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. 16-887 (RGA)
	)	CONSOLIDATED
LUPIN LTD., et al.,	)	
Defendants.	)	

SECOND AMENDED 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 Second Amended Complaint against Defendants Lupin Limited, Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), and Teva Pharmaceuticals USA, Inc. ("Teva," and together with Lupin, "Defendants") 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 Lupin Ltd. is an Indian corporation having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. Upon information and belief, Defendant Lupin Ltd., itself and through its wholly owned subsidiary and agent Lupin Pharmaceuticals, Inc. ("Lupin Pharma"), sells various drug products in the United States, including in this judicial district.

7. Upon information and belief, Defendant Lupin Pharma is a Delaware corporation and wholly owned subsidiary and agent of Defendant Lupin Ltd., having a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief Defendant Lupin Pharma sells various drug products in the United States, including in this judicial district.

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

NATURE OF THE ACTION

9. 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"), and 9,770,455 ("the '455 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

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

11. This Court has personal jurisdiction over both Lupin Ltd. and Lupin Pharma 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 Lupin Ltd. and Lupin Pharma for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

12. This Court has personal jurisdiction over both Lupin Ltd. and Lupin Pharma for the additional reasons that, *inter alia*, Lupin Ltd. and Lupin Pharma (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 products that are the subject of Abbreviated New Drug Application ("ANDA") Nos. 209416 and 210866, (3) maintain a broad distributorship network within this State, and (4) enjoy substantial income from sales of generic pharmaceutical products in this State.

13. This Court also has personal jurisdiction over both Lupin Ltd. and Lupin Pharma because they have previously been sued in this district and have not challenged personal jurisdiction, including in response to the Complaint in this action, and they have affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Cosmo Techs. Ltd. v. Lupin Ltd.*, 15-cv-00669, D.I. 67 (D. Del. Aug. 25, 2016), *Alcon*

Research Ltd. v. Lupin Ltd., 16-cv-00195, D.I. 8 (Apr. 25, 2016); *Vanda Pharm. Inc. v. Lupin Ltd.*, 15-cv-01073, D.I. 10 (D. Del. Dec. 14, 2015).

14. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, the fact that it has 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 Teva for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

15. This Court has personal jurisdiction over Teva for the additional reasons that, *inter alia*, Teva (1) has substantial, continuous, and systematic contacts with this State, (2) intends to market, sell, and/or distribute generic pharmaceutical drug products to residents of this State, including the generic product that is the subject of ANDA No. 209918, (3) maintains a broad distributorship network within this State; and (4) enjoys substantial income from sales of generic pharmaceutical products in this State.

16. This Court has personal jurisdiction over Teva because it has previously submitted to the jurisdiction of this Court, including in response to the Complaint in this action, and has availed itself 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).

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

THE PATENTS-IN-SUIT

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. On September 26, 2017, the '455 patent, titled Administration of an Anti-Obesity Compound to Individuals with Renal Impairment," was issued. A copy of the '455 patent is attached as Exhibit F.

ACTS GIVING RISE TO THIS ACTION

24. Arena owns the patents-in-suit and Eisai is an exclusive licensee of the patents-in-suit. Eisai holds New Drug Application ("NDA") No. 022529 for oral tablets containing 10 mg of the active pharmaceutical ingredient lorcaserin hydrochloride and NDA No. 208524 for extended-release-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 names "Belviq®" and "Belviq XR®."

25. 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®," "Belviq XR®," or their respective use.

26. Upon information and belief, Lupin submitted Abbreviated New Drug Application ("ANDA") No. 209416 to the FDA under § 505(j) of the Federal Food, Drug and

Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Lupin's ANDA No. 209416 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 10 mg of lorcaserin hydrochloride ("the Lupin Generic IR Product") prior to the expiration of the patents-in-suit.

27. Upon information and belief, Lupin submitted ANDA No. 210866 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Lupin's ANDA No. 210866 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of extended-release tablets containing 20 mg of lorcaserin hydrochloride ("the Lupin Generic XR Product") prior to the expiration of the patents-in-suit.

28. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Lupin certified in ANDA Nos. 209416 and 210866 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 Lupin Generic IR Product or the Lupin Generic XR Product, respectively.

29. Upon information and belief, by filing ANDA No. 209416, Lupin has represented to the FDA that the Lupin Generic IR Product has the same active ingredient as Belviq®, and has the same or substantially the same proposed labeling as Belviq®, and by filing ANDA No. 210866, Lupin has represented to the FDA that the Lupin Generic XR Product has the same active ingredient as Belviq XR®, and has the same or substantially the same proposed labeling as Belviq XR®.

30. Plaintiffs received written notification of Lupin's ANDA No. 209416 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a facsimile dated August 19, 2016 ("Lupin's Notice Letter").

31. This action was commenced within 45 days of Plaintiffs receiving Lupin's Notice Letter.

32. 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.

33. 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.

34. 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®.

35. 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 ("Teva's Notice Letter").

36. This action was commenced within 45 days of Plaintiffs receiving Teva's Notice Letter.

37. Upon information and belief, Lupin was aware of Teva's Generic Product at the time the § 505(j)(2)(A)(vii)(IV) certification in ANDA No. 210866 was filed.

38. Upon information and belief, Lupin is not the first applicant to submit a substantially complete application containing a § 505(j)(2)(A)(vii)(IV) certification for approval of a generic equivalent of Belviq XR®.

FIRST COUNT
(Infringement by Lupin of U.S. Patent No. 6,953,787)

39. Plaintiffs re-allege paragraphs 1-38 as if fully set forth herein.

40. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion of noninfringement of Claims 17, 29, 30, and 65 of the '787 patent separate and apart from any assertions of invalidity of those claims. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion that Claims 17, 29, 30, and 65 of the '787 patent are invalid based on a ground other than obviousness.

41. Lupin's submission of ANDA Nos. 209416 and 210866 to the FDA, including its respective § 505(j)(2)(A)(vii)(IV) certifications, constitutes infringement of the '787 patent under 35 U.S.C. § 271(e)(2)(A).

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

43. 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 Lupin's ANDA Nos. 209416 and 210866 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.

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

45. Upon information and belief, Lupin was aware of the existence of the '787 patent and was aware that the filing of its ANDAs and certifications with respect to the '787 patent constituted an act of infringement of that patent.

SECOND COUNT
(Infringement by Lupin of U.S. Patent No. 7,514,422)

46. Plaintiffs re-allege paragraphs 1-45 as if fully set forth herein.

47. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion of noninfringement of Claims 14, 17, and 18 of the '422 patent separate and apart from any assertions regarding the invalidity of those claims. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion that Claims 14, 17, and 18 of the '422 patent are invalid for any basis other than obviousness.

48. Lupin's submission of ANDA Nos. 209416 and 210866 to the FDA, including its respective § 505(j)(2)(A)(vii)(IV) certifications, constitutes infringement of the '422 patent under 35 U.S.C. § 271(e)(2)(A).

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

50. 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 Lupin's ANDA Nos. 209416 and 210866 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.

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

52. Upon information and belief, Lupin was aware of the existence of the '422 patent and was aware that the filing of its ANDAs and certifications with respect to the '422 patent constituted an act of infringement of that patent.

THIRD COUNT
(Infringement by Lupin of U.S. Patent No. 7,977,329)

53. Plaintiffs re-allege paragraphs 1-52 as if fully set forth herein.

54. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion of noninfringement of Claim 1 of the '329 patent separate and apart from any assertions regarding the validity of that claim. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion that Claim 1 of the '329 patent is invalid for any basis other than obviousness.

55. Lupin's submission of ANDA Nos. 209416 and 210866 to the FDA, including its respective § 505(j)(2)(A)(vii)(IV) certifications, constitutes infringement of the '329 patent under 35 U.S.C. § 271(e)(2)(A).

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

57. 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 Lupin's ANDA Nos.

209416 and 210866 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.

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

59. Upon information and belief, Lupin was aware of the existence of the ’329 patent and was aware that the filing of its ANDAs and certifications with respect to the ’329 patent constituted an act of infringement of that patent.

FOURTH COUNT
(Infringement by Lupin of U.S. Patent No. 8,207,158)

60. Plaintiffs re-allege paragraphs 1-59 as if fully set forth herein.

61. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion of noninfringement of Claim 91 of the ’158 patent separate and apart from any assertions of invalidity of that claim. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion that Claim 91 of the ’158 patent is invalid based on a ground other than obviousness.

62. Lupin’s submission of ANDA Nos. 209416 and 210866 to the FDA, including its respective § 505(j)(2)(A)(vii)(IV) certifications, constitutes infringement of the ’158 patent under 35 U.S.C. § 271(e)(2)(A).

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

64. 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 Lupin's ANDA Nos. 209416 and 210866 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.

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

66. Upon information and belief, Lupin was aware of the existence of the '158 patent and was aware that the filing of its ANDAs and certifications with respect to the '158 patent constituted an act of infringement of that patent.

FIFTH COUNT
(Infringement by Lupin of U.S. Patent No. 8,273,734)

67. Plaintiffs re-allege paragraphs 1-66 as if fully set forth herein.

68. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion of noninfringement of Claim 1 of the '734 patent separate and apart from any assertions of invalidity of that claim. In its Notice Letters for the Lupin Generic IR Product and the Lupin Generic XR Product, Lupin did not set forth an opinion that Claim 1 of the '734 patent is invalid based on a ground other than obviousness.

69. Lupin's submission of ANDA Nos. 209416 and 210866 to the FDA, including its respective § 505(j)(2)(A)(vii)(IV) certifications, constitutes infringement of the '734 patent under 35 U.S.C. § 271(e)(2)(A).

70. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Lupin Generic IR Product or the Lupin Generic XR Product, if approved by the FDA, prior to the expiration of the '734 patent, for use in accordance with its respective

proposed labeling would infringe and/or induce and/or contribute to the infringement of the ’734 patent.

71. 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 Lupin’s ANDA Nos. 209416 and 210866 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.

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

73. Upon information and belief, Lupin was aware of the existence of the ’734 patent and was aware that the filing of its ANDAs and certifications with respect to the ’734 patent constituted an act of infringement of that patent.

SIXTH COUNT
(Infringement by Lupin OF U.S. Patent No. 9,770,455)

74. Plaintiffs re-allege paragraphs 1-73 as if fully set forth herein.

75. Lupin’s submission of ANDA Nos. 209416 and 210866 to the FDA, including its respective § 505(j)(2)(A)(vii)(IV) certifications, constitutes infringement of the ’455 patent under 35 U.S.C. § 271(e)(2)(A).

76. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Lupin Generic IR Product or the Lupin Generic XR Product, if approved by the FDA, prior to the expiration of the ’455 patent, for use in accordance with its respective proposed labeling would infringe and/or induce and/or contribute to the infringement of the ’455 patent.

77. 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 Lupin’s ANDA Nos.

209416 and 210866 be a date that is not earlier than the expiration of the '455 patent, or any later expiration of exclusivity for the '455 patent to which Plaintiffs are or become entitled.

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

SEVENTH COUNT
(Infringement by Teva of U.S. Patent No. 6,953,787)

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

80. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims 17, 29, 30, and 65 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 17, 29, 30, and 65 of the '787 patent are invalid for any basis other than obviousness.

81. 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).

82. 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.

83. 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.

84. 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.

85. 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.

EIGHTH COUNT
(Infringement by Teva of U.S. Patent No. 7,514,422)

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

87. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims l4, 17, and 18 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 l4, 17, and 18 of the ’422 patent are invalid for any basis other than obviousness.

88. 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).

89. 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.

90. 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.

91. 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.

92. 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.

NINTH COUNT
(Infringement by Teva of U.S. Patent No. 7,977,329)

93. Plaintiffs re-allege paragraphs 1-92 as if fully set forth herein.

94. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claims 1 and 4-6 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 4-6 of the '329 patent are invalid for any basis other than obviousness.

95. 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).

96. 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.

97. 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.

98. 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.

99. 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.

TENTH COUNT
(Infringement by Teva OF U.S. Patent No. 8,207,158)

100. Plaintiffs re-allege paragraphs 1-99 as if fully set forth herein.

101. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claim 91 of the '158 patent separate and apart from any assertions regarding the validity of that claim. In its Notice Letter, Teva did not set forth an opinion that Claim 91 of the '158 patent is invalid for any basis other than obviousness.

102. 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).

103. 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.

104. 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.

105. 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.

106. 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.

ELEVENTH COUNT
(Infringement by Teva of U.S. Patent No. 8,273,734)

107. Plaintiffs re-allege paragraphs 1-106 as if fully set forth herein.

108. In its Notice Letter, Teva did not set forth an opinion of noninfringement of Claim 1 of the '734 patent separate and apart from any assertions regarding the validity of that claim. In its Notice Letter, Teva did not set forth an opinion that Claim 1 of the '734 patent is invalid for any basis other than obviousness.

109. 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).

110. 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.

111. 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.

112. 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.

113. 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.

TWELFTH COUNT
(Infringement by Teva of U.S. Patent No. 9,770,455)

114. Plaintiffs re-allege paragraphs 1-113 as if fully set forth herein.

115. Teva's submission of ANDA No. 209918 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '455 patent under 35 U.S.C. § 271(e)(2)(A).

116. 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 '455 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '455 patent.

117. 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 '455 patent, or any later expiration of exclusivity for the '455 patent to which Plaintiffs are or become entitled.

118. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

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

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

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

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

E. Lupin has infringed one or more claims of the ’734 patent;

F. Lupin has infringed one or more claims of the ’455 patent;

G. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin’s ANDA Nos. 209416 and 210866 shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

H. That Lupin, 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 Lupin Generic IR Product and the Lupin Generic XR 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;

I. Teva has infringed one or more claims of the ’787 patent;

J. Teva has infringed one or more claims of the ’422 patent;

K. Teva has infringed one or more claims of the ’329 patent;

L. Teva has infringed one or more claims of the ’158 patent;

M. Teva has infringed one or more claims of the ’734 patent;

N. Teva has infringed one or more claims of the ’455 patent;

O. 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;

P. 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;

Q. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur in prosecuting this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs Arena Pharmaceuticals, Inc., API Development LTD, Arena Pharmaceuticals GmbH, and Eisai Inc.

OF COUNSEL:

Bruce M. Wexler
Young J. Park
Melanie R. Rupert
Simon F. Kung
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

March 22, 2018