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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB,

Plaintiffs,

v.

CHIA TAI TIANQING PHARMACEUTICAL GROUP CO., LTD., ATHENEX, INC., and THE WHITEOAK GROUP, LLC,

Defendants.

Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively "Plaintiffs" or "AstraZeneca") bring this action for patent infringement against Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("CTTQ"), Athenex, Inc. ("Athenex"), and The WhiteOak Group, LLC ("WhiteOak") (collectively, "Defendants").

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike,

Wilmington, Delaware 19850, U.S.A.

2. Plaintiff AstraZeneca UK Limited is a private limited company organized under the laws of England and Wales, with its registered office at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, United Kingdom, CB2 0AA.

3. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. On information and belief, Defendant Chia Tai Tianqing Pharmaceutical Group Co., Ltd. is a limited company organized under the laws of China, with its principal place of business at No. 369 South Yuzhou Road, Haizhou District, Lianyungang, Jiangsu Province, P. R. China 222062.

5. On information and belief, Defendant Athenex, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1001 Main Street, Suite 600, Buffalo, New York 14203.

6. On information and belief, Defendant The WhiteOak Group, LLC is a limited liability company organized and existing under the laws of the District of Columbia, with its principal place of business at 1629 K Street NW, Suite 300, Washington, D.C. 20006.

7. On information and belief, Defendants CTTQ and Athenex are in the business of manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

8. On information and belief, Defendant CTTQ filed Abbreviated New Drug Application ("ANDA") No. 211422 seeking regulatory approval from the U.S. Food and Drug Administration ("FDA") to market and sell a proposed generic Fulvestrant Injection, 250 mg/5

mL (50 mg/mL) pre-filled syringes product throughout the United States, including within this District. On information and belief, Defendant WhiteOak is the United States agent for Defendant CTTQ with respect to ANDA No. 211422.

9. On information and belief, Defendants CTTQ, WhiteOak, and Athenex are acting in concert with respect to ANDA No. 211422 and, upon FDA approval of ANDA No. 211422, intend to manufacture, market, and sell their proposed generic Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) pre-filled syringes product throughout the United States, including within this District.

NATURE OF THE ACTION

10. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' filing of ANDA No. 211422 with the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) pre-filled syringes product (the "Proposed ANDA Product"), which is a generic version of AstraZeneca's FASLODEX® (fulvestrant) intramuscular injection product, prior to the expiration of AstraZeneca's U.S. Patent Nos. 6,774,122, 7,456,160, 8,329,680, and 8,466,139.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Defendants because Defendants have maintained continuous and systematic contacts with the State of New Jersey and this District.

13. On information and belief, Defendant CTTQ, directly or through its subsidiaries,

agents, and/or related entities, markets and sells generic pharmaceutical products throughout the United States, including in the State of New Jersey, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic pharmaceutical products. On information and belief, Defendant CTTQ, directly or through its subsidiaries, agents, and/or related entities, derives substantial revenue from goods used or consumed or services rendered in this judicial district. The Court has personal jurisdiction over Defendant CTTQ by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial, continuous, and systematic contacts with the State of New Jersey. On information and belief, Defendant CTTQ, directly or through its subsidiaries, agents, and/or related entities, intentionally markets and provides its generic pharmaceutical products to residents of this State and enjoys substantial income from this State. On information and belief, Defendant CTTQ, directly or through its subsidiaries, agents, and/or related entities, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Defendant CTTQ intends to act in concert with Defendants Athenex and WhiteOak to manufacture for distribution, and to distribute and sell the Proposed ANDA Product throughout the United States and in this judicial district. Defendant CTTQ's filing of ANDA No. 211422 confirms this intention and additionally subjects Defendant CTTQ to the specific personal jurisdiction of this Court. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016). Furthermore, it is Plaintiffs' understanding that Defendant CTTQ has consented to jurisdiction and venue in the District of New Jersey.

14. On information and belief, Defendant Athenex, directly or through its subsidiaries, agents, and/or related entities, markets and sells generic pharmaceutical products

throughout the United States, including in the State of New Jersey, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic pharmaceutical products. On information and belief, Defendant Athenex derives substantial revenue from goods used or consumed or services rendered in this judicial district. The Court has personal jurisdiction over Defendant Athenex by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial, continuous, and systematic contacts with the State of New Jersey. On information and belief, Defendant Athenex, directly or through its subsidiaries, agents, and/or related entities, intentionally markets and provides its generic pharmaceutical products to residents of this State and enjoys substantial income from this State. On information and belief, Defendant Athenex, directly or through its subsidiaries, including at least Athenex Pharmaceutical Division and Athenex Pharma Solutions, created a presence in this State through its registration with the New Jersey Department of Health and Senior Services Consumer and Environmental Health service as a drug manufacturer and wholesaler and maintains Drug and Medical Device Certificates of Registration under Registration Nos. 5005126 and 5005236. Moreover, Defendant Athenex, by virtue of its registration with the New Jersey Department of Health and Senior Services Consumer and Environmental Health service a drug manufacturer and wholesaler, is required to either designate an agent for service of process or, by default, consent to the New Jersey Secretary of State as its agent pursuant to NJAC § 8:21-3A and NJSA § 24:6B-15. On information and belief, Defendant Athenex, directly or through its subsidiaries, including at least Athenex New Jersey, maintains a place of business at 20 Commerce Drive, Suite 100, Cranford, New Jersey 07016. On information and belief, Defendant Athenex directly or through its subsidiaries, manufactures, imports, markets, and sells generic drugs throughout

the United States and in this judicial district. On information and belief, Defendant Athenex intends to act in concert with Defendants CTTQ and WhiteOak to manufacture for distribution, and to distribute and sell the Proposed ANDA Product throughout the United States and in this judicial district.

15. On information and belief, Defendant WhiteOak is the United States agent for CTTQ with respect to ANDA No. 211422. On information and belief, Defendant WhiteOak, directly or through its partners and/or related entities, derives substantial revenue from goods used or consumed or services rendered in this judicial district. This Court has personal jurisdiction over Defendant WhiteOak by virtue of, *inter alia*, its actions at the direction of Defendant CTTQ in the United States, including at least its actions as U.S. Agent for Defendant CTTQ with respect to ANDA No. 211422, by and through which Defendant WhiteOak, directly or through its partners and/or related entities, conducts business in this State, purposefully avails itself of the rights and benefits of New Jersey law, and has substantial and continuing contacts within this State. On information and belief, Defendant WhiteOak intends to act in concert with Defendants CTTQ and Athenex to manufacture for distribution, and to distribute and sell the Proposed ANDA Product throughout the United States and in this judicial district.

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

THE PATENTS-IN-SUIT

17. United States Patent No. 6,774,122 (the "'122 Patent"), entitled "Formulation," was duly and legally issued on August 10, 2004 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '122 Patent. AstraZeneca UK Limited is the beneficial owner of the '122 Patent. A copy of the '122 Patent is attached as **Appendix A**.

18. United States Patent No. 7,456,160 (the "'160 Patent"), entitled "Formulation," was duly and legally issued on November 25, 2008 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '160 Patent. AstraZeneca UK Limited is the beneficial owner of the '160 Patent. A copy of the '160 Patent is attached as **Appendix B**.

19. United States Patent No. 8,329,680 (the "'680 Patent"), entitled "Formulation," was duly and legally issued on December 11, 2012 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '680 Patent. AstraZeneca UK Limited is the beneficial owner of the '680 Patent. A copy of the '680 Patent is attached as **Appendix C**.

20. United States Patent No. 8,466,139 (the "'139 Patent"), entitled "Formulation," was duly and legally issued on June 18, 2013 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '139 Patent. AstraZeneca UK Limited is the beneficial owner of the '139 Patent. A copy of the '139 Patent is attached as **Appendix D**.

FACTUAL BACKGROUND

FASLODEX® (fulvestrant) intramuscular injection

21. FASLODEX® (fulvestrant) intramuscular injection is an estrogen receptor antagonist approved by the FDA for the treatment of: (a) HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy; (b) HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib in women with disease progression after endocrine therapy; and (c) hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced

breast cancer in postmenopausal women not previously treated with endocrine therapy.

22. FDA regulatory exclusivity for the treatment of hormone receptor positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression following endocrine therapy will expire on February 19, 2019.

23. FDA regulatory exclusivity for treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy will expire on August 25, 2020.

24. AstraZeneca UK Limited is the holder of approved New Drug Application ("NDA") No. 21-344 for FASLODEX® (fulvestrant) intramuscular injection, in 50 mg/mL dosage forms. AstraZeneca Pharmaceuticals LP is the authorized agent for matters related to NDA No. 21-344 in the United States.

25. The use of FASLODEX® (fulvestrant) intramuscular injection is covered by one or more Claims of the '122, '160, '680, and '139 Patents.

26. The '122, '160, '680, and '139 Patents have been listed for NDA No. 21-344 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

27. AstraZeneca Pharmaceuticals LP sells and distributes FASLODEX® (fulvestrant) intramuscular injection in the United States pursuant to NDA No. 21-344.

DEFENDANTS' ANDA

28. By Notice Letter dated November 2, 2018, Defendant CTTQ notified AstraZeneca that Defendants' ANDA No. 211422 ("Defendants' ANDA") was submitted to the FDA and that Defendants are seeking approval to engage in the commercial manufacture, use

and sale of the Proposed ANDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, and included within ANDA No. 211422 a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '122, '160, '680, and '139 Patents are invalid and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product. On information and belief, Defendant CTTQ listed Defendant WhiteOak as its United States designated agent with respect to ANDA No. 211422. On information and belief, Defendants CTTQ and WhiteOak are acting in concert with Defendant Athenex with respect to ANDA No. 211422.

29. On information and belief, Defendants were necessarily aware of the Patents-in-Suit when ANDA No. 211422 was filed with a Paragraph IV Certification.

30. On information and belief, the Proposed ANDA Product is a pharmaceutical formulation comprising fulvestrant, a mixture of 10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle so that the formulation comprises about 50 $mgml^{-1}$ fulvestrant.

31. On information and belief, Defendants' ANDA No. 211422 refers to and relies upon AstraZeneca's FASLODEX® (fulvestrant) intramuscular injection NDA and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and FASLODEX® (fulvestrant) intramuscular injection, including achieving a blood plasma fulvestrant concentration of at least 2.5 mg/ml^{-1} for at least 4 weeks after injection.

32. On information and belief, the Proposed ANDA Product label will have instructions for use that substantially copy the instructions for FASLODEX® (fulvestrant) intramuscular injection, including instructions for administering the Proposed ANDA Product by intramuscular injection to treat hormone dependent breast cancer. The instructions

accompanying the Proposed ANDA Product will induce others to use and/or contribute to others' use of the Proposed ANDA Product in the manner set forth in the instructions. Defendants are blocked from seeking approval from the FDA to engage in the commercial manufacture, use, sale and importation of the Proposed ANDA Product to treat HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression after endocrine therapy prior to the expiration of AstraZeneca's data exclusivity on February 19, 2019. Defendants are blocked from seeking approval from the FDA to engage in the commercial manufacture, use, sale and importation of the Proposed ANDA Product for treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy prior to the expiration of AstraZeneca's data exclusivity on August 25, 2020.

33. On information and belief, the Proposed ANDA Product will have no FDA approved, non-infringing uses.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,774,122

34. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–33 of this Complaint.

35. The use of the Proposed ANDA Product is covered by one or more Claims of the '122 Patent.

36. Defendants' submission of ANDA No. 211422 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '122 Patent constitutes infringement of one or more Claims of the '122 Patent under 35 U.S.C. § 271(e)(2).

37. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 211422 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

38. On information and belief, the Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '122 Patent under 35 U.S.C. § 271(a).

39. Upon FDA approval of ANDA No. 211422, Defendants will infringe the '122 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

40. On information and belief, Defendants had knowledge of the '122 Patent when they submitted ANDA No. 211422 to the FDA and Defendants know or should have known that they will aid and abet another's direct infringement of at least one of the Claims of the '122 Patent.

41. The Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '122 Patent.

42. Defendants had knowledge of the '122 Patent and are knowingly and willfully infringing the '122 Patent.

43. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

44. On information and belief, Defendants lacked a good faith basis for alleging

invalidity and/or non-infringement of the ’122 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants’ Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,774,122

45. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–44 of this Complaint.

46. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

47. On information and belief, Defendants have taken and plan to, intend to, and will take active steps to induce, or contribute to, the infringement of the ’122 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 211422 is approved.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,456,160

48. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–47 of this Complaint.

49. The use of the Proposed ANDA Product is covered by one or more Claims of the ’160 Patent.

50. Defendants’ submission of ANDA No. 211422 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the ’160 Patent constitutes infringement of one or more Claims of the ’160 Patent under 35 U.S.C. § 271(e)(2).

51. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA

Product immediately upon approval of ANDA No. 211422 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

52. On information and belief, the Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '160 Patent under 35 U.S.C. § 271(a).

53. Upon FDA approval of ANDA No. 211422, Defendants will infringe the '160 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

54. On information and belief, Defendants had knowledge of the '160 Patent when they submitted ANDA No. 211422 to the FDA and Defendants know or should have known that they will aid and abet another's direct infringement of at least one of the Claims of the '160 Patent.

55. The Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '160 Patent.

56. Defendants had knowledge of the '160 Patent and are knowingly and willfully infringing the '160 Patent.

57. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

58. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement of the '160 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and

this case is exceptional under 35 U.S.C. § 285.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,456,160

59. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–58 of this Complaint.

60. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

61. On information and belief, Defendants have taken and plan to, intend to, and will take active steps to induce, or contribute to, the infringement of the ’160 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 211422 is approved.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,329,680

62. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–61 of this Complaint.

63. The use of the Proposed ANDA Product is covered by one or more Claims of the ’680 Patent.

64. Defendants’ submission of ANDA No. 211422 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the ’680 Patent constitutes infringement of one or more Claims of the ’680 Patent under 35 U.S.C. § 271(e)(2).

65. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 211422 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

66. On information and belief, the Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the ’680 Patent under 35 U.S.C. § 271(a).

67. Upon FDA approval of ANDA No. 211422, Defendants will infringe the ’680 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

68. On information and belief, Defendants had knowledge of the ’680 Patent when they submitted ANDA No. 211422 to the FDA and Defendants know or should have known that they will aid and abet another’s direct infringement of at least one of the Claims of the ’680 Patent.

69. The Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the ’680 Patent.

70. Defendants had knowledge of the ’680 Patent and are knowingly and willfully infringing the ’680 Patent.

71. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

72. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement of the ’680 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants’ Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,329,680

73. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–72 of this Complaint.

74. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

75. On information and belief, Defendants have taken and plan to, intend to, and will take active steps to induce, or contribute to, the infringement of the ’680 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 211422 is approved.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 8,466,139

76. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–75 of this Complaint.

77. The use of the Proposed ANDA Product is covered by one or more Claims of the ’139 Patent.

78. Defendants’ submission of ANDA No. 211422 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the ’139 Patent constitutes infringement of one or more Claims of the ’139 Patent under 35 U.S.C. § 271(e)(2).

79. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 211422 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

80. On information and belief, the Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the ’139 Patent under 35 U.S.C. § 271(a).

81. Upon FDA approval of ANDA No. 211422, Defendants will infringe the ’139 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

82. On information and belief, Defendants had knowledge of the ’139 Patent when they submitted ANDA No. 211422 to the FDA and Defendants know or should have known that they will aid and abet another’s direct infringement of at least one of the Claims of the ’139 Patent.

83. The Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the ’139 Patent.

84. Defendants had knowledge of the ’139 Patent and are knowingly and willfully infringing the ’139 Patent.

85. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

86. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement of the ’139 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants’ Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,466,139

87. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–86 of this Complaint.

88. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and

2202.

89. On information and belief, Defendants have taken and plan to, intend to, and will take active steps to induce, or contribute to, the infringement of the ’139 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 211422 is approved.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a) Judgment that the ’122, ’160, ’680, and ’139 Patents are valid and enforceable;

b) Judgment that Defendants’ submission of ANDA No. 211422 was an act of infringement of one or more Claims of the ’122, ’160, ’680, and ’139 Patents under 35 U.S.C. § 271(e)(2);

c) Judgment that Defendants’ making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the ’122, ’160, ’680, and ’139 Patents, will directly infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of the ’122, ’160, ’680, and/or ’139 Patents;

d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 211422 shall be a date that is not earlier than the expiration of the ’122, ’160, ’680, and ’139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

e) An Order permanently enjoining Defendants, their affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendants, from making, using, offering to sell,

selling, marketing, distributing, or importing into the United States the Proposed ANDA Product until after the expiration of the ’122, ’160, ’680, and ’139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

f) Judgment declaring that infringement, inducement or contributory infringement of the ’122, ’160, ’680, and/or ’139 Patents by Defendants is willful should Defendants commercially manufacture, use, offer to sell, sell, or import into the United States the Proposed ANDA Product;

g) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys’ fees, expenses, and disbursements of this action;

h) Plaintiffs’ reasonable costs and expenses in this action; and

i) Such further and other relief as this Court deems proper and just.

Dated: December 13, 2018

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SANDOZ INC., and SANDOZ INTERNATIONAL GmbH*, C.A. No. 1:14-cv-03547-RMB-KMW ("*AstraZeneca v. Sandoz*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SAGENT PHARMACEUTICALS, INC.*, C.A. No. 1:14-cv-05539-RMB-KMW ("*AstraZeneca v. Sagent*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. GLENMARK PHARMACEUTICALS INC., USA*, C.A. No. 1:15-cv-00615-RMB-KMW ("*AstraZeneca v. Glenmark*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AGILA SPECIALTIES, INC. F/K/A STRIDES INC., ONCO THERAPIES LIMITED, MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.*, C.A. No. 1:15-cv-06039-RMB-KMW ("*AstraZeneca v. Agila*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.*, C.A. No. 1:15-cv-07009-RMB-KMW ("*AstraZeneca v. Mylan*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. TEVA PHARMACEUTICALS USA, INC.*, C.A. No. 1:15-cv-07889-RMB-KMW ("*AstraZeneca v. Teva Second Wave*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA, INC.*, C.A. No. 1:16-cv-00894-RMB-KMW ("*AstraZeneca v. InnoPharma Inc.*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA LICENSING LLC*, C.A. No. 1:16-cv-01962-RMB-KMW ("*AstraZeneca v. InnoPharma Licensing*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN INSTITUTIONAL LLC*, C.A. No. 1:16-cv-04612-RMB-KMW ("*AstraZeneca v. Mylan Institutional*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.*, C.A. No. 1:17-cv-00926-RMB-KMW ("*AstraZeneca v. Dr. Reddy's*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AMNEAL PHARMACEUTICALS LLC*, C.A. No. 1:17-cv-01968-RMB-KMW ("*AstraZeneca v. Amneal*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. HBT LABS, INC.*, C.A. No. 1:17-cv-02652-RMB-KMW ("*AstraZeneca v. HBT*")

- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. TEVA PHARMACEUTICALS USA, INC.*, C.A. No. 1:17-cv-02448-RMB-KMW ("*AstraZeneca v. Teva*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. FRESENIUS KABI USA, LLC*, C.A. No. 1:17-cv-13075-RMB-KMW ("*AstraZeneca v. Fresenius*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. APOTEX INC. and APOTEX CORP.*, C.A. No. 1:18-cv-11238-RMB-KMW ("*AstraZeneca v. Apotex*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. ACCORD HEALTHCARE, INC.*, C.A. No. 1:18-cv-12051-RMB-KMW ("*AstraZeneca v. Accord*")

The foregoing cases involve AstraZeneca's FASLODEX® (fulvestrant) intramuscular injection product. The FASLODEX® (fulvestrant) intramuscular injection cases have been assigned to Hon. Renée M. Bumb, U.S.D.J. The *AstraZeneca v. Sandoz*, *AstraZeneca v. Sagent*, and *AstraZeneca v. Glenmark* cases were consolidated by Judge Bumb under lead case, *AstraZeneca Pharms. LP, et al. v. Sandoz Inc., et al.*, Civ. No. 14-cv-03547. The *AstraZeneca v. Agila*, *AstraZeneca v. Mylan*, *AstraZeneca v. Teva Second Wave*, *AstraZeneca v. Mylan Institutional*, and *AstraZeneca v. InnoPharma Licensing* cases were consolidated by Judge Bumb under Consolidated Case No. 1:15-cv-06039. To date, the following cases have been terminated: *AstraZeneca v. Sandoz*, *AstraZeneca v. Sagent*, *AstraZeneca v. Glenmark*, *AstraZeneca v. InnoPharma Inc.*, *AstraZeneca v. Agila*, *AstraZeneca v. Mylan*, *AstraZeneca v. Mylan Institutional*, *AstraZeneca v. Dr. Reddy's*, *AstraZeneca v. Teva Second Wave*, *AstraZeneca v. InnoPharma Licensing*, *AstraZeneca v. HBT*, *AstraZeneca v. Amneal*, *AstraZeneca v. Teva*, *AstraZeneca v. Fresenius*, *AstraZeneca v. Apotex*, and *AstraZeneca v. Accord*. Plaintiffs respectfully request that this case likewise be assigned to Judge Bumb due to her familiarity with the subject matter.

Dated: December 13, 2018

Respectfully submitted,

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