

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.

WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC.—
FLORIDA, and WATSON PHARMA, 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 Watson Pharmaceuticals, Inc., Watson Laboratories, Inc.—Florida, and Watson Pharma, Inc. (collectively “Watson Defendants” or “Watson”), 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 Dr., 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 Watson Pharmaceuticals, Inc. (“Watson Pharmaceuticals”) is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

10. On information and belief, Defendant Watson Laboratories, Inc.—Florida (“Watson Florida”) is a Florida corporation with a mailing address of 311 Bonnie Circle, Corona, California 92880.

11. On information and belief, Watson Florida was formerly known as Andrx Pharmaceuticals, Inc. Watson Florida is a wholly-owned subsidiary of Andrx Corp., a Delaware corporation that is a wholly-owned subsidiary of Defendant Watson Pharmaceuticals.

12. On information and belief, defendant Watson Pharma, Inc. (“Watson Pharma”) is a Delaware corporation having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

13. On information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals. Upon information and belief, Watson Pharma distributes pharmaceutical products throughout the United States including in this judicial district and is the distributor of drugs that Watson Florida manufactures or for which Watson Florida is the named applicant on approved Abbreviated New Drug Applications (“ANDA”).

14. The Watson Defendants work in concert with one another and with other direct and indirect subsidiaries of Watson Pharmaceuticals (“Watson subsidiaries”) to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

15. 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(b), and 28 U.S.C. §§ 2201 and 2202.

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

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

18. This Court has personal jurisdiction over Watson Pharma by virtue of its incorporation in Delaware.

19. As alleged herein, this Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Florida, and Watson Pharma, by virtue of the fact that, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement, or actively induced another to do so, that has led to foreseeable harm and injury to Plaintiffs, all Delaware corporations.

20. As further alleged herein, this Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Florida, and Watson Pharma because they, either directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware. These activities further demonstrate that Watson Pharmaceuticals, Watson Florida, and Watson Pharma have continuous and systematic contacts with Delaware.

21. Watson Pharmaceuticals, Watson Florida, and Watson Pharma are agents of each other and/or work in concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the generic trospium chloride extended release capsules described in ANDA No. 91-289 (defined below).

22. Watson Pharmaceuticals, through its own actions and the actions of one or more Watson subsidiaries, actively engages in a concerted effort to sell generic products throughout the United States, including Delaware. Upon information and belief, Watson Pharmaceuticals organizes its operation by division—Generic, Brand, and Distribution—and reports its financial results to investors by reference to the divisions. Watson Pharmaceuticals consolidates its financial results with the Watson subsidiaries in its Securities and Exchange Commission filings at least for 2007 to date and does not provide separate financial reports for each Watson subsidiary.

23. Upon information and belief, the Generic Division, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relies on contributions from Watson Pharmaceuticals, Watson Florida, and Watson Pharma, each of whom work in concert with the others to further the aims of the Generic Division. Upon information and belief, Watson Florida submits ANDAs and manufactures Generic Division products. These and other Generic Division products are marketed and sold by Watson Pharma.

24. Upon information and belief, Watson Pharmaceuticals, Watson Florida, and Watson Pharma share common employees, officers, and directors. Upon information and belief, Watson Pharmaceuticals and Watson Pharma share common employees, officers, and directors.

Upon information and belief, Watson Florida and Watson Pharma share common employees, officers, and directors.

25. Further demonstrating the close interconnections between the Defendant Watson entities, on its website, Watson Pharmaceuticals identifies the addresses of a Watson Florida facility (4955 Orange Drive, Davie, Florida) and a Watson Pharma facility (360 Mount Kemble Avenue, Morristown, New Jersey) as two of its own locations. Conversely, Watson Florida provided Watson Pharmaceuticals' Corona, California address as its mailing address on its annual report filed with the Secretary of State in Florida on January 27, 2009. Watson Pharmaceuticals also issues press releases on behalf of its subsidiaries, including Watson Florida, and often claims actions of its subsidiaries as its own.

26. Watson Pharmaceuticals' web site states that its Generic Division has a portfolio of 150 pharmaceutical products, which includes Watson Florida products, and states that the Generic Division filed 13 new ANDAs and launched 11 new products. And in its 2008 Annual Report, Watson Pharmaceuticals explains that "We sell our generic prescription products primarily under the 'Watson Laboratories' and 'Watson Pharma' labels." The ANDAs for the majority of these products in Watson Pharmaceuticals' portfolio are nominally in the name of Watson Florida and another subsidiary, Watson Laboratories Inc.—Nevada.

27. Upon information and belief, Watson Florida is the named applicant in ANDAs for numerous generic drugs ("Watson Florida ANDAs"), including many that are actively being sold and used in the United States. Drugs manufactured under these ANDAs are sold in Delaware and elsewhere.

28. Upon information and belief, Watson Florida also manufactures at least some of the drugs for which it is the nominal ANDA applicant.

29. Upon information and belief, Watson Pharma, a Delaware entity, is the distributor of drugs for which Watson Florida is the named applicant in the FDA's Approved Drug Product List. Watson Pharma, acting as the agent of Watson Florida and Watson Pharmaceuticals, markets and sells many, if not all, of these drugs in Delaware. Upon information and belief, Watson Florida and Watson Pharma are parties to one or more contractual agreements for distributing drugs made under Watson Florida ANDAs. Upon information and belief, these agreements are less than arms-length.

30. Watson Pharma is licensed to do business in Delaware and, upon information and belief, has sales personnel assigned to cover Delaware for the purpose of marketing and selling Generic Division Products, including Watson Florida products.

31. For example, various drugs for which Watson Florida is the named ANDA applicant are distributed by Watson Pharma and are available at various retail pharmacies in Delaware including Walgreens/Happy Harry's and Rite Aid. Upon information and belief, Watson Pharmaceuticals and/or Watson Florida realizes revenue from the distribution of Watson Florida drugs by Watson Pharma, where such distribution results in sales of the drugs in Delaware or to persons in Delaware.

32. Besides using Watson Pharma's channels to distribute drugs in Delaware and elsewhere, Watson Florida has other contacts with Delaware. In particular, Watson Florida purposefully availed itself of Delaware's courts by joining as a plaintiff with other parties filing a complaint for patent infringement in the District of Delaware on January 15, 2009 against Lupin, another generic manufacturer. *Sciele Pharma Inc., et al v. Lupin Ltd.*, Case no. 1:09-cv-00037-JJF, Complaint (Jan. 15, 2009).

33. In addition, upon information and belief, Watson Florida is a wholly owned subsidiary of Andrx Corp., a Delaware corporation, and several Watson Florida drugs are still manufactured and sold under the Andrx trademark.

34. Upon information and belief, each of Watson Pharmaceuticals, Watson Florida, and Watson Pharma, as part of Watson Pharmaceuticals' Generic Division, will manufacture, market, and/or sell within the United States the generic trospium chloride extended release capsules described in ANDA No. 91-289 if FDA approval is granted.

35. If ANDA No. 91-289 is approved, the generic trospium chloride extended release capsules which are charged with infringing the patent-in-suit, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing and dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

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

THE PATENT IN SUIT

37. 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").

38. 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

39. As discussed in further detail below, Watson filed ANDA No. 91-289 seeking to market a generic drug that references SANCTURA XR[®] and is allegedly bioequivalent to SANCTURA XR[®]. SANCTURA XR[®] is protected by the '978 patent.

40. The filing of ANDA No. 91-289 evidences an intent by Watson to place its product into every market where SANCTURA XR[®] is currently found, including the District of Delaware and thereby cause tortious injury to Plaintiffs' rights which are secured by the '978 patent.

41. Upon information and belief, Watson submitted Abbreviated New Drug Application ("ANDA") No. 91-289 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) in the name of Watson Florida. 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 Watson Generic Product"). ANDA No. 91-289 specifically seeks FDA approval to market the Watson Generic Product prior to the expiration of the '978 patent.

42. 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.

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

44. Upon information and belief, Watson Pharmaceuticals played an active role in the submission of ANDAs for its Generic Division, including in the submission of ANDA No. 91-289.

45. Upon information and belief, the Watson Pharmaceuticals Board of Directors' Regulatory Compliance Committee has oversight responsibility for compliance with legal and regulatory requirements for "any and all laws or regulations" relating to "the import, export, development, manufacturing, distribution and sale of the Company's products (including the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder)," which includes the preparation and filing of ANDAs. Thus, upon information and belief, this committee of Watson Pharmaceuticals board members has ultimate responsibility for the filing of ANDA No. 91-289.

46. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Watson alleged in ANDA No. 91-289 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 Watson Generic Product and/or that the claims of the '978 patent are invalid and unenforceable.

47. Plaintiffs received written notification of ANDA No. 91-289 and Watson's §505(j)(2)(A)(vii)(IV) allegations from Watson on or about June 2, 2009 ("Paragraph IV letter"). Such Paragraph IV letter was signed by Janet Vaughn, Director, Regulatory Affairs, Watson Laboratories, Inc.—Florida. Upon information and belief, Janet Vaughn has also identified herself as Director, Regulatory Affairs at Watson Pharmaceuticals.

48. The stated purpose of the Paragraph IV letter was to notify Plaintiffs that Defendants had filed a certification with the FDA under 21 C.F.R. § 314.95(c)(1) in conjunction with ANDA No. 91-289 for approval, *inter alia*, to commercially manufacture and sell generic versions of SANCTURA XR[®] trospium chloride extended release capsules. The Paragraph IV

letter alleged that the '978 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the Watson Generic Product.

49. The Paragraph IV letter failed to comply with the requirements of 21 U.S.C. § 355(j)(2)(B)(iv)(II), *inter alia*, because it contained very limited information about the generic formulation for which Defendants filed ANDA No. 91-289.

50. Since receiving the Paragraph IV letter, Plaintiffs have attempted to obtain information on the Watson Generic Product and to procure a copy of ANDA No. 91-289 from Watson. Watson has yet to provide the ANDA for Plaintiffs' review.

COUNT I

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

51. Paragraphs 1 to 50 are incorporated herein as set forth above.

52. The Watson Defendants submitted ANDA No. 91-289 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 Watson Generic Product. By submitting the application, the Defendants have committed an act of infringement with respect to the '978 patent under 35 U.S.C. § 271(e)(2).

53. The Watson Defendants, individually and collectively, will be involved in the manufacture, sale, and/or distribution of the Watson Generic Product within the United States if the ANDA is approved by the FDA.

54. The commercial manufacture, use, sale, and/or offer for sale within the United States of the product that is the subject of ANDA No. 91-289 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, and either by direct infringement under 35 U.S.C. § 271(a) and/or indirect infringement under 35 U.S.C. §§ 271(b).

COUNT II
(Infringement of the '978 Patent Under 35 U.S.C. § 271(b))

55. Paragraphs 1 to 54 are incorporated herein as set forth above.

56. Upon information and belief, Watson Pharmaceuticals and Watson Pharma, individually and collectively, are involved in plans for the marketing and distribution of the Watson Generic Product and will be involved in marketing and distributing the Watson Generic Product if and when approved by the FDA.

57. Watson Pharmaceuticals and Watson Pharma, individually and collectively, actively induced Watson Florida to submit ANDA No. 91-289 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 Watson Generic Product and are actively inducing and planning to actively induce Watson Florida to commit the acts that will constitute direct infringement upon approval of the ANDA.

58. By actively inducing infringement, Watson Pharmaceuticals and Watson Pharma have committed an act of indirect infringement with respect to the '978 patent under 35 U.S.C. § 271(b).

59. Any commercial manufacture, use, offer for sale within the United States, and/or importation into the United States of the Watson Generic Products prior to patent expiry will infringe the '978 patent.

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

60. Paragraphs 1 to 59 are incorporated herein as set forth above.

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

62. 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.

63. Defendants have 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 Watson Generic Product prior to patent expiry.

64. Defendants have made, and will continue to make, substantial preparation in the United States to actively induce the manufacture, use, sale, offers to sell, and importation of the Watson Generic Product prior to patent expiry.

65. Defendants' actions, including, but not limited to, the filing of ANDA No. 91-289 indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

66. Upon information and belief, the commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Product prior to patent expiry, and the active inducement of such activities will infringe the '978 patent.

67. 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 Watson Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, sale within the United States, and/or importation into the United States of the Watson Generic Product prior to patent expiry by any or all Defendants, will infringe the '978 patent.

INJUNCTIVE RELIEF

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

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

70. Plaintiffs will be irreparably harmed by Watson Pharma'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 the Watson Defendants, individually and/or collectively, have infringed the '978 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 91-289 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale within the United States, and/or importation into the United States of the Watson Generic Product prior to patent expiry will constitute an act of infringement of the '978 patent;

b. That judgment be entered that Watson Pharmaceuticals has infringed the '978 patent under 35 U.S.C. § 271(b) by inducing Watson Florida to submit ANDA No. 91-289 under

the Federal Food, Drug, and Cosmetic Act and to commit infringing acts upon approval of the ANDA, and that the commercial manufacture, use, offer for sale, sale within the United States, and/or importation into the United States of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '978 patent;

c. That judgment be entered that Watson Pharma has infringed the '978 patent under 35 U.S.C. § 271(b) by inducing Watson Florida to submit ANDA No. 91-289 under the Federal Food, Drug, and Cosmetic Act and to commit infringing acts upon approval of the ANDA, and that the commercial manufacture, use, offer for sale, sale within the United States, and/or importation into the United States of the Watson Generic Product prior to patent expiry will constitute an act of infringement of the '978 patent;

d. That judgment be entered that commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Watson Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, sale within the United States, and/or importation into the United States of the Watson Generic Product prior to patent expiry by any or all Defendants, will infringe the '978 patent.

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

f. 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. 91-289 shall be a date which is not earlier than the expiration date of the '978 patent including any extensions;

g. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Watson Pharmaceuticals, Watson Florida, Watson Pharma, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their 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 Watson Generic Product or products not colorably different from the Watson Generic Product;

h. 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;

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

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

Dated: July 13, 2009

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