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Attorneys for Plaintiffs AstraZeneca LP and AstraZeneca AB

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA LP and ASTRAZENECA AB, Plaintiffs, v. BREATH LIMITED Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs AstraZeneca LP and AstraZeneca AB (collectively, "AstraZeneca") for their Complaint herein, aver as follows:

NATURE OF THE ACTION

1. This is an action for a judgment of patent infringement arising under the patent laws of the United States, Title 35, United States Code.

JURISDICTION AND VENUE

2. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

3. This Court has personal jurisdiction over defendant because counsel for Breath Limited ("Breath") stated that Breath will consent to jurisdiction in the District of New Jersey for any action AstraZeneca might be considering bringing against Breath's ANDA No. 78-404, which is the action averred in this Complaint.

4. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PARTIES

5. AstraZeneca LP is a limited partnership organized and existing under the laws of the State of Delaware, having its principal place of business at 1800 Concord Pike, Wilmington, Delaware.

6. AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at S 151 85 Södertälje, Sweden.

7. AstraZeneca LP is the holder of an approved New Drug Application ("NDA"), No. 20-929, for the manufacture and sale of budesonide inhalation suspension for the maintenance treatment of asthma and as a prophylactic therapy in children 12 months to 8 years

of age. AstraZeneca LP markets and sells this composition in the United States under the trade name PULMICORT RESPULES® (budesonide inhalation suspension).

8. Upon information and belief, defendant Breath is a company organized and existing under the laws of the United Kingdom, having its principal place of business at 88 Mount Pleasant, Biggin Hill, Westerham, Kent, United Kingdom.

THE PATENT-IN-SUIT

9. AstraZeneca AB is the lawful owner of all right, title, and interest in and to the following United States patent, including all right to sue and to recover for past infringement thereof, which patent contains one or more claims covering PULMICORT RESPULES® and its use:

A. United States Patent No. 7,524,834, entitled "STERILE POWDERS, FORMULATIONS, AND METHODS FOR PRODUCING THE SAME" ("the '834 patent"), a copy of which is attached hereto as Exhibit A, which was duly and legally issued April 28, 2009, naming Ann-Kristin Karlsson, Cheryl Larrivee-Elkins, and Ove Molin as the inventors.

BREATH'S ANDA FOR BUDESONIDE INHALATION SUSPENSION, 0.25 AND 0.5 mg/2 ml

10. Upon information and belief, Breath submitted Abbreviated New Drug Application ("ANDA") No. 78-404 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), in order to obtain approval to engage in the commercial manufacture, use, or sale of budesonide inhalation suspension, 0.25 mg/2ml and 0.5 mg/2 ml, a generic version of PULMICORT RESPULES®, before the expiration of the '834 patent.

11. Upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), defendant's budesonide inhalation suspension, 0.25 mg/2ml and 0.5 mg/2 ml together with its package insert, and its use are the subject of one or more claims of the '834 patent.

12. Upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), Breath's ANDA No. 78-404 contains information to show that budesonide inhalation suspension, 0.25 and 0.5 mg/2 ml, (a) is bioequivalent to PULMICORT RESPULES®, (b) has the same active ingredient as PULMICORT RESPULES®, (c) has the same route of administration, dosage form, and strength as PULMICORT RESPULES®, and (d) has the same, or substantially the same, proposed labeling as PULMICORT RESPULES®.

13. In a letter dated July 28, 2009 addressed to AstraZeneca LP and AstraZeneca AB, Breath sent a "Notification of Certification for U.S. Patent No. 7,524,834 B2 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act" ("the ANDA Notice"). The ANDA Notice does not provide any valid basis for concluding that the '834 patent is invalid, unenforceable and/or not infringed. AstraZeneca received the ANDA Notice on July 29, 2009.

14. Upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), Breath's submission of ANDA No. 78-404 was an act of infringement of one or more claims of the '834 patent, under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

15. Upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), defendant's manufacture, use, sale, and/or offer for sale of budesonide inhalation suspension, 0.25 mg/2ml and 0.5 mg/2 ml, will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '834 patent.

16. Upon information and belief, defendant has been aware of the existence of the '834 patent, but nevertheless has been and is now infringing one or more claims of the '834

patent. This infringement by the defendant has been deliberate and in disregard of AstraZeneca's lawful rights under the '834 patent, thus rendering this case "exceptional", as that term is set forth in 35 U.S.C. § 285.

17. The acts of infringement by the defendant set forth above will cause AstraZeneca irreparable harm for which it has no adequate remedy at law, including irreparable harm within the state of New Jersey and this Judicial District, and will continue unless preliminarily and permanently enjoined by this Court.

RELIEF

WHEREFORE, AstraZeneca prays for judgment against the defendant as follows:

A. Adjudging that the '834 patent is valid and enforceable;

B. Adjudging that the defendant has infringed the '834 patent, and that the sale, offer for sale, and/or manufacture by the defendant of budesonide inhalation suspension, 0.25 mg/2ml and 0.5 mg/2 ml, if marketed, will infringe, induce infringement of, and/or contribute to infringement of the '834 patent;

C. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Breath's ANDA No. 78-404, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date which is not earlier than the last date of expiration of the '834 patent;

D. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, the defendant, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product or its use that infringes the '834 patent;

E. Declaring this an exceptional case and awarding AstraZeneca its attorney fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

F. Awarding AstraZeneca such other and further relief as this Court may deem just and proper.

Respectfully submitted,

DATED: August 12, 2009

By s/John E. Flaherty

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