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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.

TEVA PHARMACEUTICALS USA, INC. and  
TEVA PHARMACEUTICAL INDUSTRIES  
LTD.,

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 Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Defendants" or "Teva").

**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 Teva USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd., and is an agent or affiliate of Teva Ltd.

5. On information and belief, Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petah Tikva, Israel.

6. On information and belief, Defendants are 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, Defendants acted in concert to develop the proposed generic product that is the subject of Abbreviated New Drug Application (“ANDA”) No. 208640, 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. On information and belief, Teva USA's preparation and submission of ANDA No. 208640 was done collaboratively with, and at least in part for the benefit of, Teva Ltd.

#### **NATURE OF THE ACTION**

8. 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. 208640, filed with the FDA seeking approval to engage in the commercial manufacture, use and sale of fulvestrant injection, 50 mg/mL, 5mL pre-filled syringes (the "Proposed ANDA Product"), which is a generic version of AstraZeneca's FASLODEX<sup>®</sup> (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**

9. 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.

10. 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.

11. 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.

12. This Court has personal jurisdiction over Teva USA 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, Teva USA: (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 0100250184; (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 Registration No. 5000583; (3) is registered with the New Jersey Department of Health Food and Drug Safety Program as a wholesale drug establishment and maintains a Drug and Medical Device Certificate of Registration under Registration No. 5003436; (4) intentionally markets and provides its generic pharmaceutical products to residents of this State; and (5) enjoys substantial income from this State. On information and belief, Teva USA is the U.S. registered agent for Defendants with respect to Defendants' ANDA No. 208640.

13. This Court has personal jurisdiction over Teva Ltd. 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, Teva Ltd.: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; and (3) maintains a physical presence within this State at least through its wholly-owned subsidiary Teva API, Inc. ("Teva API") and through its 142,000 square foot facility location in

Montvale, New Jersey. On information and belief, Teva Ltd.'s subsidiary, Teva API, is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. On information and belief, Teva API maintains its principal place of business in this State and is registered with the New Jersey Department of Treasury under identification number 0100026877. On information and belief, Teva Ltd. is a DMF holder for fulvestrant, the active ingredient in AstraZeneca's FASLODEX<sup>®</sup> (fulvestrant injection) and Defendants' Proposed ANDA Product, and Teva API is the U.S. registered agent for Teva Ltd. for matters related to its DMF for fulvestrant.

14. On information and belief, Teva Ltd., directly or through its subsidiaries including Teva USA and Teva API, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district. According to Teva Ltd.'s 2014 20-F Report, Teva Ltd. "the world's leading generic medicines manufacturer, with a global portfolio of more than 1,000 molecules . . . provid[ing] medicines that treat millions of patients every day, around the world. [Teva Ltd.'s] generic business is ranked in leading positions in the United States and Europe . . . [and is] one of the world's leading manufacturers of APIs, with operations around the globe."

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

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

**THE PATENTS-IN-SUIT**

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

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

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

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

**FACTUAL BACKGROUND**

**FASLODEX<sup>®</sup> (fulvestrant injection)**

21. FASLODEX<sup>®</sup> (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.

22. AstraZeneca UK Limited is the holder of approved New Drug Application (“NDA”) No. 21-344 for FASLODEX<sup>®</sup> (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.

23. The use of FASLODEX<sup>®</sup> (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.”

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

**DEFENDANTS’ ANDA**

25. By the Notice Letter dated October 22, 2015, Defendant Teva USA notified AstraZeneca that Defendants’ ANDA No. 208640, submitted to the FDA by Teva USA, 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. 208640 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.

26. On information and belief, Defendants were necessarily aware of the Patents-in-Suit when ANDA No. 208640 was filed with a Paragraph IV Certification.

27. 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.

28. On information and belief, ANDA No. 208640 refers to and relies upon the FASLODEX<sup>®</sup> (fulvestrant injection) NDA and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and FASLODEX<sup>®</sup> (fulvestrant injection).

29. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for FASLODEX<sup>®</sup> (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**

30. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 29 of this Complaint.

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



32. Defendants' submission of ANDA No. 208640 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).

33. 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. 208640 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

34. 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).

35. Upon FDA approval of ANDA No. 208640, 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).

36. On information and belief, Defendants had knowledge of the '122 Patent when they submitted ANDA No. 208640 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.

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

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

39. 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.

40. 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**

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

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

43. 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. 208640 is approved.

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

44. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 43 of this Complaint.

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

46. Defendants' submission of ANDA No. 208640 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).

47. 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. 208640 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

48. 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).

49. Upon FDA approval of ANDA No. 208640, 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).

50. On information and belief, Defendants had knowledge of the '160 Patent when they submitted ANDA No. 208640 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.

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

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

53. 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.

54. 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**

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

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

57. 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. 208640 is approved.

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

58. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 57 of this Complaint.

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

60. Defendants' submission of ANDA No. 208640 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).

61. 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. 208640 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

62. 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).

63. Upon FDA approval of ANDA No. 208640, 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).

64. On information and belief, Defendants had knowledge of the '680 Patent when Defendants submitted ANDA No. 208640 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.

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

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

67. 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.

68. 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**

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

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

71. 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. 208640 is approved.

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

72. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 71 of this Complaint.

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

74. Defendants' submission of ANDA No. 208640 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).

75. 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. 208640 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

76. 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).

77. Upon FDA approval of ANDA No. 208640, 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).

78. On information and belief, Defendants had knowledge of the '139 Patent when they submitted ANDA No. 208640 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.

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

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

81. 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.

82. 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**

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

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

85. 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. 208640 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. 208640 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. 208640 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: November 3, 2015

Respectfully submitted,

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AstraZeneca UK Limited, and  
AstraZeneca AB*

**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 (“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”)*

The foregoing cases involve FASLODEX<sup>®</sup> (fulvestrant) injection, a product marketed by AstraZeneca that contains a fulvestrant formulation. The FASLODEX<sup>®</sup> (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.

Dated: November 3, 2015

Respectfully submitted,

By: s/John E. Flaherty

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