**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF INDIANA**
**INDIANAPOLIS DIVISION**

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| TAKEDA GMBH,<br>TEIJIN LIMITED,<br>TEIJIN PHARMA LIMITED, and<br>SUNOVION PHARMACEUTICALS INC.,<br><br>Plaintiffs,<br><br>v.<br><br>APOTEX INC. and APOTEX CORP.,<br><br>Defendants. | ) | Civil Action No. 1:12-cv-01073-TWP-DML |

**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Takeda GmbH , Teijin Limited, Teijin Pharma Limited and Sunovion Pharmaceuticals Inc. (collectively "Plaintiffs"), by their attorneys, for their First Amended Complaint against Apotex Inc. and Apotex Corp. (collectively "Apotex"), allege as follows:

**NATURE OF THE ACTION**

1. This is an action for infringement of U.S. Patent Nos. 6,767,901 ("the '901 patent"), 6,939,559 ("the '559 patent"), and 7,235,247 ("the '247 patent"). This suit arises out of the filing by Apotex of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a copy of Plaintiffs' successful Omnaris® Nasal Spray product, prior to the expiration of the '901 patent, the '559 patent and the '247 patent.

**THE PARTIES**

2. Plaintiff Takeda GmbH (formerly known as Nycomed GmbH) ("Takeda")

is a corporation organized and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Strasse 2, Konstanz, Germany 78467.

3. Plaintiff Teijin Limited is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-1, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo 100-8585, Japan.

4. Plaintiff Teijin Pharma Limited ("Teijin Pharma") (collectively with Teijin Limited, "Teijin") is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-1, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo 100-8585, Japan.

5. Plaintiff Sunovion Pharmaceuticals Inc. ("Sunovion") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

6. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Dr., Weston, Ontario M9L 1T9, Canada.

7. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

## JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Apotex Inc. and Apotex Corp. because, *inter alia*, they have purposefully availed themselves of the benefits and protections of Indiana's laws such that they should reasonably anticipate being haled into court here. On

information and belief, Apotex Inc. and Apotex Corp. have had persistent, continuous and systematic contacts with this judicial district, including, *inter alia*, maintaining a distribution and operations center and other facilities in Indiana and deriving substantial revenue from the development, manufacture and/or sale of generic pharmaceutical products that are sold or shipped in, into, or from Indiana.

10. Upon information and belief, Apotex Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products intended for the U.S. market, including Indiana, through various operating subsidiaries, including Apotex Corp., pursuant to approvals from the FDA.

11. Apotex Inc. is seeking approval from the FDA to manufacture and sell a generic copy of Omnaris® in the United States, including Indiana, and upon information and belief, Apotex Inc. and Apotex Corp. will, upon receiving FDA approval, work in concert to distribute that product in the United States from a distribution facility in Indiana and the Southern District of Indiana.

12. Upon information and belief, Apotex Corp. is a wholly-owned distribution affiliate of Apotex Inc., and Apotex Corp. is in the business of, among other things, buying generic copies of branded pharmaceutical products from Apotex Inc. and selling and distributing those products in the United States, including Indiana, pursuant to Apotex Inc.'s FDA approvals.

13. Upon information and belief, Apotex Corp. operates the distribution and operations center in Indianapolis through which it distributes Apotex products for sale throughout the United States pursuant to approvals that Apotex Inc. holds from the FDA.

14. Upon information and belief, Apotex Inc. and Apotex Corp. each are a party to one or more contractual agreements regarding the distribution of generic pharmaceutical

products in, into, or from the State of Indiana and the Southern District of Indiana.

15. Upon information and belief, and consistent with their practice with respect to other generic products, Apotex Inc. and Apotex Corp. acted in concert to prepare and file ANDA No. 202625.

16. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**BACKGROUND**

17. Omnaris® Nasal Spray is a prescription drug product approved by the FDA for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older and perennial allergic rhinitis in adults and adolescents 12 years of age and older. The active ingredient in Omnaris® Nasal Spray is ciclesonide.

18. Teijin developed proprietary technology used in the formulation of Omnaris® Nasal Spray. Takeda prepared and filed the New Drug Application ("NDA") with the FDA and is the holder of approved NDA 22-004 for Omnaris® Nasal Spray. Sunovion is the exclusive distributor of Omnaris® Nasal Spray in the United States.

19. The '901 patent, entitled "Ciclesonide Contained Pharmaceutical Composition for Application to Mucosa" (Exhibit A hereto), was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 27, 2004. Takeda owns the '901 patent and Sunovion is the exclusive licensee of the '901 patent.

20. The '559 patent, entitled "Pharmaceutical Composition for Application to Mucosa" (Exhibit B hereto), was duly and legally issued by the USPTO on September 6, 2005. When the original Complaint was filed in this action, Teijin Pharma owned the '559 patent. On October 1, 2012, Teijin Pharma assigned the '559 patent to Teijin Limited. Takeda is the

exclusive licensee of the ’559 patent with respect to ciclesonide compositions, such as Omnaris® Nasal Spray, and Sunovion is a sublicensee of the ’559 patent.

21. The ’247 patent, entitled “Pharmaceutical Composition for Application to Mucosa” (Exhibit C hereto), was duly and legally issued by the USPTO on June 26, 2007. When the original Complaint was filed in this action, Teijin Pharma owned the ‘247 patent. On October 1, 2012, Teijin Pharma assigned the ‘247 patent to Teijin Limited. Takeda is the exclusive licensee of the ’247 patent with respect to ciclesonide compositions, such as Omnaris® Nasal Spray, and Sunovion is a sublicensee of the ’247 patent.

22. One or more of the claims of each of the ’901 patent, the ’559 patent and the ’247 patent claim Omnaris® Nasal Spray, and each of the ’901 patent, the ’559 patent and the ’247 patent has been listed in connection with that drug product in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the “Orange Book.”

23. By letter dated June 20, 2012 (the “Notice Letter”), Apotex notified Plaintiffs that Apotex had submitted to the FDA an ANDA, No. 202625, seeking approval for a nasal spray drug product containing ciclesonide in the same concentration and dosage as Omnaris® Nasal Spray (“Apotex’s ANDA Product”). Upon information and belief, Apotex’s ANDA Product uses the formulation contained in Omnaris® Nasal Spray. The purpose of filing the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex’s ANDA Product in the United States prior to the expiration of the ’901 patent, the ’559 patent and the ’247 patent.

24. In the Notice Letter, Apotex also notified Plaintiffs that Apotex had included in its ANDA certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA with respect to the '901 patent, the '559 patent and the '247 patent asserting that each of those patents is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product.

**COUNT I - INFRINGEMENT OF THE '901 PATENT**

25. Plaintiffs incorporate each of the preceding paragraphs 1-23 as if fully set forth herein.

26. Apotex's submission of ANDA No. 202625 seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's ANDA Product before the expiration of the '901 patent is an act of infringement of the '901 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

27. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon approval of ANDA No. 202625.

28. The manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product would infringe one or more claims of the '901 patent pursuant to 35 U.S.C. § 271(a).

29. Plaintiffs will be substantially and irreparably damaged by infringement of the '901 patent. Unless Apotex is enjoined from infringing the '901 patent Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II - INFRINGEMENT OF THE '559 PATENT**

30. Plaintiffs incorporate each of the preceding paragraphs 1-28 as if fully set

forth herein.

31. Apotex's submission of ANDA No. 202625 seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's ANDA Product before the expiration of the '559 patent is an act of infringement of the '559 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon approval of ANDA No. 202625.

33. The manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product would infringe one or more claims of the '559 patent pursuant to 35 U.S.C. § 271(a).

34. Plaintiffs will be substantially and irreparably damaged by infringement of the '559 patent. Unless Apotex is enjoined from infringing the '559 patent Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT III - INFRINGEMENT OF THE '247 PATENT**

35. Plaintiffs incorporate each of the preceding paragraphs 1-33 as if fully set forth herein.

36. Apotex's submission of ANDA No. 202625 seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's ANDA Product before the expiration of the '247 patent is an act of infringement of the '247 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product

immediately and imminently upon approval of ANDA No. 202625.

38. The manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product would infringe one or more claims of the '247 patent pursuant to 35 U.S.C. § 271(a).

39. Plaintiffs will be substantially and irreparably damaged by infringement of the '247 patent. Unless Apotex is enjoined from infringing the '247 patent Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that United States Patent No. 6,767,901 has been infringed pursuant to 35 U.S.C. § 271(e)(2) by Apotex's submission to the FDA of its ANDA No. 202625 and will be infringed pursuant to 35 U.S.C. § 271(a) by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product;

(b) A judgment that United States Patent No. 6,939,559 has been infringed pursuant to 35 U.S.C. § 271(e)(2) by Apotex's submission to the FDA of its ANDA No. 202625 and will be infringed pursuant to 35 U.S.C. § 271(a) by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product;

(c) A judgment that United States Patent No. 7,235,247 has been infringed pursuant to 35 U.S.C. § 271(e)(2) by Apotex's submission to the FDA of its ANDA No. 202625 and will be infringed pursuant to 35 U.S.C. § 271(a) by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product;

(d) A judgment providing that the effective date of any FDA approval of ANDA No. 202625 and any other ANDA filed by Apotex seeking approval to manufacture, use,

offer for sale, sell, and/or import Apotex's ANDA Product or any product that infringes United States Patent No. 6,767,901 be not earlier than the expiration date of that patent, inclusive of any extension(s) and any additional period(s) of exclusivity;

(e) A judgment providing that the effective date of any FDA approval of ANDA No. 202625 and any other ANDA filed by Apotex seeking approval to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product or any product that infringes United States Patent No. 6,939,559 be not earlier than the expiration date of that patent, inclusive of any extension(s) and any additional period(s) of exclusivity;

(f) A judgment providing that the effective date of any FDA approval of ANDA No. 202625 and any other ANDA filed by Apotex seeking approval to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product or any product that infringes United States Patent No. 7,235,247 be not earlier than the expiration date of that patent, inclusive of any extension(s) and any additional period(s) of exclusivity;

(g) A preliminary and permanent injunction enjoining Apotex Inc., Apotex Corp., and all persons acting in concert with Apotex Inc. and/or Apotex Corp., from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's ANDA product, or any other drug product that infringes United States Patent No. 6,767,901, prior to the expiration of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(h) A preliminary and permanent injunction enjoining Apotex Inc., Apotex Corp., and all persons acting in concert with Apotex Inc. and/or Apotex Corp., from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's ANDA product, or any other drug product that infringes United States Patent No.

6,939,559, prior to the expiration of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(i) A preliminary and permanent injunction enjoining Apotex Inc., Apotex Corp., and all persons acting in concert with Apotex Inc. and/or Apotex Corp., from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's ANDA product, or any other drug product that infringes United States Patent No. 7,235,247, prior to the expiration of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(j) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(k) Costs and expenses in this action; and

(l) Such further and other relief as this Court may deem just and proper.

Dated: February 13, 2013

Respectfully submitted,

By: *Jessamyn S. Berniker*

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 13th day of February 2013, a copy of the foregoing was filed with the Clerk of Court using the CM/ECF system. Service of this filing will be made on all ECF-registered counsel by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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