20. Belcher had notice of the '683 patent prior to undertaking its acts of infringement. Belcher's 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. Belcher's filing of its ANDA constitutes a wholly unjustified infringement of the '683 patent, and makes this action exceptional under 35 U.S.C. § 285.

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

Count II – Infringement of the '684 Patent by Belcher

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

23. Belcher's submission of its ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Belcher'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).

24. Unless enjoined by this Court, upon FDA approval of ANDA No. 78-355, Belcher will infringe the '684 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Belcher's Proposed Products in the United States.

25. Belcher had notice of the '684 patent prior to undertaking its acts of infringement. Belcher's 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. Belcher's filing of its ANDA constitutes a wholly unjustified infringement of the '684 patent, and makes this action exceptional under 35 U.S.C. § 285.

26. Plaintiffs will be substantially harmed if Belcher'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 Belcher has infringed one or more claims of the '683 patent;
- B. A Judgment declaring that Belcher has infringed one or more claims of the '684 patent;
- C. An Order that the effective date of any FDA approval of Belcher's ANDA No. 78-355 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 Belcher's ANDA No. 78-355 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 Belcher and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from making, using, importing, offering to sell, or selling Belcher's Proposed Products until after the expiration of the '683 patent, including any regulatory or patent term extension;
- F. Preliminary and permanent injunctions enjoining Belcher and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from making, using, importing, offering to sell, or selling Belcher'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 Belcher'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 Belcher's Proposed Products will directly infringe or induce and/or contribute to infringement of the '684 patent;

I. If Belcher engages in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Belcher'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 Belcher engages in the commercial manufacture, use, importation into the United States, offer to sell, or sale of Belcher'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: February 20, 2008

Respectfully submitted,

s/ Charles M. Lizza
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