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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.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.

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 Mylan Pharmaceuticals Inc. ("Mylan Pharms"), Mylan Laboratories Limited ("Mylan Labs") and Mylan Inc. (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 2 Kingdom St, London W2 6BD, United Kingdom.

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 Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317. On information and belief, Mylan Inc. is the parent company of Mylan Labs and Mylan Pharms. On information and belief, Mylan Inc. is the parent company of Agila Specialties Inc. (formerly known as Strides Inc.) ("Agila") and Onco Therapies Limited ("Onco"). On information and belief, Agila is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 201 South Main Street, Suite 3, Lambertville, NJ 08530.

5. On information and belief, Mylan, Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

6. On information and belief, Mylan Pharms is primarily responsible for the marketing, distribution, and sales of Mylan Inc.'s products.

7. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc., and is an agent or affiliate of Mylan Labs. Mylan Pharms is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

8. On information and belief, Defendant Mylan Laboratories Limited is a wholly owned subsidiary of Mylan Inc., and is an agent or affiliate of Mylan Pharms. Mylan Labs is a corporation organized and existing under the laws of India, having its principal place of business at Opp. IIM, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka 560076, India.

9. On information and belief, Mylan Labs conducts business through and with Agila and/or Mylan Pharms. On information and belief, Mylan Labs, Agila and Mylan Pharms conduct business under the direction and on behalf of Mylan Inc.

10. On information and belief, Defendants acted in concert to develop the proposed generic product that is the subject of Abbreviated New Drug Application ("ANDA") No. 207640, and to seek regulatory approval from the U.S. Food and Drug Administration ("FDA") to market and sell the proposed ANDA product throughout the United States, including within this District.

11. On information and belief, Defendants, with or through Agila and Onco, participated in the preparation and/or filing of Defendants' ANDA No. 207640.

12. On information and belief, Agila originally filed with the FDA, pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), ANDA No. 207640 concerning the Proposed ANDA Product, which was assembled and caused to be filed by Onco. Agila originally submitted to the FDA ANDA No. 207640 on behalf of Onco, and was the U.S. registered agent for Onco with respect to ANDA No. 207640. On information and

belief, Mylan Pharms is now the U.S. registered agent for Mylan Labs with respect to Defendants' ANDA No. 207640.

NATURE OF THE ACTION

13. 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' ANDA No. 207640, filed with the FDA seeking approval to engage in the commercial manufacture, use and sale of fulvestrant injection, 50 mg/mL (the "Proposed ANDA Product"), which is a generic version of AstraZeneca's FASLODEX® (fulvestrant) 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

14. 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.

15. This Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of New Jersey and this District.

16. On information and belief, Defendants collaborate to market and sell generic pharmaceutical products, pursuant to the Abbreviated New Drug Application process, 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. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

17. This Court has personal jurisdiction over Mylan Inc. 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, Mylan Inc: (1) is registered with the State of New Jersey Division of Revenue and Enterprise Services and maintains a Business Registration Certificate under entity identification number 0100971292; (2) is registered with the New Jersey Department of Health Food and Drug Safety Program as a manufacturer and wholesale drug establishment and maintains a Drug and Medical Device Certificate of Registration under the trade name Mylan Pharmaceuticals Inc. and parent company name Mylan Inc. under Registration No. 5003762; (3) intentionally markets and provides its generic pharmaceutical products to residents of this State; (4) enjoys substantial income from this State; and (5) maintains a physical presence within this State at least through its wholly-owned subsidiary, Agila Specialties Inc. (formerly known as Strides Inc.). On information and belief, Mylan Inc.'s subsidiary, Agila, is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 201 South Main Street, Suite 3, Lambertville, NJ 08530. On information and belief, Agila originally submitted to the FDA ANDA No. 207640 on behalf of Onco, and was the U.S. registered agent for Onco with respect to ANDA No. 207640. On information and belief, Agila maintains its principal place of business in this State and is registered with the New Jersey Department of Treasury under entity identification number 0100791546. Agila has previously submitted to personal jurisdiction in this judicial district. *See Baxter Healthcare Corp. et al. v. Agila Specialties Private Ltd. et al*., C.A. No. 14-07094-FSH-MAH (D.N.J.), at D.I. 16.

18. On information and belief, Mylan Inc., directly or through its subsidiaries including Mylan Pharms, Mylan Labs, and Agila, manufactures, imports, markets, and sells

generic drugs throughout the United States and in this judicial district. According to Mylan Inc.'s 2014 10-K Report, Mylan Inc. "holds the number one ranking in the U.S. generics prescription market in terms of sales and the number two ranking in terms of prescriptions dispensed. Approximately one in every 13 prescriptions dispensed in the U.S. is a Mylan [Inc.] product. . . . In the U.S., [Mylan Inc. has] one of the largest product portfolios among all generic pharmaceutical companies, consisting of approximately 360 products . . . ."

19. This Court has personal jurisdiction over Mylan Pharms 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, Mylan Pharms: (1) is registered with the State of New Jersey Division of Revenue and Enterprise Services and maintains a Business Registration Certificate under entity identification number 0100214277; (2) is registered with the New Jersey Department of Health Food and Drug Safety Program as a manufacturer and wholesale drug establishment and maintains a Drug and Medical Device Certificate of Registration under the trade name Mylan Pharmaceuticals Inc. and parent company name Mylan Inc. under Registration No. 5003762; (3) intentionally markets and provides its generic pharmaceutical products to residents of this State; and (4) enjoys substantial income from this State. On information and belief, Agila originally submitted to the FDA ANDA No. 207640 on behalf of Onco, and was the U.S. registered agent for Onco with respect to ANDA No. 207640. On information and belief, Mylan Pharms is now the U.S. registered agent for Mylan Labs with respect to Defendants' ANDA No. 207640.

20. This Court has personal jurisdiction over Mylan Labs 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.

By letter dated September 8, 2015 (the "Notice Letter"), sent on behalf of Mylan Pharms, on behalf of Mylan Labs, Mylan Pharms notified AstraZeneca that it informed the FDA that the applicant for ANDA No. 207640 "was changed from Onco Therapies Limited to Mylan Laboratories Limited, and that the U.S. contact was changed from Agila Specialties Inc. to Mylan Pharmaceuticals Inc." On information and belief, Mylan Labs conducts business through and with Agila, Onco Therapies Limited ("Onco"), Mylan Pharms and Mylan Inc. On information and belief, Onco assembled and caused Agila to file with the FDA, pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), ANDA No. 207640 concerning the Proposed ANDA Product. On information and belief, Agila originally submitted to the FDA ANDA No. 207640 on behalf of Onco, and was the U.S. registered agent for Onco with respect to ANDA No. 207640. On information and belief, Mylan Pharms is now the U.S. registered agent for Mylan Labs with respect to Defendants' ANDA No. 207640.

21. Upon information and belief, Defendants intend to manufacture for distribution and distribute and sell generic equivalents of AstraZeneca's FASLODEX® (fulvestrant injection) product throughout the United States and in this judicial district.

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

THE PATENTS-IN-SUIT

23. 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.

24. 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.

25. 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.

26. 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 injection)

27. FASLODEX® (fulvestrant injection) is an estrogen receptor antagonist approved by the FDA for the treatment of hormone receptor positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

28. AstraZeneca UK Limited is the holder of approved New Drug Application ("NDA") No. 21-344 for FASLODEX® (fulvestrant 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.

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

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

DEFENDANTS' ANDA

31. By the Notice Letter dated September 8, 2015, sent on behalf of Mylan Pharms, on behalf of Mylan Labs, Defendant Mylan Pharms notified AstraZeneca that Defendants' ANDA No. 207640, originally submitted to the FDA by Agila on behalf of Onco, sought 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. 207640 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, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product. By the Notice Letter, Defendant Mylan Pharms also notified AstraZeneca that it informed the FDA that the applicant for ANDA No. 207640 "was changed from Onco Therapies Limited to Mylan Laboratories Limited, and that the U.S. contact was changed from Agila Specialties Inc. to Mylan Pharmaceuticals Inc."

32. On information and belief, Agila originally submitted to the FDA ANDA No. 207640 on behalf of Onco, and was the U.S. registered agent for Onco with respect to ANDA

No. 207640. On information and belief, Mylan Pharms is now the U.S. registered agent for Mylan Labs with respect to Defendants' ANDA No. 207640.

33. On information and belief, Defendants were necessarily aware of the Patents-in-Suit when ANDA No. 207640 was filed with a Paragraph IV Certification.

34. The Notice Letter contained no allegations that the Claims of the '122, '160, '680 and '139 Patents are not infringed by the Proposed ANDA Product.

35. On information and belief, ANDA No. 207640 refers to and relies upon the FASLODEX® (fulvestrant injection) NDA and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and FASLODEX® (fulvestrant injection).

36. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for FASLODEX® (fulvestrant injection), including instructions for administering the Proposed ANDA Product by intramuscular injection to treat 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.

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

37. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 36 of this Complaint.

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

39. Defendants' submission of ANDA No. 207640 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).

40. 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. 207640 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

41. 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).

42. Upon FDA approval of ANDA No. 207640, 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).

43. On information and belief, Defendants had knowledge of the '122 Patent when they submitted ANDA No. 207640 to the FDA and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '122 Patent.

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

45. Defendants have knowledge of the '122 Patent and are knowingly and willfully infringing the '122 Patent.

46. 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.

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

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

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

50. 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. 207640 is approved.

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

51. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 50 of this Complaint.

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

53. Defendants' submission of ANDA No. 207640 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).

54. 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. 207640 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

55. 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).

56. Upon FDA approval of ANDA No. 207640, 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).

57. On information and belief, Defendants had knowledge of the '160 Patent when they submitted ANDA No. 207640 to the FDA and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '160 Patent.

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

59. Defendants have knowledge of the '160 Patent and are knowingly and willfully infringing the '160 Patent.

60. 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.

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

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

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

64. 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. 207640 is approved.

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

65. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 64 of this Complaint.

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

67. Defendants' submission of ANDA No. 207640 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).

68. 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. 207640 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

69. 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).

70. Upon FDA approval of ANDA No. 207640, 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).

71. On information and belief, Defendants had knowledge of the '680 Patent when Defendants submitted ANDA No. 207640 to the FDA and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '680 Patent.

72. The Notice Letter lacks any legal or factual basis for non-infringement of any Claims of the '680 Patent.

73. Defendants have knowledge of the '680 Patent and are knowingly and willfully infringing the '680 Patent.

74. 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.

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

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

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

78. 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. 207640 is approved.

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

79. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 78 of this Complaint.

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

81. Defendants' submission of ANDA No. 207640 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).

82. 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. 207640 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

83. 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).

84. Upon FDA approval of ANDA No. 207640, 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).

85. On information and belief, Defendants had knowledge of the '139 Patent when they submitted ANDA No. 207640 to the FDA and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '139 Patent.

86. The Notice Letter lacks any legal or factual basis for non-infringement of any Claims of the '139 Patent.

87. Defendants have knowledge of the '139 Patent and are knowingly and willfully infringing the '139 Patent.

88. 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.

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

90. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 89 of this Complaint.

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

92. 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. 207640 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. 207640 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 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. 207640 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: September 21, 2015

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 LTD., GLENMARK GENERICS LTD., and 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

The foregoing cases involve FASLODEX® (fulvestrant) injection, a product marketed by AstraZeneca that contains a fulvestrant formulation. The FASLODEX® (fulvestrant) injection cases have been assigned to Hon. Renee M. Bumb, U.S.D.J. On May 7, 2015, the *AstraZeneca v. Sandoz*, *AstraZeneca v. Sagent*, and *AstraZeneca v. Glenmark* cases were consolidated by Judge Bumb as Consolidated Case No. 1:14-cv-03547-RMB-KMW. Plaintiffs respectfully request that this case likewise be assigned to Judge Bumb due to her familiarity with the subject matter.

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Respectfully submitted,

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