IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DEY, L.P. and DEY, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	C.A. No. _____
SEPRACOR INC.,	)	
	)	
Defendant,	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs, Dey, L.P. and Dey, Inc. (collectively "Dey") for its complaint for a declaratory judgment against Defendant, Sepracor Inc. ("Sepracor"), allege as follows:

INTRODUCTION

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent No. 6,451,289 ("the '289 patent"). Defendant Sepracor filed the '289 patent along with United States Patent Nos. 5,362,755, 5,547,994, 5,760,090, 5,844,002, and 6,083,993 (collectively "the method-of-use patents"), with the Food and Drug Administration ("FDA") for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), as patents that could reasonably be asserted against anyone marketing or seeking to market a generic levalbuterol hydrochloride inhalation solution. In July 2005, Dey filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market 3 mL generic levalbuterol hydrochloride inhalation solution products ("3mL levalbuterol"). Under the applicable statutory scheme, Dey cannot get final approval for its 3mL levalbuterol until entry of an order of non-infringement or invalidity on all of the patents asserted against the company filing the first ANDA for 3mL levalbuterol.

2. Breath Limited ("Breath") was the first to file an ANDA on 3mL levalbuterol. Sepracor sued Breath for infringement of all six of the Orange Book listed patents. Sepracor and Breath settled their litigation without the entry of an order signed by the Court finding each of the six patents invalid or not infringed. Until 180 days after Breath chooses to market its 3mL levalbuterol, or 75 days after the entry of a final order finding each of the six patents invalid or not infringed, the FDA is prohibited from granting final approval to any ANDA for 3mL levalbuterol. Under its settlement agreement with Sepracor, Breath's license to market a 3mL levalbuterol will not take effect until August 20, 2012, unless another generic company enters the market earlier. A copy of Sepracor's press release regarding the settlement is attached as Exhibit 1.

3. Sepracor sued Dey on the five method-of-use patents. It did not sue Dey on the '289 patent. Because the '289 patent is listed in the Orange Book and the Breath case has settled without a finding that the '289 patent is invalid or not infringed, the FDA is prohibited from granting final approval to Dey's tentatively approved 3mL levalbuterol. Accordingly, Dey seeks entry of a declaratory judgment that the manufacture, use, or sale of its ANDA product does not infringe any valid claim of the '289 patent.

THE PARTIES

4. Plaintiff Dey, L.P. is a Delaware limited partnership having a principal place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey, L.P.'s registered agent for service of process in Delaware is the Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware, 19801.

5. Plaintiff Dey, Inc. is a Delaware corporation having a principle place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey, Inc's registered agent for service

of process in Delaware is the Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware, 19801.

6. On information and belief, Defendant Sepracor, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts, 01752.

JURISDICTION AND VENUE

7. This action is brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.,* and 21 U.S.C. § 355(j)(5)(B), based upon an actual controversy between the parties to declare that Dey is free to continue to seek final FDA approval of ANDA No. 77-800, and upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import its proposed levalbuterol hydrochloride solution products as described in the ANDA.

8. This Court has original jurisdiction over the subject matter of this Action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

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

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b) and by Sepracor's choice of forum in related case C.A. No. 06-113-JJF.

PATENT IN SUIT

11. On its face the '289 patent entitled "Albuterol Formulations" indicates it was issued by the United States Patent and Trademark Office on November 8, 1994 and is owned by Sepracor. The '289 patent claims, *inter alia,* a levalbuterol hydrochloride solution product that is free of chelating agents. A copy of the '289 patent is attached to this complaint as Exhibit 2.

THE APPLICABLE LAW

12. In December 2003, Congress passed the Medicare Modernization Act of 2003 ("MMA"). Title XI of that Act entitled "Access to Affordable Pharmaceuticals," made certain changes to the Hatch Waxman Act. The changes included a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an Orange Book listed patent if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV Certification. 21 U.S.C. § 355(j)(5)(B).

13. The MMA also added forfeiture provisions for the 180-day exclusivity awarded to the first to file pursuant to the Hatch Waxman Act. 21 U.S.C. § 355(j)(5)(D). The forfeiture provisions require, *inter alia*, the entry of a judgment of non-infringement or invalidity with respect to all of the patents asserted against the first to file whether or not those patents are asserted against subsequent ANDA filers. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

ACTS GIVING RISE TO THE ACTION

14. Upon information and belief, Sepracor is the current holder of approved New Drug Application ("NDA") No. 20-837 for XOPENEX® (levalbuterol hydrochloride) inhalation solution.

15. According to the Orange Book listings, XOPENEX®, or treatment methods using XOPENEX®, are claimed in the method-of-use patents and the '289 patent.

16. In a letter dated January 9, 2006, and addressed to Sepracor, Dey gave written notice that it had submitted to the FDA, ANDA No. 77-800 which contained "Paragraph IV Certifications," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). In particular, pursuant to ANDA No. 77-800 and Dey's Paragraph IV Certifications, Dey notified Sepracor that Dey intends to engage in the commercial manufacture, use and sale of the proposed 3mL levalbuterol that is the subject of ANDA No. 77-800.

17. On or about February 22, 2006, Sepracor filed in the District of Delaware an action against Dey for patent infringement of five of the six Orange Book listed patents (the method-of-use patents) under 35 U.S.C. §§ 271(e)(2) and 281. Sepracor alleged that the act of infringement relates to, *inter alia*, Dey's filing of ANDA 77-800 for approval to market 3mL levalbuterol.

18. Sepracor further alleged that upon FDA approval of Dey's ANDA No. 77-800, Dey will infringe one or more claims of the method-of-use patents by making, offering to sell, selling and/or importing Dey's 3mL levalbuterol in the United States, and/or by actively inducing and/or contributing to the infringement by others.

19. Sepracor did not allege that Dey's filing of ANDA 77-800 for approval to market 3mL levalbuterol would infringe the '289 patent or that upon FDA approval of ANDA No. 77-800, Dey will infringe one or more claims of the '289 patent by making, offering to sell, selling and/or importing Dey's 3mL levalbuterol in the United States, and/or by actively inducing and/or contributing to the infringement of others.

20. Breath was the first company to file an ANDA on 3mL levalbuterol. On October 21, 2005, Sepracor filed suit against Breath in the District of Massachusetts (the "Massachusetts case"). In its complaint, Sepracor alleged, *inter alia*, that manufacture, use or sale of the Breath ANDA product would infringe all six of the Orange Book listed patents—the five method-of-use patents and the '289 patent.

21. On May 1, 2008 the Massachusetts case settled without the entry of a judgment or order executed by a court finding that the six patents in suit were invalid or not infringed. The order of dismissal signed by the Judge in the Massachusetts case contains no finding of invalidity or non-infringement of the method-of-use patents or the '289 patent.

22. Until the entry of a judgment or an order of no infringement or invalidity is signed and entered by a court with respect to all six of the patents Breath was sued on—including the '289 patent – which Dey was not sued on—Breath's exclusivity will not be triggered and Dey's ANDA product, which does not infringe any valid claim of the six Orange Book patents, will be kept off the market, depriving the general public the availability of a low-cost generic 3mL levalbuterol product.

23. A declaration of rights between the parties is necessary to establish that Dey has not, does not and will not infringe any valid and/or enforceable claim of the '289 patent.

COUNT I

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '289 PATENT

24. Dey repeats each of the foregoing paragraphs as if fully set fourth herein.

25. There is a substantial and continuing controversy between Sepracor and Dey and a declaration of rights is both necessary and appropriate to establish that Dey does not infringe any claim of the '289 patent.

26. The '289 patent claims, *inter alia*, a levalbuterol hydrochloride solution that does not contain chelating agents. *See* Exhibit 2.

27. There are four independent claims in the '289 patent—claims 1, 2, 11 and 12. Each of these claims requires that there be no chelating agent in the claimed formulation. Claim 1 discloses a formulation "free of chelating agents." *See* '289 patent, col. 5 ll. 49-50. Claims 2, 11 and 12 disclose a formulation that "does not contain a chelating agent." *See* col. 6 ll. 4-5, ll. 44-45 and ll. 56-57.

28. The levalbuterol hydrochloride solution that is the subject of Dey's ANDA No. 77-800 contains EDTA. *See* ANDA, section 3.2.P.2.1.2 attached hereto as Exhibit 3. EDTA is a

chelating agent. *See id.* The product that is the subject of Dey's ANDA No. 77-800 cannot, therefore, infringe any claim of the '289 patent.

29. Because the product that is the subject of ANDA 77-800 contains a chelating agent, the manufacture, marketing, use, offer for sale, sale and/or importation of the product that is the subject of Dey's ANDA 77-800 will not directly infringe, induce or contribute to the infringement by others of the '289 patent, nor can the claims of the '289 patent be infringed by the filing of Dey's ANDA 77-800.

COUNT II

DECLARATORY JUDGMENT OF INVALIDITY OF THE '289 PATENT

30. Dey repeats each of the foregoing paragraphs as if fully set forth herein.

31. There is a substantial and continuing controversy between Sepracor and Dey as to the validity of the '289 patent.

32. The '289 patent is invalid under 35 U.S.C. §§ 101 *et seq.* including §§ 101, 102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Dey respectfully requests that the Court enter judgment as follows:

A. Declaring that the claims of the '289 patent have not been infringed by the filing of Dey's ANDA 77-800;

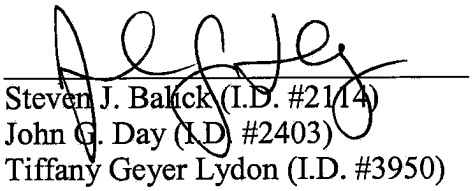
B. Declaring that the manufacture marketing, use, offer for sale, sale and/or importation of the product that is the subject of Dey's ANDA 77-800 will not directly infringe, or induce or contribute to the infringement by others of any claims of the '289 patent;

C. Declaring that the '289 patent is invalid;

D. Awarding Dey attorneys' fees and costs; and

E. Awarding Dey such other and further relief as the Court may deem just and proper.

ASHBY & GEDDES



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