IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE INTELLECTUAL PROPERTY MANAGEMENT LIMITED and GLAXOSMITHKLINE LLC (f/k/a SMITHKLINE BEECHAM CORPORATION),	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GlaxoSmithKline Intellectual Property Management Limited ("Glaxo IP") and GlaxoSmithKline LLC (formerly known as SmithKline Beecham Corporation) ("GSK") (collectively, "Plaintiffs"), for their Complaint against Defendant Sandoz Inc. ("Sandoz"), hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 6,858,596 (the "'596 Patent"), 7,101,866 (the "'866 Patent"), and 7,541,350 (the "'350 Patent"), arising under the patent laws of the United States, 35 U.S.C. §§ 271 and 281.

2. This action relates to the following Abbreviated New Drug Application ("ANDA") filed with the U.S. Food and Drug Administration ("FDA"): ANDA No. 203338 filed by Sandoz for approval to market 0.0275 mg/Inh of fluticasone furoate metered nasal spray, a proposed generic version of Plaintiffs' VERAMYST® drug product.

PARTIES

3. Plaintiff Glaxo IP is a company incorporated in England and Wales having a registered office at 980 Great West Road, Brentford, Middlesex, TW8 9GS.

4. Plaintiff GSK is a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, PA 19102.

5. Upon information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

6. Upon information and belief, following any FDA approval of ANDA No. 203338, Sandoz will make, use, offer to sell, and/or sell the generic product that is the subject of ANDA No. 203338 throughout the United States, and/or import such generic product into the United States.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 100, et seq. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

8. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 203338 that has led to foreseeable harm and injury to Plaintiffs.

9. This Court also has personal jurisdiction over Sandoz because, *inter alia*, it has purposely availed itself of the rights and benefits of the laws of Delaware by engaging in

systematic and continuous contacts with Delaware such that it should reasonably anticipate being hauled into court here. On information and belief, Sandoz has persistent, systematic, and continuous contacts with Delaware as set forth below.

10. On information and belief, Sandoz regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware.

11. On information and belief, by virtue of, *inter alia*, Sandoz's sales-related activities in Delaware, including, but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of Delaware, this Court has personal jurisdiction over Sandoz.

12. On information and belief, Sandoz is licensed to distribute pharmaceuticals in the state of Delaware and is in the business of making and selling generic pharmaceutical products for sale throughout the United States, including Delaware. Upon further information and belief, Sandoz is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale CSR" of drug products. *See* https://dpronline.delaware.gov/mylicense%20weblookup/SearchResults.aspx.

13. Sandoz has previously availed itself of this jurisdiction for the purpose of litigating its patent suits. *See, e.g., Sandoz Inc. v Pfizer Inc.*, C.A. No. 10-104 (D. Del.). Sandoz has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., Aventis Pharma S.A. v. Sandoz Inc.*, C.A. No. 11-043 (D. Del.). Sandoz has also submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Sandoz consented to jurisdiction and filed counterclaims in, *inter alia*, *Genzyme Corp. v. Sandoz Inc.*, C.A. No. 10-429 (D. Del.); *Cephalon Inc. v. Sandoz Inc.*, C.A.

No. 10-123 (D. Del.); *Allergan Inc. v. Sandoz Inc.*, C.A. 10-024 (D. Del.); *Daiichi Sankyo Co., Ltd. v. Sandoz Inc.*, C.A. No. 09-898 (D. Del.); *Bone Care Int'l LLC v. Sandoz Inc.*, C.A. No. 09-524 (D. Del.); *Pfizer Inc. v. Sandoz Inc.*, C.A. No. 09-310 (D. Del.); *Abbott Labs. v. Sandoz Inc.*, C.A. No. 09-215 (D. Del.); *Medicis Pharms. Corp. v. Mylan Inc. et al.*, C.A. No. 09-033 (D. Del.); *Wyeth v. Sandoz Inc.*, C.A. No. 08-317 (D. Del.); and *AstraZeneca Pharms. LP v. Sandoz Inc.*, C.A. No. 07-807 (D. Del).

14. On information and belief, by virtue of, *inter alia*, Sandoz's filing of ANDA No. 203338, and the associated systematic and continuous activities within the state of Delaware, including but not limited to the development of generic drug products for sale to residents of Delaware, this Court has general and specific personal jurisdiction over Sandoz. These activities satisfy due process and confer personal jurisdiction over Sandoz consistent with the Delaware Long Arm Statute.

VERAMYST®

15. GSK holds approved New Drug Application ("NDA") No. 22-051 for VERAMYST®, the active ingredient of which is fluticasone furoate. VERAMYST® was approved by the FDA on April 27, 2007. VERAMYST® metered nasal spray is approved for the treatment of symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older.

16. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the following patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to VERAMYST®: the '596 Patent, the '866 Patent, and the '350 Patent.

17. The '596 Patent, the '866 Patent, and the '350 Patent are collectively referred to herein as the "Patents-in-Suit."

THE PATENTS-IN-SUIT

18. Glaxo IP is the owner of the entire right, title, and interest in the '596 Patent, entitled "Formulation Containing Anti-Inflammatory Androstane Derivative," which was duly and legally issued on February 22, 2005. A true and correct copy of the '596 Patent is attached hereto at **Exhibit A**.

19. Glaxo IP is the owner of the entire right, title, and interest in the '866 Patent, entitled "Anti-Inflammatory Androstane Derivative," which was duly and legally issued on September 5, 2006. A true and correct copy of the '866 Patent is attached hereto at **Exhibit B**.

20. Glaxo IP is the owner of the entire right, title, and interest in the '350 Patent, entitled "Formulation Containing Anti-Inflammatory Androstane Derivative," which was duly and legally issued on June 2, 2009. A true and correct copy of the '350 Patent is attached hereto at **Exhibit C**.

21. GSK is licensed under the Patents-in-Suit with exclusive rights to sell VERAMYST® in the United States.

INFRINGEMENT BY SANDOZ

22. By letter dated November 8, 2011 ("the Sandoz Notice Letter"), Sandoz notified GSK that it had purportedly submitted ANDA No. 203338 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of generic 0.0275 mg/Inh fluticasone furoate metered nasal spray before the expiration of the Patents-in-Suit. Upon information and

belief, Sandoz intends to engage in the commercial manufacture, use, importation, sale, and/or offer for sale of generic 0.0275 mg/Inh fluticasone furoate metered nasal spray promptly upon receiving FDA approval to do so.

23. The Sandoz Notice Letter was received by GSK on November 9, 2011.

24. By filing ANDA No. 203338, Sandoz has necessarily represented to the FDA that its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray has the same active ingredients as VERAMYST®, has the same route of administration, dosage form, and strength as VERAMYST® and is bioequivalent to VERAMYST®.

25. In the Sandoz Notice Letter, Sandoz notified GSK that its ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in Sandoz's opinion, certain claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of Sandoz's proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray.

26. The Sandoz Notice Letter does not contest infringement by Sandoz's proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray of claims 1-31 and 36-39 of the '596 Patent, claims 1-3, 6-8, 10-12, 21, 24-25, 33, 48, 50-51, 53, 55, 58-60, 62-64, 66-67, 71, 73, 75-76, 78-80, 90-91, 93-94, 96, 98, 101-103, 105-107, 109, 111, 115, 117, and 119 of the '866 Patent, or claims 1-7 of the '350 Patent.

27. Sandoz has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by submitting ANDA No. 203338 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, importation, offer to sell, and/or sale of generic 0.0275 mg/Inh fluticasone furoate metered nasal spray before the expiration of the terms of the Patents-in-Suit.

28. The commercial manufacture, use, offer for sale, sale, and/or importation of the proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray for which Sandoz seeks approval in its ANDA will directly and/or indirectly infringe one or more claims of the Patents-in-Suit.

29. Plaintiffs are entitled under 35 U.S.C. § 271(e)(4) to full relief from Sandoz's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 203338 relating to Sandoz's proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray shall not be earlier than the expiration of the Patents-in-Suit.

30. This Complaint is being filed before the expiration of the forty-five day period from the date GSK received the Sandoz Notice Letter.

COUNT ONE: INFRINGEMENT OF THE '596 PATENT

31. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-30 of this Complaint.

32. Sandoz's submission of ANDA No. 203338 to obtain approval to engage in the commercial manufacture, use, importation, offer to sell, and/or sale of generic 0.0275 mg/Inh fluticasone furoate metered nasal spray before the expiration (and any additional periods of exclusivity) of the Patents-in-Suit constitutes infringement of one or more of the claims of the '596 Patent under 35 U.S.C. § 271(e)(2)(A).

33. Sandoz's commercial manufacture, use, offer to sell, sale, or importation of its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray prior to the expiration of the '596 Patent, or its inducement of or contribution to such conduct, would further infringe the '596 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Sandoz's filing of its ANDA

and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '596 Patent.

34. Upon FDA approval of ANDA No. 203338, Sandoz will further infringe the '596 Patent by making, using, offering to sell, and/or selling generic 0.0275 mg/Inh fluticasone furoate metered nasal spray in the United States and/or importing such nasal spray into the United States before the expiration (and any additional periods of exclusivity) of the Patents-in-Suit, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

35. By selling, offering for sale, and/or importing its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray, Sandoz will actively encourage and/or instruct others on how to use its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray in a way that infringes at least one claim of the '596 Patent. Sandoz knows, will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '596 Patent.

36. Sandoz had actual knowledge of the '596 Patent prior to filing ANDA No. 203338 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '596 Patent. This is an exceptional case.

37. If Sandoz's infringement of the '596 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law. Both the balance of the hardships as between Plaintiffs and Sandoz and the public interest further support this Court enjoining Sandoz's infringing activities.

COUNT TWO: INFRINGEMENT OF THE '866 PATENT

38. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-37 of this Complaint.

39. Sandoz's submission of ANDA No. 203338 to obtain approval to engage in the commercial manufacture, use, importation, offer to sell, and/or sale of generic 0.0275 mg/Inh fluticasone furoate metered nasal spray before the expiration (and any additional periods of exclusivity) of the Patents-in-Suit constitutes infringement of one or more of the claims of the '866 Patent under 35 U.S.C. § 271(e)(2)(A).

40. Sandoz's commercial manufacture, use, offer to sell, sale, or importation of its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray prior to the expiration of the '866 Patent, or its inducement of or contribution to such conduct, would further infringe the '866 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Sandoz's filing of its ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '866 Patent.

41. Upon FDA approval of ANDA No. 203338, Sandoz will further infringe the '866 Patent by making, using, offering to sell, and/or selling generic 0.0275 mg/Inh fluticasone furoate metered nasal spray in the United States and/or importing such nasal spray into the United States before the expiration (and any additional periods of exclusivity) of the Patents-in-Suit, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

42. By selling, offering for sale, and/or importing its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray, Sandoz will actively encourage and/or instruct others on how to use its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray in a way that infringes at least one claim of the '866 Patent. Sandoz knows, will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '866 Patent.

43. Sandoz had actual knowledge of the '866 Patent prior to filing ANDA No. 203338 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '866 Patent. This is an exceptional case.

44. If Sandoz's infringement of the '866 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law. Both the balance of the hardships as between Plaintiffs and Sandoz and the public interest further support this Court enjoining Sandoz's infringing activities.

COUNT THREE: INFRINGEMENT OF THE '350 PATENT

45. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-44 of this Complaint.

46. Sandoz's submission of ANDA No. 203338 to obtain approval to engage in the commercial manufacture, use, importation, offer to sell, and/or sale of generic 0.0275 mg/Inh fluticasone furoate metered nasal spray before the expiration (and any additional periods of exclusivity) of the Patents-in-Suit constitutes infringement of one or more of the claims of the '350 Patent under 35 U.S.C. § 271(e)(2)(A).

47. Sandoz's commercial manufacture, use, offer to sell, sale, or importation of its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray prior to the

expiration of the '350 Patent, or its inducement of or contribution to such conduct, would further infringe the '350 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Sandoz's filing of its ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '350 Patent.

48. Upon FDA approval of ANDA No. 203338, Sandoz will further infringe the '350 Patent by making, using, offering to sell, and/or selling generic 0.0275 mg/Inh fluticasone furoate metered nasal spray in the United States and/or importing such nasal spray into the United States before the expiration (and any additional periods of exclusivity) of the Patents-in-Suit, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

49. By selling, offering for sale, and/or importing its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray, Sandoz will actively encourage and/or instruct others on how to use its proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray in a way that infringes at least one claim of the '350 Patent. Sandoz knows, will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '350 Patent.

50. Sandoz had actual knowledge of the '350 Patent prior to filing ANDA No. 203338 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '350 Patent. This is an exceptional case.

51. If Sandoz's infringement of the '350 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law. Both the balance of

the hardships as between Plaintiffs and Sandoz and the public interest further support this Court enjoining Sandoz's infringing activities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

A. A judgment that Sandoz has infringed each of the Patents-in-Suit;

B. A judgment that the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray would infringe each of the Patents-in-Suit;

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently restraining and enjoining Sandoz, its officers, agents, attorneys and employees, and those acting in privity or concert with Sandoz, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of generic 0.0275 mg/Inh fluticasone furoate metered nasal spray, until after the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

D. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the aforementioned ANDA No. 203338 for Sandoz's proposed generic 0.0275 mg/Inh fluticasone furoate metered nasal spray shall not be earlier than the latest expiration date of the Patents-in-Suit;

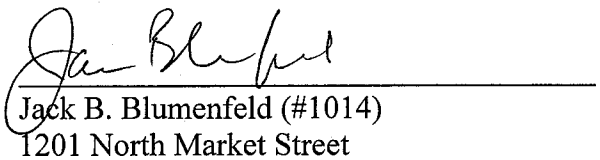
E. Damages or other monetary relief to Plaintiffs if Sandoz engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of generic 0.0275 mg/Inh fluticasone furoate metered nasal spray before the latest expiration date of

any of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

F. A declaration that this is an exceptional case and an award of costs, expenses, and reasonable attorneys' fees of this action, pursuant to at least 35 U.S.C. §§ 271(e)(4) and 285; and

G. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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