

REDACTED

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.

PADDOCK LABORATORIES, INC. and
[REDACTED]

Defendants.

C.A. No. 10-851-GMS

JURY TRIAL REQUESTED

**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT AGAINST
PADDOCK LABORATORIES, INC. AND [REDACTED]**

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

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 7,781,448 ("the '448 patent") and 7,781,449 ("the '449 patent") under 35 U.S.C. § 271(a), (b), (e)(2), and (g).

THE PARTIES

2. 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.

3. 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.

4. 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.

5. 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 the ’448 and ’449 patents, attached hereto as Exhibit A and B, respectively.

6. Allergan markets SANCTURA XR[®] in the United States. SANCTURA XR[®] is a prescription drug approved for treating overactive bladder and is covered by the ’448 and ’449 patents.

7. 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 ’448 and ’449 patents.

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 ’448 and ’449 patents.

9. Plaintiffs, individually and collectively, have been and will be injured by the acts complained of herein.

10. On information and belief, Defendant Paddock Laboratories, Inc. (“Paddock”) is a corporation organized and existing under the laws of the State of Minnesota, with headquarters at 3940 Quebec Ave. North, Minneapolis, MN 55427.

11. On information and belief, Paddock is in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial district.

12. On information and belief, Defendant [REDACTED]

[REDACTED]

[REDACTED]

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1 *et seq*, and Title 28, Sections 2201 and 2202.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

15. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

16. 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 '448 and '449 patents.

17. The Court has personal jurisdiction over Paddock by virtue of its systematic and continuous contacts with this jurisdiction.

18. The Court also has personal jurisdiction over Defendants Paddock and [REDACTED] 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.

19. Upon information and belief, Paddock and Sidmak, acting in concert, submitted Abbreviated New Drug Application (“ANDA”) No. 20-1291 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) under the name Paddock Laboratories, Inc.

20. ANDA No. 20-1291 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 Paddock Generic Product”).

21. ANDA No. 20-1291 specifically seeks FDA approval to market the Paddock Generic Product prior to the expiration of the ’448 and ’449 patents.

22. The filing of ANDA No. 20-1291 evidences an intent by Defendants to place their 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 ’448 and ’449 patents.

23. Paddock, either directly or through an agent, 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.

24. Paddock, through its own actions and the actions of one or more Paddock agents, actively engages in a concerted effort to sell generic products throughout the United States, including Delaware.

25. Upon information and belief, Paddock realizes revenue from the distribution of Paddock drugs, where such distribution results in sales of the drugs in Delaware or to persons in Delaware.

26. On information and belief, Paddock has derived substantial revenue from sales of pharmaceutical products in Delaware, including sales of over \$950,000 in 2009.

27. On information and belief, Paddock has entered into contracts with and/or purchased goods or services from companies located in Delaware.

28. On information and belief, Paddock has entered into long term contracts with companies located in Delaware.

29. Paddock has previously availed itself of this forum for the purposes of litigating its patent disputes. Paddock's contacts with this jurisdiction include its ongoing litigation in this court, in the matter of *Allergan, Inc., et al. v. Paddock Laboratories, Inc.*, 10-501-GMS (D. Del), which also relates to ANDA No. 20-1291, and in which Paddock has filed counterclaims.

30. On information and belief, Defendants [REDACTED]
[REDACTED]

31. On information and belief, Defendant [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

32. On information and belief, Defendants Paddock and [REDACTED]
[REDACTED]

33. On information and belief, Defendants Paddock and [REDACTED]
[REDACTED]

34. On information and belief, [REDACTED]

[REDACTED]

[REDACTED]

35. On information and belief, [REDACTED]

[REDACTED]

36. If ANDA No. 20-1291 is approved, the Paddock Generic Product which is charged with infringing the patents-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.

THE PATENTS IN SUIT

37. On August 24, 2010, the '448 patent titled "Once Daily Dosage Forms of Trospium," was duly and legally issued by the United States Patent and Trademark Office ("PTO").

38. On August 24, 2010, the '449 patent titled "Trospium Chloride Treatment Method," was duly and legally issued by the PTO.

**ACTS GIVING RISE TO THIS ACTION FOR
INFRINGEMENT OF THE '448 AND '449 PATENTS**

39. Allergan, Inc. is the holder of an approved New Drug Application ("NDA") No. 22-103 for SANCTURA XR[®] trospium chloride extended-release capsules. The '448 and '449 patents are 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[®].

40. On or about September 14, 2010, Plaintiffs Allergan and Supernus received a letter from the law firm of Merchant & Gould stated to be written on behalf of Paddock. (“Paragraph IV letter”). The stated purpose of the Paragraph IV letter was to provide notification of the filing of ANDA No. 20-1291 with a certification under §505(j)(2)(A)(vii)(IV). The Paragraph IV letter stated, *inter alia*, that Paddock had applied for approval to commercially manufacture and sell generic versions of SANCTURA XR[®] trospium chloride extended release capsules (“Paddock Generic Product”). The Paragraph IV letter alleged that the ’448 and ’449 patents are invalid and/or will not be infringed by the commercial manufacture, use or sale of the Paddock Generic Product.

41. The Paddock Generic Product is indicated for oral administration once-a-day, and the proposed labeling includes instructions for once-a-day administration.

42. The ANDA purports that the Paddock Generic Product is bioequivalent to SANCTURA XR[®].

COUNT I
(Infringement of the ’448 Patent Under 35 U.S.C. § 271(e)(2))

43. Paragraphs 1 to 42 are incorporated herein as set forth above.

44. Paddock submitted ANDA No. 20-1291 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Paddock Generic Product. By submitting the application, Paddock has committed an act of infringement with respect to the ’448 patent under 35 U.S.C. § 271(e)(2).

45. Paddock will be involved in the manufacture, sale, and/or distribution of the Paddock Generic Product within the United States if ANDA No. 20-1291 is approved by the FDA.

46. Paddock and [REDACTED]

[REDACTED]

47. [REDACTED]

[REDACTED]

48. The commercial manufacture, use, sale, offer for sale within the United States and/or importation into the United States of the product that is the subject of ANDA No. 20-1291 before the expiration of the '448 patent will constitute an act of infringement of the '448 patent either literally or under the doctrine of equivalents, and either directly or indirectly under 35 U.S.C. § 271(a), (b), and/or (g).

COUNT II
(Infringement of the '449 Patent Under 35 U.S.C. § 271(e)(2))

49. Paragraphs 1 to 48 are incorporated herein as set forth above.

50. Paddock submitted ANDA No. 20-1291 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Paddock Generic Product. By submitting the application, Paddock has committed an act of infringement with respect to the '449 patent under 35 U.S.C. § 271(e)(2).

51. Paddock will be involved in the manufacture, sale, and/or distribution of the Paddock Generic Product within the United States if ANDA No. 20-1291 is approved by the FDA.

52. Paddock and [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

53. [REDACTED]

[REDACTED]
[REDACTED]

54. The commercial manufacture, use, sale, offer for sale within the United States and/or importation into the United States of the product that is the subject of ANDA No. 20-1291 before the expiration of the '449 patent will constitute an act of infringement of the '449 patent either literally or under the doctrine of equivalents, and either directly or indirectly under 35 U.S.C. § 271(a) and/or (b).

COUNT III
(Infringement of the '448 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, Defendant [REDACTED]

[REDACTED]
[REDACTED]

57. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

58. [REDACTED]

[REDACTED]

59. Any commercial manufacture, use, offer for sale within the United States, and/or importation into the United States of the Paddock Generic Products prior to patent expiry will infringe the '448 patent.

COUNT IV
(Infringement of the '449 Patent Under 35 U.S.C. § 271(b))

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

61. Upon information and belief, [REDACTED]

[REDACTED]

[REDACTED]

62. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

63. [REDACTED]

[REDACTED]

64. Any commercial manufacture, use, offer for sale within the United States, and/or importation into the United States of the Paddock Generic Products prior to patent expiry will infringe the '449 patent.

COUNT V
**(Declaratory Judgment of Infringement of the '448 Patent
Under 35 U.S.C. § 271(a), (b), and (g))**

65. Paragraphs 1 to 64 are incorporated herein as set forth above.

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

67. 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.

68. 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 Paddock Generic Product prior to patent expiry.

69. 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 Paddock Generic Product prior to patent expiry.

70. Defendants' actions, including, but not limited to, the filing of ANDA No. 20-1291 indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

71. Upon information and belief, the commercial manufacture, use, offer for sale, and/or importation of the Paddock Generic Product prior to patent expiry, and the active inducement of such activities will infringe the '448 patent.

72. 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 Paddock 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 Paddock Generic Product prior to patent expiry by any or all Defendants, will infringe the '448 patent, either literally or under the doctrine of equivalents, and either directly or indirectly under 35 U.S.C. § 271(a), (b), and/or (g).

COUNT VI
**(Declaratory Judgment of Infringement of the '449 Patent
Under 35 U.S.C. § 271(a) and (b))**

73. Paragraphs 1 to 72 are incorporated herein as set forth above.

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

75. 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.

76. 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 Paddock Generic Product prior to patent expiry.

77. 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 Paddock Generic Product prior to patent expiry.

78. Defendants' actions, including, but not limited to, the filing of ANDA No. 20-1291 indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

79. Upon information and belief, the commercial manufacture, use, offer for sale, and/or importation of the Paddock Generic Product prior to patent expiry, and the active inducement of such activities will infringe the '449 patent.

80. 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 Paddock 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 Paddock Generic Product prior to patent expiry by any or all Defendants, will infringe the '449 patent, either literally or under the doctrine of equivalents, and either directly or indirectly under 35 U.S.C. § 271(a) and/or (b).

INJUNCTIVE RELIEF

81. Plaintiffs will be irreparably harmed by Defendants' 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 Paddock and [REDACTED] individually and/or collectively, have infringed the '448 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 20-1291 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 Paddock Generic Product prior to patent expiry will constitute an act of infringement of the '448 patent;

b. That judgment be entered that [REDACTED] has infringed the '448 patent under 35 U.S.C. § 271(b) by inducing Paddock to submit ANDA No. 20-1291 under the Federal Food, Drug, and Cosmetic Act and to commit infringing acts upon approval of ANDA No. 20-1291, and that the commercial manufacture, use, offer for sale, sale within the United States, and/or importation into the United States of the Paddock Generic Products prior to patent expiry will constitute an act of infringement of the '448 patent;

c. That judgment be entered that commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Paddock 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 Paddock Generic Product prior to patent expiry by any or all Defendants, will infringe the '448 patent.

d. That a declaration be issued under 28 U.S.C. § 2201 that if Paddock, and/or [REDACTED] 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 Paddock Generic Product prior to patent expiry, it will constitute an act of infringement of the '448 patent;

e. 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. 20-1291 shall be a date which is not earlier than the expiration date of the '448 patent including any extensions;

f. That judgment be entered that Paddock and [REDACTED] individually and/or collectively, have infringed the '449 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 20-1291 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 Paddock Generic Product prior to patent expiry will constitute an act of infringement of the '449 patent;

g. That judgment be entered that [REDACTED] has infringed the '449 patent under 35 U.S.C. § 271(b) by inducing Paddock to submit ANDA No. 20-1291 under the Federal Food, Drug, and Cosmetic Act and to commit infringing acts upon approval of ANDA No. 20-1291, and that the commercial manufacture, use, offer for sale, sale within the United States, and/or importation into the United States of the Paddock Generic Products prior to patent expiry will constitute an act of infringement of the '449 patent;

h. That judgment be entered that commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Paddock 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 Paddock Generic Product prior to patent expiry by any or all Defendants, will infringe the '449 patent.

i. That a declaration be issued under 28 U.S.C. § 2201 that if Paddock, and/or [REDACTED] 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 Paddock Generic Product prior to patent expiry, it will constitute an act of infringement of the '449 patent;

j. 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. 20-1291 shall be a date which is not earlier than the expiration date of the '449 patent including any extensions;

k. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Paddock, [REDACTED] 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 Paddock Generic Product or products not colorably different from the Paddock Generic Product;

l. 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;

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

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

Dated: October 13, 2010

FISH & RICHARDSON P.C.

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