IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARENA PHARMACEUTICALS, INC., API DEVELOPMENT LTD, ARENA PHARMACEUTICALS GMBH, and EISAI INC.	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Arena Pharmaceuticals, Inc. ("Arena Pharma"), API Development LTD ("API"), Arena Pharmaceuticals GmbH ("Arena GmbH") (collectively, "Arena"), and Eisai Inc. ("Eisai," and together with Arena, "Plaintiffs"), for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.," and together with Teva USA, "Teva"), hereby allege as follows:

THE PARTIES

1. Plaintiff Arena Pharma is a Delaware corporation having a principal place of business at 6154 Nancy Ridge Drive, San Diego, CA 92121.

2. Plaintiff API is a company organized and existing under the laws of the Cayman Islands having a principal place of business at M&C Corporate Services Limited, PO Box 309GT, Ugland House, South Church Street, George Town, Grand Cayman, Cayman Islands.

3. Plaintiff Arena GmbH is a company organized and existing under the laws of Switzerland having a principal place of business at Untere Brühlstrasse 4, CH-4800 Zofingen, Switzerland.

4. API and Arena GmbH are wholly owned subsidiaries of Arena Pharma.

5. Plaintiff Eisai is a Delaware corporation having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

6. Upon information and belief, Defendant Teva USA is a Delaware corporation and wholly owned subsidiary and agent of Defendant Teva Ltd., having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Defendant Teva USA sells various drug products in the United States, including in this judicial district.

7. Upon information and belief, Defendant Teva Ltd. is an Israeli corporation, having a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel. Upon information and belief, Defendant Teva Ltd., itself and through its wholly owned subsidiary and agent Teva USA, sells various drug products in the United States, including in this judicial district.

NATURE OF THE ACTION

8. This is a civil action concerning the infringement of United States Patent Nos. 6,953,787 ("the '787 patent"), 7,514,422 ("the '422 patent"), 7,977,329 ("the '329 patent"), 8,207,158 ("the '158 patent"), 8,273,734 ("the '734 patent"), 8,546,379 ("the '379 patent"), 8,575,149 ("the '149 patent"), 8,999,970 ("the '970 patent"), and 9,169,213 ("the '213 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

JURISDICTION AND VENUE

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

10. This Court has personal jurisdiction over both Teva USA and Teva Ltd. by virtue of, *inter alia*, the fact that they have committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs Arena and Eisai. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

11. This Court has personal jurisdiction over both Teva USA and Teva Ltd. for the additional reasons that, *inter alia*, Teva USA and Teva Ltd. (1) have substantial, continuous, and systematic contacts with this State, (2) intend to market, sell, and/or distribute generic pharmaceutical drug products to residents of this State, including the generic product that is the subject of Abbreviated New Drug Application ("ANDA") No. 209918, (3) maintain a broad distributorship network within this State; and (4) enjoy substantial income from sales of generic pharmaceutical products in this State.

12. This Court has personal jurisdiction over both Teva USA and Teva Ltd. because they have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g.*, *Teva Pharm. USA, Inc. v. Dr. Reddy's Labs., Ltd.*, C.A. No. 16-1267, D.I. 1 (D. Del. Dec. 19, 2016); *Teva Pharm. USA, Inc. v. Biocon Ltd.*, C.A. No. 16-278, D.I. 1 (D. Del. Apr. 19, 2016).

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PATENTS-IN-SUIT

14. On October 11, 2005, the '787 patent, titled "$5HT_{2C}$ Receptor Modulators," was issued. A copy of the '787 patent is attached as Exhibit A.

15. On April 7, 2009, the '422 patent, titled "$5HT_{2C}$ Receptor Modulators," was issued. A copy of the '422 patent is attached as Exhibit B.

16. On July 12, 2011, the '329 patent, titled "$5HT_{2C}$ Receptor Modulators," was issued. A copy of the '329 patent is attached as Exhibit C.

17. On June 26, 2012, the '158 patent, titled "$5HT_{2C}$ Receptor Modulators," was issued. A copy of the '158 patent is attached as Exhibit D.

18. On September 25, 2012, the '734 patent, titled "$5HT_{2C}$ Receptor Modulators," was issued. A copy of the '734 patent is attached as Exhibit E.

19. On October 1, 2013, the '379 patent, titled "$5HT_{2C}$ Receptor Modulators," was issued. A copy of the '379 patent is attached as Exhibit F.

20. On November 5, 2013, the '149 patent, titled "$5HT_{2C}$ Receptor Modulators," was issued. A copy of the '149 patent is attached as Exhibit G.

21. April 7, 2015, the '970 patent, titled "Administration of an Anti-Obesity Compound to Individuals with Renal Impairment," was issued. A copy of the '970 patent is attached as Exhibit H.

22. On October 27, 2015, the '213 patent, titled "Method of Weight Management," was issued. A copy of the '213 patent is attached as Exhibit I.

ACTS GIVING RISE TO THIS ACTION

23. Arena owns the patents-in-suit. Eisai is an exclusive licensee and holds New Drug Application ("NDA") No. 208524 for oral tablets containing 20 mg of the active

pharmaceutical ingredient lorcaserin hydrochloride. Eisai markets and sells these tablets in the United States under the brand name "Belviq XR®."

24. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Belviq XR® or its use.

25. Upon information and belief, Teva submitted ANDA No. 209918 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Teva's ANDA No. 209918 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 20 mg of lorcaserin hydrochloride ("the Teva Generic Product") prior to the expiration of the patents-in-suit.

26. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Teva certified in ANDA No. 209918 that the claims of the patents-in-suit are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Teva Generic Product.

27. Upon information and belief, by filing ANDA No. 209918, Teva has represented to the FDA that the Teva Generic Product has the same active ingredient as Belviq XR®, and has the same or substantially the same proposed labeling as Belviq XR®.

28. Plaintiffs received written notification of Teva's ANDA No. 209918 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated February 21, 2017 ("Notice Letter").

29. This action was commenced within 45 days of Plaintiffs receiving the Notice Letter.

FIRST COUNT
Infringement by Teva of U.S. Patent No. 6,953,787

30. Plaintiffs re-allege paragraphs 1-29 as if fully set forth herein.

31. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims 1, 3, 5-6, 8, 15, 17-25, and 29-30 of the '787 patent separate and apart from any assertions of invalidity of those claims. In its Notice Letter, Teva did not set forth an opinion that Claims 1, 3, 5-6, 8, 15, 17-25, and 29-30 of the '787 patent are invalid for any basis other than obviousness.

32. Teva's submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '787 patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the expiration of the '787 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '787 patent.

34. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva's ANDA No. 209918 be a date that is not earlier than the expiration of the '787 patent, or any later expiration of exclusivity for the '787 patent to which Plaintiffs are or become entitled.

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

36. Upon information and belief, Teva was aware of the existence of the '787 patent and was aware that the filing of its ANDA and certification with respect to the '787 patent constituted an act of infringement of that patent.

SECOND COUNT
Infringement by Teva of U.S. Patent No. 7,514,422

37. Plaintiffs re-allege paragraphs 1-36 as if fully set forth herein.

38. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims l-3, 5-14, 17-20, and 23-26 of the '422 patent separate and apart from any assertions regarding the validity of those claims. In its Notice Letter, Teva did not set forth an opinion that Claims l-3, 5-14, 17-20, and 23-26 of the '422 patent are invalid for any basis other than obviousness.

39. Teva's submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '422 patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the expiration of the '422 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '422 patent.

41. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva's ANDA No. 209918 be a date that is not earlier than the expiration of the '422 patent, or any later expiration of exclusivity for the '422 patent to which Plaintiffs are or become entitled.

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

43. Upon information and belief, Teva was aware of the existence of the '422 patent and was aware that the filing of its ANDA and certification with respect to the '422 patent constituted an act of infringement of that patent.

THIRD COUNT
Infringement by Teva of U.S. Patent No. 7,977,329

44. Plaintiffs re-allege paragraphs 1-43 as if fully set forth herein.

45. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims 1 and 4-8 of the '329 patent separate and apart from any assertions regarding the validity of those claims. In its Notice Letter, Teva did not set forth an opinion that Claims 1 and 4-8 of the '329 patent are invalid for any basis other than obviousness.

46. Teva's submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '329 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the expiration of the '329 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '329 patent.

48. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva's ANDA No. 209918 be a date that is not earlier than the expiration of the '329 patent, or any later expiration of exclusivity for the '329 patent to which Plaintiffs are or become entitled.

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

50. Upon information and belief, Teva was aware of the existence of the '329 patent and was aware that the filing of its ANDA and certification with respect to the '329 patent constituted an act of infringement of that patent.

FOURTH COUNT
Infringement by Teva of U.S. Patent No. 8,207,158

51. Plaintiffs re-allege paragraphs 1-50 as if fully set forth herein.

52. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims 1-4, 7-8, 10, 31-34, 37-38, 40, 61-64, 67-68, 70, 91-94, 97-98, and 100 of the '158 patent separate and apart from any assertions regarding the validity of those claims. In its Notice Letter, Teva did not set forth an opinion that Claims 1-4, 7-8, 10, 31-34, 37-38, 40, 61-64, 67-68, 70, 91-94, 97-98, and 100 of the '158 patent are invalid for any basis other than obviousness.

53. Teva's submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '158 patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the expiration of the '158 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '158 patent.

55. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva's ANDA No.

209918 be a date that is not earlier than the expiration of the '158 patent, or any later expiration of exclusivity for the '158 patent to which Plaintiffs are or become entitled.

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

57. Upon information and belief, Teva was aware of the existence of the '158 patent and was aware that the filing of its ANDA and certification with respect to the '158 patent constituted an act of infringement of that patent.

FIFTH COUNT
Infringement by Teva of U.S. Patent No. 8,273,734

58. Plaintiffs re-allege paragraphs 1-57 as if fully set forth herein.

59. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims 1, 3, 5-7, 9, 11-12, 14, 16-18, 20, 22-24, 26, 28-30, 32, 34-35, 37, 39-41, 43, and 45 of the '734 patent separate and apart from any assertions regarding the validity of those claims. In its Notice Letter, Teva did not set forth an opinion that Claims 1, 3, 5-7, 9, 11-12, 14, 16-18, 20, 22-24, 26, 28-30, 32, 34-35, 37, 39-41, 43, and 45 of the '734 patent are invalid for any basis other than obviousness.

60. Teva's submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '734 patent under 35 U.S.C. § 271(e)(2)(A).

61. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the expiration of the '734 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '734 patent.

62. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva's ANDA No. 209918 be a date that is not earlier than the expiration of the '734 patent, or any later expiration of exclusivity for the '734 patent to which Plaintiffs are or become entitled.

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

64. Upon information and belief, Teva was aware of the existence of the '734 patent and was aware that the filing of its ANDA and certification with respect to the '734 patent constituted an act of infringement of that patent.

SIXTH COUNT
Infringement by Teva of U.S. Patent No. 8,546,379

65. Plaintiffs re-allege paragraphs 1-64 as if fully set forth herein.

66. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims 1-18 of the '379 patent separate and apart from any assertions regarding the validity of those claims. In its Notice Letter, Teva did not set forth an opinion that Claims 1-18 of the '379 patent are invalid for any basis other than obviousness.

67. Teva's submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '379 patent under 35 U.S.C. § 271(e)(2)(A).

68. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the expiration of the '379 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '379 patent.

69. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva's ANDA No. 209918 be a date that is not earlier than the expiration of the '379 patent, or any later expiration of exclusivity for the '379 patent to which Plaintiffs are or become entitled.

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

71. Upon information and belief, Teva was aware of the existence of the '379 patent and was aware that the filing of its ANDA and certification with respect to the '379 patent constituted an act of infringement of that patent.

SEVENTH COUNT
Infringement by Teva of U.S. Patent No. 8,575,149

72. Plaintiffs re-allege paragraphs 1-71 as if fully set forth herein.

73. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims 1-4, 6-14, and 16 of the '149 patent separate and apart from any assertions regarding the validity of those claims. In its Notice Letter, Teva did not set forth an opinion that Claims 1-4, 6-14, and 16 of the '149 patent are invalid for any basis other than obviousness.

74. Teva's submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '149 patent under 35 U.S.C. § 271(e)(2)(A).

75. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the

expiration of the ’149 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the ’149 patent.

76. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva’s ANDA No. 209918 be a date that is not earlier than the expiration of the ’149 patent, or any later expiration of exclusivity for the ’149 patent to which Plaintiffs are or become entitled.

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

78. Upon information and belief, Teva was aware of the existence of the ’149 patent and was aware that the filing of its ANDA and certification with respect to the ’149 patent constituted an act of infringement of that patent.

EIGHTH COUNT
Infringement by Teva of U.S. Patent No. 8,999,970

79. Plaintiffs re-allege paragraphs 1-78 as if fully set forth herein.

80. Teva’s submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the ’970 patent under 35 U.S.C. § 271(e)(2)(A).

81. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the expiration of the ’970 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the ’970 patent.

82. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva’s ANDA No.

209918 be a date that is not earlier than the expiration of the ’970 patent, or any later expiration of exclusivity for the ’970 patent to which Plaintiffs are or become entitled.

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

84. Upon information and belief, Teva was aware of the existence of the ’970 patent and was aware that the filing of its ANDA and certification with respect to the ’970 patent constituted an act of infringement of that patent.

NINTH COUNT
Infringement by Teva of U.S. Patent No. 9,169,213

85. Plaintiffs re-allege paragraphs 1-84 as if fully set forth herein.

86. Teva’s submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the ’213 patent under 35 U.S.C. § 271(e)(2)(A).

87. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Teva Generic Product, if approved by the FDA, prior to the expiration of the ’213 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the ’213 patent.

88. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva’s ANDA No. 209918 be a date that is not earlier than the expiration of the ’213 patent, or any later expiration of exclusivity for the ’213 patent to which Plaintiffs are or become entitled.

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

90. Upon information and belief, Teva was aware of the existence of the '213 patent and was aware that the filing of its ANDA and certification with respect to the '213 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Teva has infringed one or more claims of the '787 patent;

B. Teva has infringed one or more claims of the '422 patent;

C. Teva has infringed one or more claims of the '329 patent;

D. Teva has infringed one or more claims of the '158 patent;

E. Teva has infringed one or more claims of the '734 patent;

F. Teva has infringed one or more claims of the '379 patent;

G. Teva has infringed one or more claims of the '149 patent;

H. Teva has infringed one or more claims of the '970 patent;

I. Teva has infringed one or more claims of the '213 patent;

J. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Teva's ANDA No. 209918 shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

K. That Teva, its officers, agents, servants and employees, and those persons acting in concert, participation, or in privity with any of them, and their successors or assigns, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing into the United States the Teva Generic Product and any other product

that infringes or induces or contributes to the infringement of one or more claims of the patents-in-suit prior to their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

L. That Plaintiffs be awarded the attorneys' fees, costs and expenses that they incur in prosecuting this action; and

M. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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