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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.		)	Civil Action No. _____
		)	
SANDOZ INC.,		)	
		)	
Defendant.		)	
_____		)	

**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 the defendant Sandoz, Inc. (“Sandoz”) because, *inter alia*, Sandoz has purposefully availed itself of the rights and benefits of New Jersey law. Upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), Sandoz is currently doing business in this Judicial District by maintaining a place of business here and by engaging in the sale of a range of pharmaceutical products here.

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<sup>®</sup> (budesonide inhalation suspension).

8. Upon information and belief, defendant Sandoz is a company organized and existing under the laws of the Colorado, having its corporate headquarters at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

### **THE PATENTS-IN-SUIT**

9. AstraZeneca AB is the lawful owner of all right, title, and interest in and to the following United States patents, including all right to sue and to recover for past infringement thereof, which patents contain one or more claims covering the PULMICORT RESPULES<sup>®</sup> product and its method of use.

A. United States Patent No. 6,598,603, entitled “METHOD FOR TREATING RESPIRATORY DISEASES” (“the ‘603 patent”), a copy of which is attached hereto as Exhibit A, which was duly and legally issued July 29, 2003, naming Bertil Andersson, Thor-Bjorn Conradsson, and Goran Eriksson as the inventors.

B. 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 B, which was duly and legally issued April 28, 2009, naming Ann-Kristen Karlsson, Cheryl Larrivee-Elkins, and Ove Molin as the inventors.

### **THE ‘603 AND ‘834 PATENTS AND SANDOZ’S ANDA FOR BUDESONIDE INHALATION SUSPENSION, 0.25, 0.5, AND 1.0 mg/2 ml**

10. Upon information and belief, Sandoz submitted Abbreviated New Drug Application (“ANDA”) No. 201966 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/2 ml, 0.5 mg/2 ml, and 1.0 mg/2 ml, a generic version of PULMICORT RESPULES<sup>®</sup>, before the expiration of the ‘603 and ‘834 patents.

11. Upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), defendant’s budesonide inhalation suspension, 0.25 mg/2ml, 0.5 mg/2 ml, and 1.0 mg/2 ml together with its package insert, and its use are the subject of one or more claims of the ‘603 and ‘834 patents.

12. Upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), Sandoz’s ANDA No. 201966 contains information to show that budesonide inhalation suspension, 0.25 mg/2 ml, 0.5 mg/2 ml, and 1.0 mg/2 ml, (a) is bioequivalent to PULMICORT RESPULES<sup>®</sup>, (b) has the same active ingredient as PULMICORT RESPULES<sup>®</sup>, (c) has the same route of administration, dosage form, and strength as PULMICORT RESPULES<sup>®</sup>, and (d) has the same, or substantially the same, proposed labeling as PULMICORT RESPULES<sup>®</sup>.

13. In a letter dated September 23, 2010 addressed, *inter alia*, to AstraZeneca LP and AstraZeneca AB, Sandoz sent a “Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B) of Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95” (“the ANDA Notice”). The ANDA Notice does not provide any valid basis for concluding that the ‘603 and ‘834 patents are invalid, unenforceable and/or not infringed. AstraZeneca received the ANDA Notice on September 24, 2010.

14. Upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), Sandoz’s submission of ANDA No. 201966 was an act of infringement of one or more claims of the ‘603 and ‘834 patents, 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, 0.5 mg/2 ml, and 1.0 mg/2 ml, will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '603 and '834 patents.

16. Upon information and belief, defendant has been aware of the existence of the '603 and '834 patents, but nevertheless has been and is now infringing one or more claims of the patents-in-suit in disregard of AstraZeneca's lawful rights under the '603 and '834 patents, 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 '603 and '834 patents are valid and enforceable;
- B. Adjudging that the defendant has infringed the '603 and '834 patents, and that the sale, offer for sale, and/or manufacture by the defendant of budesonide inhalation suspension, 0.25 mg/2ml, 0.5 mg/2 ml, and 1.0 mg/2 ml, if marketed, will infringe, induce infringement of, and/or contribute to infringement of the '603 and '834 patents;
- C. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sandoz's ANDA No. 201966, 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 '603 and '834 patents;
- 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 '603 and '834 patents;

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: November 4, 2010

By s/ John E. Flaherty

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*AstraZeneca LP and AstraZeneca AB*

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

I hereby certify that the patents at issue in this case are the subject of the following actions pending in this court before the Honorable Renee Marie Bumb:

*AstraZeneca LP and AstraZeneca AB v. Breath Limited and AstraZeneca LP and AstraZeneca AB v. Apotex, Inc. and Apotex Corp., Consolidated Civil Action No. 08-CV-1512 (RMB)(AMD)(District of New Jersey) .*

Respectfully submitted,

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