

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SEPRACOR INC.,

Plaintiff,

vs.

BARR LABORATORIES, INC.

Defendant.

C.A. No. 07-_____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Sepracor Inc. (“Sepracor”), for its Complaint against Defendant Barr Laboratories, Inc. (“Barr”) hereby alleges as follows:

THE PARTIES

1. Sepracor is a Delaware corporation having its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.
2. On information and belief, Barr is a Delaware corporation having a place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey, 07677.

NATURE OF ACTION

3. This is a civil action against Barr for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and more particularly 35 U.S.C. §§ 271(e)(2) and 281. The act of infringement relates to, *inter alia*, Barr’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) for approval of copies of certain of Sepracor’s XOPENEX® (levalbuterol hydrochloride) inhalation solutions prior to the expiration of various United States Patents owned by Sepracor.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Barr because Barr is a Delaware corporation with a registered office in Delaware and/or because Barr has designated an agent in Delaware for service of process.

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

PATENTS IN SUIT

7. United States Patent 5,362,755 (“the ‘755 patent”) entitled, “Method for Treating Asthma Using Optically Pure (R)-Albuterol” was duly and legally issued by the United States Patent and Trademark Office on November 8, 1994. Sepracor is and has been the owner of the ‘755 patent. A true and correct copy of the ‘755 patent is attached hereto as Exhibit A.

8. United States Patent 5,547,994 (“the ‘994 patent”) entitled, “Method for Treating Asthma Using Optically Pure R(-) Albuterol” was duly and legally issued by the United States Patent and Trademark Office on August 20, 1996. Sepracor is and has been the owner of the ‘994 patent. A true and correct copy of the ‘994 patent is attached hereto as Exhibit B.

9. United States Patent 5,760,090 (“the ‘090 patent”) entitled, “Method for Treating Asthma Using Optically Pure R(-) Albuterol” was duly and legally issued by the United States Patent and Trademark Office on June 2, 1998. Sepracor is and has been the owner of the ‘090 patent. A true and correct copy of the ‘090 patent is attached hereto as Exhibit C.

10. United States Patent 5,844,002 (“the ‘002 patent”) entitled, “Method for Inducing Bronchodilation Using Optically Pure R(-) Albuterol” was duly and legally issued by the United

States Patent and Trademark Office on December 1, 1998. Sepracor is and has been the owner of the '002 patent. A true and correct copy of the '002 patent is hereto as Exhibit D.

11. United States Patent 6,083,993 (“the ‘993 patent”) entitled, “Method for Treating Bronchospasm Using Optically Pure R(-) Albuterol” was duly and legally issued by the United States Patent and Trademark Office on July 4, 2000. Sepracor is and has been the owner of the ‘993 patent. A true and correct copy of the ‘993 patent is attached hereto as Exhibit E.

12. Sepracor is the current holder of approved New Drug Application (“NDA”) No. 20-837 for XOPENEX® (levalbuterol hydrochloride) inhalation solutions.

ACTS GIVING RISE TO THIS ACTION

13. On information and belief, Barr filed its ANDA No. 78-860, allegedly under the provisions of 21 U.S.C. § 355(j), with the FDA in order to obtain approval to engage in the commercial manufacture, importation, use or sale of copies of certain XOPENEX® (levalbuterol hydrochloride) inhalation solutions (“Barr’s Levalbuterol Inhalation Solutions”) before the expiration of Sepracor’s ‘755, ‘994, ‘090, ‘002, and ‘993 patents (collectively “Sepracor Patents”), which collectively cover Sepracor’s XOPENEX® (levalbuterol hydrochloride) inhalation solutions and the FDA approved method of use thereof.

14. In a letter dated May 31, 2007, Barr notified Sepracor that it filed its ANDA No. 78-860 seeking approval to engage in the commercial manufacture, importation, use or sale of Barr's Levalbuterol Inhalation Solutions and further notifying Sepracor that Barr had filed a patent certification pursuant to section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), directed to the Sepracor Patents.

15. Specifically, in its letter dated May 31, 2007, Barr stated that it filed its ANDA No. 78-860 to obtain approval from the FDA to engage in the commercial manufacture,

importation, use or sale of Barr's Levalbuterol Inhalation Solutions before expiration of the Sepracor Patents, each of which is listed in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

16. In its letter dated May 31, 2007, Barr further stated generally that its ANDA No. 78-860 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Barr's opinion, Sepracor's Patents are invalid, unenforceable, and/or not infringed.

17. As part of its letter dated May 31, 2007, Barr asserted more specific purported grounds on which Barr asserts that the Sepracor Patents are either invalid and/or not infringed. Barr's letter asserts no specific grounds for unenforceability of the Sepracor Patents.

COUNT I - INFRINGEMENT OF THE SEPRACOR PATENTS

18. Sepracor incorporates by reference each of the averments of paragraphs 1 through 17 as though fully set forth.

19. Under 35 U.S.C. § 271(e)(2)(A), Barr's submission to the FDA of ANDA No. 78-860 to obtain approval for the commercial manufacture, importation, use or sale of Barr's Levalbuterol Inhalation Solutions in the United States before the expiration date of the Sepracor Patents constitutes an act of infringement of one or more claims of each of the Sepracor Patents.

20. Upon FDA approval of Barr's ANDA No. 78-860, Barr will infringe one or more claims of each of the Sepracor Patents by making, offering to sell, selling and/or importing Barr's Levalbuterol Inhalation Solutions in the United States, and/or by actively inducing and/or contributing to infringement by others (collectively "infringe," "infringement," or "infringed"), unless this Court orders that the effective date of any FDA approval of Barr's ANDA shall be no earlier than the expiration date of the Sepracor Patents.

21. Barr has actual notice of each of the Sepracor Patents and, upon information and belief, was aware that the filing of its ANDA No. 78-860 and certification with respect to the Sepracor Patents constituted an act of infringement of one or more claims of the Sepracor Patents.

22. This action was brought before the expiration of forty-five (45) days from the date of receipt by Sepracor of Barr's letter dated May 31, 2007.

23. Sepracor will be substantially and irreparably harmed and damaged by Barr's infringement if not enjoined.

24. Sepracor has no adequate remedy at law.

25. This case is an exceptional one, and Sepracor is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Sepracor prays for judgment as follows:

(A) A judgment declaring that Barr has infringed and that Barr's making, using, selling, offering to sell or importing of Barr's Levalbuterol Inhalation Solutions will infringe one or more claims of each of the Sepracor Patents.

(B) A judgment declaring that the effective date of any approval of Barr's ANDA No. 78-860 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for Barr's Levalbuterol Inhalation Solutions must be no earlier than the expiration date of the last to expire of the infringed Sepracor Patents.

(C) A permanent injunction enjoining Barr, its officers, agents, attorneys and employees and anyone acting in concert with them, from making, using, selling, offering to sell,

or importing Barr's Levalbuterol Inhalation Solutions until after the expiration of the last to expire of the infringed Sepracor Patents.

(D) A judgment that this action is an exceptional case and that Sepracor is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

(E) A judgment awarding Sepracor costs and expenses in this action.

(F) For such other and further relief as the Court deems just and proper.

July 12, 2007

THE BAYARD FIRM

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