IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, ENDO PHARMACEUTICALS SOLUTIONS INC. and SUPERNUS PHARMACEUTICALS, INC. Plaintiffs, v. SANDOZ, INC. Defendants.	C.A. No. _____ **JURY TRIAL REQUESTED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Endo Pharmaceuticals Solutions Inc., and Supernus Pharmaceuticals, Inc. (collectively "Plaintiffs") for their complaint against Sandoz, Inc. ("Sandoz"), to the best of their knowledge, information and belief, hereby allege as follows:

THE PARTIES

1. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware and has headquarters at 2525 Dupont Drive, Irvine, California 92612.

2. Plaintiff Allergan USA, Inc. is a corporation organized and existing under the laws of the State of Delaware and has headquarters at 2525 Dupont Drive, Irvine, California 92612.

3. Plaintiff Allergan Sales, LLC is a corporation organized and existing under the laws of the State of Delaware and has headquarters at 2525 Dupont Drive, Irvine, California 92612.

4. Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC, (collectively "Allergan") are pharmaceutical companies engaged in the research, development, sale, and

marketing of pharmaceuticals, including ophthalmic, neurologic, and urologic drugs. Allergan holds certain exclusive rights to U.S. Patent No. 7,410,978 ("the '978 patent"), attached hereto as Exhibit A.

5. Plaintiff Endo Pharmaceutical Solutions Inc. ("EPS") is a corporation organized and existing under the laws of the State of Delaware and has its headquarters at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. EPS holds certain exclusive rights to the '978 patent.

6. EPS is a wholly owned subsidiary of Endo Pharmaceuticals Inc. ("Endo"), a corporation organized and existing under the laws of Delaware and having its headquarters at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty pharmaceutical company engaged in the research, development, sale, and marketing of prescription pharmaceuticals.

7. Allergan and Endo co-market SANCTURA XR® in the United States. SANCTURA XR® is a prescription drug approved for treating overactive bladder and is covered by the '978 patent. Allergan and EPS, individually and collectively, have been and will be injured by the acts complained of herein.

8. Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus") is a Delaware corporation having a principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850. Supernus owns the '978 patent. Supernus has been and will be injured by the acts complained of herein.

9. On information and belief, Defendant Sandoz, Inc. ("Sandoz") is a corporation organized and existing under the laws of the State of Colorado, having a place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

10. Upon information and belief, Sandoz is in the business of manufacturing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district and is registered to distribute drugs in the State of Delaware.

JURISDICTION AND VENUE

11. This is an action for infringement of the '978 patent under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*, including §§ 271(e)(2) and 271(a), and 28 U.S.C. §§ 2201 and 2202.

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

13. An actual, substantial, and justiciable controversy exists between Plaintiffs, each individually and collectively, and Sandoz as to the infringement and validity of the '978 patent.

14. This Court has personal jurisdiction over Sandoz by virtue of the fact that, *inter alia*, it has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs, all Delaware corporations.

15. This Court also has personal jurisdiction over Sandoz by virtue of the fact that it 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. These activities further demonstrate that Sandoz has continuous and systematic contacts with Delaware.

16. On information and belief, Sandoz has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Sandoz has 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 *Endo Pharmaceuticals Inc. v. Sandoz Inc.,* C.A. No. 08 - 534 (D. Del.); *Wyeth v. Sandoz Inc*., C.A. No. 08 - 317 (D. Del.); and *AstraZeneca Pharmaceuticals LP v. Sandoz Inc*., C.A. No. 07 - 807 (D. Del).

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT IN SUIT

18. On August 12, 2008, the '978 patent titled "Once Daily Dosage Forms of Trospium," was duly and legally issued by the United States Patent and Trademark Office ("PTO").

19. Allergan, Inc. is the holder of an approved New Drug Application ("NDA") No. 22-103 for SANCTURA XR® trospium chloride extended-release capsules. The '978 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") at the U.S. Food and Drug Administration ("FDA") in connection with SANCTURA XR®.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE '978 PATENT

20. Upon information and belief, Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 91-635 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, and sale throughout the United States, including Delaware, of generic trospium chloride extended-release capsules, containing 60 mg of trospium chloride ("the Sandoz Generic Product"). ANDA No. 91-635 specifically seeks FDA approval to market the Sandoz Generic Product prior to the expiration of the '978 patent.

21. Upon information and belief, the proposed generic product is indicated for oral administration once-a-day, and the proposed labeling includes instructions for once-a-day administration.

22. Upon information and belief, the ANDA purports that the proposed generic trospium chloride extended-release capsules are bioequivalent to SANCTURA XR®.

23. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Sandoz alleged in ANDA No. 91-635 that the claims of the '978 patent are not infringed by the commercial manufacture, use or sale throughout the United States including Delaware of the Sandoz Generic Product and/or that the claims of the '978 patent are invalid and unenforceable.

24. Plaintiffs received written notification of ANDA No. 91-635 and Sandoz's § 505(j)(2)(A)(vii)(IV) allegations from Sandoz on or about November 4, 2009 ("Paragraph IV letter").

25. The stated purpose of the Paragraph IV letter was to notify Plaintiffs that Sandoz had filed a certification with the FDA under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) in conjunction with ANDA No. 91-635 for approval to commercially manufacture and sell the Sandoz Generic Product. The Paragraph IV letter alleged that the '978 patent will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz Generic Product.

26. Attached to the Paragraph IV letter was a "Detailed Statement" of the factual and legal basis for Sandoz's opinion that the '978 patent was invalid, unenforceable and/or not infringed. The Detailed Statement alleged that the '978 patent was invalid and unenforceable.

27. Upon information and belief, if FDA approval is granted, Sandoz will manufacture, market, and/or sell throughout the United States, including in Delaware, the generic trospium chloride extended release capsules described in ANDA No. 91-635.

COUNT I

(Infringement of the '978 Patent Under 35 U.S.C. § 271(e)(2))

28. Paragraphs 1 to 27 are incorporated herein as set forth above.

29. Sandoz submitted ANDA No. 91-635 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Sandoz Generic Product. By submitting the application, Sandoz has committed an act of infringement with respect to the '978 patent under 35 U.S.C. § 271(e)(2).

30. Sandoz has stated its intention to manufacture, sell, and/or distribute the Sandoz Generic Product within the United States if the ANDA is approved by the FDA.

31. The commercial manufacture, use, sale, and/or offer for sale within the United States of the Sandoz Generic Product before the expiration of the '978 patent will constitute an act of infringement of the '978 patent either literally or under the doctrine of equivalents under 35 U.S.C. § 271(a).

COUNT II

(Declaratory Judgment of Infringement of the '978 Patent Under 35 U.S.C. § 271(a))

32. Paragraphs 1 to 31 are incorporated herein as set forth above.

33. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

34. There is a concrete, real, and immediate dispute between the parties creating an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

35. Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell within the United States, and/or import into the United States the Sandoz Generic Product prior to patent expiry.

36. Sandoz's actions, including, but not limited to, the filing of ANDA No. 91-635 indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

37. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of the Sandoz Generic Product prior to patent expiry will infringe the '978 patent.

38. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale within the United States, and/or importation within the United States of the Sandoz Generic Product prior to patent expiry will infringe the '978 patent.

INJUNCTIVE RELIEF

39. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

JURY DEMAND

Plaintiffs demand a jury trial for any issues so triable.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Sandoz has infringed the ’978 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 91-635 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale or sale within the United States and/or importation into the United States of the Sandoz Generic Product prior to patent expiry will constitute an act of infringement of the ’978 patent;

b. That a declaration be issued under 28 U.S.C. § 2201 that if Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, or any other persons acting or attempting to act in active concert or participation with Sandoz or acting on its behalf, engage in the commercial manufacture, use, offer for sale, or sale within the United States and/or importation into the United States of the Sandoz Generic Product prior to patent expiry, it will constitute an act of infringement of the ’978 patent;

c. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 91-635 shall be a date which is not earlier than the expiration date of the ’978 patent including any extensions;

d. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Sandoz or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Sandoz Generic Product or products not colorably different from the Sandoz Generic Product;

e. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. § 271(e)(4)(C), including by an accounting, as appropriate;

f. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

g. That this Court award such other and further relief as it may deem just and proper.

Dated: November 19, 2009

FISH & RICHARDSON P.C.

By: */s/ William J. Marsden, Jr.*

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