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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. HBT LABS, INC., Defendant.	Civil Action 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 HBT Labs, Inc. ("Defendant" or "HBT").

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 HBT Labs, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 536 Vanguard Way, Brea, California 92821.

5. On information and belief, Defendant 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.

NATURE OF THE ACTION

6. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendant's ANDA No. 209714, filed with the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of Fulvestrant Injection, 250 mg/5 mL (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

7. 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.

8. On information and belief, this Court has personal jurisdiction over Defendant

because, *inter alia*, it has maintained or will maintain continuous and systematic contacts with the State of New Jersey and this District.

9. On information and belief, Defendant intentionally markets and sells 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 District, or by offering to sell and selling, or causing others to offer to sell or sell, generic pharmaceutical products. On information and belief, Defendant has or will derive substantial revenue from goods used or consumed or services rendered in this District. Furthermore, Defendant's Notice Letter reserves the right to rely upon any prior art or defenses that have been asserted in the various district court litigations commenced concerning the Patents-in-Suit, the majority of which were brought and/or are currently pending in this District.[1]

[1] The Hatch-Waxman litigations pending before the Hon. Renée Marie Bumb of the United States District Court of the District of New Jersey, and certified as related litigations in the HBT New Jersey Complaint under L. Civ. R. 11.2, are the following: *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"); 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.*

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

THE PATENTS-IN-SUIT

11. 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.

12. 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.

13. 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.

14. 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

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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"); and 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").

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

15. FASLODEX® (fulvestrant) intramuscular injection is an estrogen receptor antagonist approved by the FDA for the treatment of hormone receptor (HR)-positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy. FASLODEX® (fulvestrant) intramuscular injection is also approved by the FDA for the treatment of 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, which is subject to new indication exclusivity until February 19, 2019.

16. 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.

17. The use of FASLODEX® (fulvestrant) intramuscular 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."

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

DEFENDANT'S ANDA

19. By letter dated March 27, 2017 (the "Notice Letter"), Defendant HBT notified AstraZeneca that Defendant's ANDA No. 209714, submitted to the FDA by HBT, sought approval to engage in the commercial manufacture, use, sale and importation of the Proposed ANDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, and included within ANDA No. 209714 a certification pursuant to 21 U.S.C. § 505(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.

20. On information and belief, Defendant was necessarily aware of the Patents-in-Suit when ANDA No. 209714 was filed with a Paragraph IV Certification.

21. 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.

22. On information and belief, ANDA No. 209714 refers to and relies upon the FASLODEX® (fulvestrant) intramuscular injection NDA and contains data that, according to Defendant, 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 $ngml^{-1}$ for at least 4 weeks after injection.

23. On information and belief, the Proposed ANDA Product 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 receptor (HR)-positive metastatic breast cancer in humans. 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. Defendant HBT is 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. 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

24. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 23 of this Complaint.

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

26. Defendant's submission of ANDA No. 209714 under 21 U.S.C. § 505(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).

27. On information and belief, Defendant plans to, intends 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. 209714 and will direct physicians

and patients on the use of the Proposed ANDA Product through product labeling.

28. 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 one or more Claims of the '122 Patent under 35 U.S.C. § 271(a).

29. Upon FDA approval of ANDA No. 209714, Defendant will infringe one or more Claims of 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).

30. On information and belief, Defendant had knowledge of the '122 Patent when it submitted ANDA No. 209714 to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of one or more Claims of the '122 Patent.

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

32. Defendant has knowledge of the '122 Patent and is knowingly and willfully infringing the '122 Patent.

33. 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.

34. On information and belief, Defendant lacked a good faith basis for alleging non-infringement and invalidity of the '122 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant's 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

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

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

37. On information and belief, Defendant has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of one or more Claims of the '122 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 209714 is approved.

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

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

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

40. Defendant's submission of ANDA No. 209714 under 21 U.S.C. § 505(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).

41. On information and belief, Defendant plans to, intends 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. 209714 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

42. 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 one or more Claims of the '160 Patent under 35 U.S.C. § 271(a).

43. Upon FDA approval of ANDA No. 209714, Defendant will infringe one or more Claims of 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).

44. On information and belief, Defendant had knowledge of the '160 Patent when it submitted ANDA No. 209714 to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of one or more Claims of the '160 Patent.

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

46. Defendant has knowledge of the '160 Patent and is knowingly and willfully infringing the '160 Patent.

47. 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.

48. On information and belief, Defendant lacked a good faith basis for alleging non-infringement and invalidity of the '160 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant's 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

49. Plaintiffs hereby reallege and incorporate by reference the allegations of

paragraphs 1 – 48 of this Complaint.

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

51. On information and belief, Defendant has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of one or more Claims of the '160 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 209714 is approved.

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

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

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

54. Defendant's submission of ANDA No. 209714 under 21 U.S.C. § 505(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).

55. On information and belief, Defendant plans to, intends 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. 209714 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

56. 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 one or more Claims of the '680 Patent under 35 U.S.C. § 271(a).

57. Upon FDA approval of ANDA No. 209714, Defendant will infringe one or

more Claims of 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).

58. On information and belief, Defendant had knowledge of the '680 Patent when it submitted ANDA No. 209714 to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of one or more Claims of the '680 Patent.

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

60. Defendant has knowledge of the '680 Patent and is knowingly and willfully infringing the '680 Patent.

61. 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.

62. On information and belief, Defendant lacked a good faith basis for alleging non-infringement and invalidity of the '680 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant's 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

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

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

65. On information and belief, Defendant has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of one or more Claims of the '680 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 209714 is approved.

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

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

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

68. Defendant's submission of ANDA No. 209714 under 21 U.S.C. § 505(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).

69. On information and belief, Defendant plans to, intends 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. 209714 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

70. 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 one or more Claims of the '139 Patent under 35 U.S.C. § 271(a).

71. Upon FDA approval of ANDA No. 209714, Defendant will infringe one or more Claims of 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).

72. On information and belief, Defendant had knowledge of the '139 Patent when it submitted ANDA No. 209714 to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of one or more Claims of the '139 Patent.

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

74. Defendant has knowledge of the '139 Patent and is knowingly and willfully infringing the '139 Patent.

75. 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.

76. On information and belief, Defendant lacked a good faith basis for alleging non-infringement and invalidity of the '139 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant's 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

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

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

79. On information and belief, Defendant has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of one or more Claims of the '139 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 209714 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 Defendant's submission of ANDA No. 209714 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 Defendant's 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. 209714 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 Defendant, its affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendant, 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 Defendant is willful should Defendant 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: April 18, 2017

Respectfully submitted,

By: s/ John E. Flaherty

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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*")
- *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*")

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*, *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*, and *AstraZeneca v. Dr. Reddy's*. The following cases remain pending before Judge Bumb: *AstraZeneca v. Teva* and *AstraZeneca v. InnoPharma Licensing* (continuing under lead case, *AstraZeneca Pharms. LP, et al. v. Agila Specialties, Inc., et al.*, Civ. No. 15-cv-06039 (Consolidated)), and *AstraZeneca v. Amneal* (Civ. No. 1:17-cv-01968). Plaintiffs respectfully request that this case likewise be assigned to Judge Bumb due to her familiarity with the subject matter.

Dated: April 18, 2017

Respectfully submitted,

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