IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC. Defendants.	Civil Action No. 1:15-cv-183 (Keeley) Electronically filed: October 15, 2015

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").

NATURE OF THE ACTION

1. 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.

THE PARTIES

2. 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.

3. 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.

4. 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.

5. 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").

6. 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.

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

9. 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.

10. 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.

11. 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.

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

13. 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.

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 West Virginia 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 West Virginia, 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 West Virginia law, and its substantial, continuous, and systematic contacts with the State of West Virginia. On information and belief, Mylan Inc: (1) is registered with the State of West Virginia Secretary of State as a Foreign Corporation, Business Purpose 3254 - Manufacturing - Chemical Manufacturing - Pharmaceutical and Medicine Manufacturing (in-Vitro diagnostic) and maintains Organization Identification Number 230499; (2) maintains an agent in the State of West Virginia for service of process; (3) files an Annual Report in the State of West Virginia every year from at least 2005-2015; (4) intentionally markets and provides its generic pharmaceutical products to residents of this State; (5) enjoys substantial income from this State;

and (6) maintains a physical presence within this State through its wholly-owned subsidiaries, including Mylan Pharms and Mylan Technologies, Inc.

18. On information and belief, Mylan Inc., directly or through its subsidiaries including Mylan Pharms, Mylan Labs, and Mylan Technologies, Inc., 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 West Virginia law, and its substantial, continuous, and systematic contacts with the State of West Virginia. On information and belief, Mylan Pharms: (1) has its principal office in the State of West Virginia at 781 Chestnut Ridge Road, Morgantown, WV, 26505; (2) is registered with the State of West Virginia Secretary of State as a Domestic Corporation, Business Purpose 3254 - Manufacturing - Chemical Manufacturing - Pharmaceutical and Medicine Manufacturing (in-Vitro diagnostic) and maintains Organization Identification Number 20402; (3) maintains an agent in the State of West Virginia for service of process; (4) files an Annual Report in the State of West Virginia every year from at least 1992-present; (5) intentionally markets and provides its generic pharmaceutical products to residents of this State; and (6) enjoys substantial income from this State.

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

21. 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 West Virginia law, and its substantial, continuous, and systematic contacts with the State of West Virginia. 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, 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.

22. 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.

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

24. On September 21, 2015, Plaintiffs filed a complaint against Defendants for patent infringement in the United States District Court for the District of New Jersey. The resulting

action, Civ. Action No. 1: l 5-cv-07009-RMB-KMW ("the New Jersey FASLODEX® Action") is presently pending. A copy of the complaint in the New Jersey FASLODEX® Action, excluding exhibits, is attached hereto as Exhibit A. The New Jersey complaint alleges essentially the same acts of infringement as the present complaint.

25. Based on Defendants' continuous and systematic business contacts with New Jersey, they should be subject to personal jurisdiction in the District of New Jersey; however, Defendants may assert that they are not subject to such jurisdiction.

26. Plaintiffs are therefore filing the instant complaint, which has identical infringement claims against Defendants as the New Jersey FASLODEX® Action, a so-called Hatch-Waxman "protective suit," to preserve their right for a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

THE PATENTS-IN-SUIT

27. 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 Exhibit B.

28. 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 Exhibit C.

29. 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 Exhibit D.

30. 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 Exhibit E.

FACTUAL BACKGROUND

FASLODEX® (fulvestrant) injection

31. 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.

32. 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.

33. 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."

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

DEFENDANTS' ANDA

35. 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."

36. 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.

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

38. 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.

39. 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).

40. 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

41. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 40 of this Complaint.

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

43. 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).

44. 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.

45. 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).

46. 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).

47. 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.

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

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

50. 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.

51. 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

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

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

54. 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

55. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 54 of this Complaint.

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

57. 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).

58. 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.

59. 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).

60. 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).

61. 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.

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

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

64. 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.

65. 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

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

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

68. 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

69. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 68 of this Complaint.

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

71. 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).

72. 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.

73. 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).

74. 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).

75. 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.

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

77. Defendants have knowledge of the ’680 Patent and are knowingly and willfully infringing the ’680 Patent.

78. 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.

79. 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

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

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

82. 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

83. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 82 of this Complaint.

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

85. 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).

86. 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.

87. 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).

88. 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).

89. 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.

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

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

92. 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.

93. 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

94. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 93 of this Complaint.

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

96. 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: October 15, 2015

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, AND ASTRAZENECA AB,

Plaintiffs,

BY COUNSEL:

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