UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC, *Plaintiff*, v. WATSON LABORATORIES, INC., and ACTAVIS, INC. *Defendants*.	)	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius") brings this action for patent infringement against Defendants Watson Laboratories, Inc. and Actavis, Inc. (collectively "Watson").

1. This is an action by Fresenius against Watson for infringement of United States Patent Nos. 5,714,520 ("the '520 patent"), 5,731,355 ("the '355 patent"), 5,731,356 ("the '356 patent") and 5,908,869 ("the '869 patent"). This action arises out of Watson's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of Diprivan®, an innovative intravenously administered sedative and anesthetic, prior to the expiration of the '520, '355, '356 and '869 patents.

THE PARTIES

Fresenius

2. Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius Kabi USA, LLC was formerly known as APP Pharmaceuticals, LLC ("APP").

Watson

3. On information and belief, Defendant Actavis, Inc. ("Actavis"), known as Watson Pharmaceuticals, Inc. until on or around January 24, 2013, is a Nevada corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. Upon information and belief, Defendant Watson Laboratories, Inc. ("Watson Labs") is a Delaware corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054..

5. On information and belief, Watson Labs is a wholly-owned subsidiary of Actavis, and is controlled by Actavis.

6. On information and belief, both Watson Labs and Actavis submitted, collaborated and/or acted in concert in the preparation or submission of ANDA Number 205307 ("Watson ANDA").

JURISDICTION AND VENUE

Subject Matter Jurisdiction

7. This action for patent infringement arises under 35 U.S.C. § 271.

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

Personal Jurisdiction Over Watson

9. Upon information and belief, this Court has personal jurisdiction over Watson Labs because they are incorporated within this district.

10. Further, this Court has jurisdiction over both Actavis and Watson Labs, at least because both have engaged in continuous and systematic contacts with Delaware and/or purposefully availed themselves of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Watson's pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

11. Additionally, Watson Labs has been sued for patent infringement in this district and not only did not contest personal jurisdiction but also purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this court. *See Merck & Co Inc. v. Watson Laboratories Inc.*, C.A. No. 05-658.

12. As well, Actavis, as Watson Pharmaceuticals Inc., has been sued for patent infringement in this district and has not contested personal jurisdiction. *See, e.g.*, *Avanir*, C.A. No. 12-258; *Bayer*, C.A. No. 12-1726. Actavis, as Watson Pharmaceuticals, further has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in lawsuits filed in this Court. *See, e.g., Sunovion Pharmaceuticals Inc. v. Watson Pharmaceuticals Inc*., C.A. No. 12-993.

Venue

13. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and 1400(b).

BACKGROUND

The Patents-in-Suit

United States Patent No. 5,714,520

14. The ‘520 patent, entitled “Propofol Compostion [sic] Containing Edetate,” was duly and lawfully issued on February 3, 1998 to inventors Christopher Buchan Jones and John Henry Platt. The named inventors assigned the ‘520 patent to Zeneca Ltd. (“Zeneca”). The ‘520 patent was subsequently assigned to APP Pharmaceuticals, LLC, which later changed its name to Fresenius Kabi USA, LLC. Accordingly, Fresenius is the owner of all rights, title and interest in the ‘520 patent. The ‘520 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as “The Orange Book” (“Orange Book”) with respect to Diprivan®. The ‘520 patent will expire on September 22, 2015. A true and accurate copy of the ‘520 patent is attached hereto as Exhibit A.

United States Patent No. 5,731,355

15. The ‘355 patent, entitled “Pharmaceutical Compositions of Propofol and Edetate,” was duly and lawfully issued on March 24, 1998 to inventors Christopher Buchan Jones and John Henry Platt. The named inventors assigned the ‘355 patent to Zeneca. The ‘355 patent was subsequently assigned to APP, and Fresenius is the owner of all rights, title and interest in the ‘355 patent. The ‘355 patent is listed in the Orange Book with respect to Diprivan® and will expire on September 22, 2015. A true and accurate copy of the ‘355 patent is attached hereto as Exhibit B.

United States Patent No. 5,731,356

16. The ‘356 patent, entitled “Pharmaceutical Compositions of Propofol and Edetate,” was duly and lawfully issued on March 24, 1998 to inventors Christopher Buchan Jones and John Henry Platt. The named inventors assigned the ‘356 patent to Zeneca. The ‘356 patent was subsequently assigned to APP, and Fresenius is the owner of all rights, title and interest in the ‘356 patent. The ‘356 patent is listed in the Orange Book with respect to Diprivan® and will

expire on September 22, 2015. A true and accurate copy of the '356 patent is attached hereto as Exhibit C.

United States Patent No. 5,908,869

17. The '869 patent, entitled "Propofol Composition Containing Edetate," was duly and lawfully issued on June 1, 1999 to inventors Christopher Buchan Jones and John Henry Platt. The named inventors assigned the '869 patent to Zeneca. The '869 patent was subsequently assigned to APP, and Fresenius is the owner of all rights, title and interest in the '869 patent. The '869 patent is listed in the Orange Book with respect to Diprivan® and will expire on September 22, 2015. A true and accurate copy of the '869 patent is attached hereto as Exhibit D.

The Diprivan® Drug Product

18. Fresenius currently sells, promotes, distributes and markets Diprivan® (propofol) injectable emulsion in the United States.

19. Diprivan® is indicated, generally speaking, for the induction and maintenance of general anesthesia and sedation in certain patient populations.

20. Fresenius holds an approved New Drug Application ("NDA") No. 19627 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection with the Diprivan® 1% (propofol) injectable emulsion product containing 10 mg propofol per 1 ml of emulsion.

The Watson ANDA

21. Watson filed with the FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10mg propofol per 1 ml of emulsion formulation, in 20 mL, 50 mL and 100

mL vials, that Watson asserts is a generic copy of Diprivan® ("Watson's generic Diprivan® products") prior to the expiration of the '520, '355, '356 and '869 patents.

22. The FDA assigned the Watson ANDA the number 205307.

23. Watson also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '520, '355, '356 and '869 patents are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Watson's generic Diprivan® products ("Watson's Paragraph IV Certification").

24. By letter dated April 24, 2013, Watson notified Fresenius that it had filed an ANDA seeking approval to market Watson's generic Diprivan® products prior to the expiration of the '520, '355, '356 and '869 patents ("Watson Notice Letter").

25. This action is being commenced before the expiration of forty-five days from the date of receipt of the Watson Notice Letter.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 5,714,520 BY WATSON

26. The allegations of paragraphs 1-24 are realleged and incorporated herein by reference.

27. The use of Watson's generic Diprivan® products is covered by one or more claims of the '520 patent.

28. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Watson's generic Diprivan® products would infringe one or more claims of the '520 patent.

29. Watson has infringed the '520 patent by submitting the Watson ANDA to the FDA seeking approval to market Watson's generic Diprivan® products containing propofol before the expiration of the '520 patent.

30. Upon information and belief, Defendants Watson Labs and Actavis acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted and/or directed the submission of the Watson ANDA to the FDA.

31. Defendants Watson Labs and Actavis induced the infringement of the '520 patent by actively and knowingly aiding and abetting the preparation and submission of the Watson ANDA and in the preparation to sell Watson's generic Diprivan® products in the United States.

32. Watson was aware of the '520 patent when engaging in these knowing and purposeful activities and was aware that filing the Watson ANDA with Watson's Paragraph IV Certification with respect to the '520 patent constituted an act of infringement of the '520 patent.

33. Use of Watson's generic Diprivan® products in accordance with and as directed by Watson's proposed labeling for that product would infringe one or more claims of the '520 patent.

34. Upon information and belief, Watson intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Watson's generic Diprivan® products with its proposed labeling immediately and imminently upon approval of the Watson ANDA.

35. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '520 patent when the Watson ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

36. Upon information and belief, Watson knows that Watson's generic Diprivan® products and the proposed labeling for Watson's generic Diprivan® products is especially made or adapted for use in infringing the '520 patent and that Watson's generic Diprivan® products

and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '520 patent immediately and imminently upon approval of the Watson ANDA.

37. The foregoing actions by Watson constitute and/or would constitute infringement of the '520 patent, active inducement of infringement of the '520 patent and/or contribution to the infringement by others of the '520 patent.

38. Upon information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringing the '520 patent, actively inducing infringement of the '520 patent and/or contributing to the infringement by others of the '520 patent.

39. Fresenius will be substantially and irreparably harmed by Watson's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Watson is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Watson's generic Diprivan® products.

40. Watson's activities render this case an exceptional one, and Fresenius is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 5,731,355 BY WATSON

41. The allegations of paragraphs 1-24 are realleged and incorporated herein by reference.

42. The use of Watson's generic Diprivan® products is covered by one or more claims of the '355 patent.

43. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Watson's generic Diprivan® products would infringe one or more claims of the '355 patent.

44. Watson has infringed the '355 patent by submitting the Watson ANDA to the FDA seeking approval to market Watson's generic Diprivan® products containing propofol before the expiration of the '355 patent.

45. Upon information and belief, Defendants Watson Labs and Actavis acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted and/or directed the submission of the Watson ANDA to the FDA.

46. Defendants Watson Labs and Actavis induced the infringement of the '355 patent by actively and knowingly aiding and abetting the preparation and submission of the Watson ANDA and in the preparation to sell Watson's generic Diprivan® products in the United States.

47. Watson was aware of the '355 patent when engaging in these knowing and purposeful activities and was aware that filing the Watson ANDA with Watson's Paragraph IV Certification with respect to the '355 patent constituted an act of infringement of the '355 patent.

48. Use of Watson's generic Diprivan® products in accordance with and as directed by Watson's proposed labeling for that product would infringe one or more claims of the '355 patent.

49. Upon information and belief, Watson intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Watson's generic Diprivan® products with its proposed labeling immediately and imminently upon approval of the Watson ANDA.

50. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '355 patent when the Watson ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

51. Upon information and belief, Watson knows that Watson's generic Diprivan® products and the proposed labeling for Watson's generic Diprivan® products is especially made or adapted for use in infringing the '355 patent and that Watson's generic Diprivan® products and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '355 patent immediately and imminently upon approval of the Watson ANDA.

52. The foregoing actions by Watson constitute and/or would constitute infringement of the '355 patent, active inducement of infringement of the '355 patent and/or contribution to the infringement by others of the '355 patent.

53. Upon information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringing the '355 patent, actively inducing infringement of the '355 patent and/or contributing to the infringement by others of the '355 patent.

54. Fresenius will be substantially and irreparably harmed by Watson's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Watson is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Watson's generic Diprivan® products.

55. Watson's activities render this case an exceptional one, and Fresenius is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 5,731,356 BY WATSON

56. The allegations of paragraphs 1-24 are realleged and incorporated herein by reference.

57. The use of Watson's generic Diprivan® products is covered by one or more claims of the '356 patent.

58. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Watson's generic Diprivan® products would infringe one or more claims of the '356 patent.

59. Watson has infringed the '356 patent by submitting the Watson ANDA to the FDA seeking approval to market Watson's generic Diprivan® products containing propofol before the expiration of the '356 patent.

60. Upon information and belief, Defendants Watson Labs and Actavis acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted and/or directed the submission of the Watson ANDA to the FDA.

61. Defendants Watson Labs and Actavis induced the infringement of the '356 patent by actively and knowingly aiding and abetting the preparation and submission of the Watson ANDA and in the preparation to sell Watson's generic Diprivan® products in the United States.

62. Watson was aware of the '356 patent when engaging in these knowing and purposeful activities and was aware that filing the Watson ANDA with Watson's Paragraph IV Certification with respect to the '356 patent constituted an act of infringement of the '356 patent.

63. Use of Watson's generic Diprivan® products in accordance with and as directed by Watson's proposed labeling for that product would infringe one or more claims of the '356 patent.

64. Upon information and belief, Watson intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Watson's generic Diprivan® products with its proposed labeling immediately and imminently upon approval of the Watson ANDA.

65. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '356 patent when the Watson ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

66. Upon information and belief, Watson knows that Watson's generic Diprivan® products and the proposed labeling for Watson's generic Diprivan® products is especially made or adapted for use in infringing the '356 patent and that Watson's generic Diprivan® products and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '356 patent immediately and imminently upon approval of the Watson ANDA.

67. The foregoing actions by Watson constitute and/or would constitute infringement of the '356 patent, active inducement of infringement of the '356 patent and/or contribution to the infringement by others of the '356 patent.

68. Upon information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringing the '356 patent, actively inducing infringement of the '356 patent and/or contributing to the infringement by others of the '356 patent.

69. Fresenius will be substantially and irreparably harmed by Watson's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Watson is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Watson's generic Diprivan® products.

70. Watson's activities render this case an exceptional one, and Fresenius is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 5,908,869 BY WATSON

71. The allegations of paragraphs 1-24 are realleged and incorporated herein by reference.

72. The use of Watson's generic Diprivan® products is covered by one or more claims of the '869 patent.

73. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Watson's generic Diprivan® products would infringe one or more claims of the '869 patent.

74. Watson has infringed the '869 patent by submitting the Watson ANDA to the FDA seeking approval to market Watson's generic Diprivan® products containing propofol before the expiration of the '869 patent.

75. Upon information and belief, Defendants Watson Labs and Actavis acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted and/or directed the submission of the Watson ANDA to the FDA.

76. Defendants Watson Labs and Actavis induced the infringement of the '869 patent by actively and knowingly aiding and abetting the preparation and submission of the Watson ANDA and in the preparation to sell Watson's generic Diprivan® products in the United States.

77. Watson was aware of the '869 patent when engaging in these knowing and purposeful activities and was aware that filing the Watson ANDA with Watson's Paragraph IV Certification with respect to the '869 patent constituted an act of infringement of the '869 patent.

78. Use of Watson's generic Diprivan® products in accordance with and as directed by Watson's proposed labeling for that product would infringe one or more claims of the '869 patent.

79. Upon information and belief, Watson intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Watson's generic Diprivan® products with its proposed labeling immediately and imminently upon approval of the Watson ANDA.

80. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '869 patent when the Watson ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

81. Upon information and belief, Watson knows that Watson's generic Diprivan® products and the proposed labeling for Watson's generic Diprivan® products is especially made or adapted for use in infringing the '869 patent and that Watson's generic Diprivan® products and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '869 patent immediately and imminently upon approval of the Watson ANDA.

82. The foregoing actions by Watson constitute and/or would constitute infringement of the '869 patent, active inducement of infringement of the '869 patent and/or contribution to the infringement by others of the '869 patent.

83. Upon information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringing the '869 patent, actively inducing infringement of the '869 patent and/or contributing to the infringement by others of the '869 patent.

84. Fresenius will be substantially and irreparably harmed by Watson's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Watson is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Watson's generic Diprivan® products.

85. Watson's activities render this case an exceptional one, and Fresenius is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. A judgment that Watson's submission of the Watson ANDA No. 205307 infringes one or more claims of the '520, '355, '356 and '869 patents and that the making, using, offering to sell, or selling in the United States, or importing into the United States of Watson's generic Diprivan® products prior to the expiration of the '520, '355, '356 or '869 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of these patents;

b. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Watson ANDA No. 205307 seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10mg propofol per 1 ml of emulsion formulation, in 20 mL, 50 mL and 100 mL vials, or any product or compound the use of which infringes the '520, '355, '356 and '869 patents, shall be a date that is not earlier than the expiration of these patents;

c. An Order permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Watson's generic Diprivan® products, or any other product or

compound the use of which infringes the ‘520, ‘355, ‘356 or ‘869 patents, or inducing or contributing to the infringement of the ‘520, ‘355, ‘356 or ‘869 patents until after the expiration of these patents;

d. An Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Watson ANDA No. 205307 before the expiration of the ‘520, ‘355, ‘356 and ‘869 patents;

e. An award of Plaintiff’s damages or other monetary relief to compensate Plaintiff if Defendants engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ generic Diprivan® products, or any product or compound the use of which infringes the ‘520, ‘355, ‘356 and ‘869 patents, or the inducement or contribution of the foregoing, prior to the expiration of these patents in accordance with 35 U.S.C. § 271(e)(4)(C);

f. A judgment that this is an exceptional case and awarding Plaintiff its attorneys’ fees under 35 U.S.C. § 285;

g. An award of Plaintiff’s reasonable costs and expenses in this action; and

h. An award of any further and additional relief to Plaintiff as this Court deems just and proper.

Dated: June 6, 2013

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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