John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB.

OF COUNSEL:

Lisa B. Pensabene
Filko Prugo
Will C. Autz
O'MELVENY & MYERS LLP
7 Times Square
New York, NY 10036
(212) 326-2000

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

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs, v. SANDOZ INC. and SANDOZ INTERNATIONAL GMBH, Defendants.	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 Defendants Sandoz Inc. and Sandoz International GmbH (collectively "Defendants" or "Sandoz").

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 Sandoz Inc. is a corporation organized and existing under the laws of the state of Colorado, with a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

5. On information and belief, Defendant Sandoz International GmbH is a German corporation with a principal place of business at Industriestrasse 25, Holzkirchen 83607, Germany.

6. On information and belief, Defendant Sandoz Inc. is in the business of manufacturing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district, and is registered to distribute drugs in the State of New Jersey.

7. On information and belief, Defendant Sandoz Inc. is a subsidiary of Defendant Sandoz International GmbH, and the two companies have at least one common officer and/or director.

8. On information and belief, Defendant Sandoz Inc. is the United States arm of Defendant Sandoz International GmbH.

9. On information and belief, Defendant Sandoz International GmbH conducts its United States business operations, in part, through Defendant Sandoz Inc.

10. On information and belief, Defendant Sandoz Inc. is controlled and/or dominated by Defendant Sandoz International GmbH.

11. On information and belief, the acts of Defendant Sandoz Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation and awareness of, and at least in part for the benefit of, Defendant Sandoz International GmbH.

NATURE OF THE ACTION

12. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of the filing by Sandoz Inc. of Abbreviated New Drug Application ("ANDA") No. 205935 with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use and sale of its Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) product ("Sandoz's 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

13. 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.

14. This Court has personal jurisdiction over Sandoz Inc. because of its continuous and systematic contacts with this State. On information and belief, Sandoz Inc.: (1) maintains its principal place of business in this State; (2) is registered to do business in this State; (3) intentionally markets and provides its generic pharmaceutical products to residents of this State; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales in this State. Moreover, Sandoz Inc. has previously submitted to personal jurisdiction in this judicial district.

15. This Court has personal jurisdiction over Sandoz International GmbH by virtue of, *inter alia*, its direction and control of the business of Sandoz Inc., through which it conducts business in this State, purposefully avails itself of the rights and benefits of New Jersey law, and has substantial and continuing contacts within this State. On information and belief, Sandoz International GmbH directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Sandoz Inc., throughout the United States and in this State, and this State is a likely destination for Sandoz's ANDA Product.

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

THE PATENTS-IN-SUIT

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

18. United States Patent No. 7,456,160 (the "'160 patent"), entitled "Formulation," was duly and legally issued on November 25, 2008 and will expire on January 9, 2021, with an

additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '160 patent. AstraZeneca UK Limited is the beneficial owner of the '160 patent. A copy of the '160 patent is attached as Appendix B.

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

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

FACTUAL BACKGROUND

FASLODEX® (fulvestrant injection)

21. 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.

22. 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.

23. 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."

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

SANDOZ'S ANDA

25. By letter dated April 21, 2014 (the "Notice Letter"), Sandoz Inc. notified AstraZeneca that it submitted to the FDA ANDA No. 205935 seeking approval to engage in the commercial manufacture, use and sale of Sandoz's ANDA Product prior to the expiration of the '122, '160, '680, and '139 patents, and included within its ANDA 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 Sandoz's ANDA Product.

26. On information and belief, Defendant Sandoz International GmbH knowingly encouraged, directed, and actively induced Defendant Sandoz Inc. to file ANDA No. 205935 with a Paragraph IV Certification.

27. On information and belief, Defendants were necessarily aware of the patents-in-suit when Sandoz Inc. filed ANDA No. 205935 with a Paragraph IV Certification.

28. The Notice Letter contained no allegations that the claims of the '122, '160, '680, and '139 patents are not infringed by Sandoz's ANDA Product.

29. On information and belief, Sandoz's ANDA No. 205935 refers to and relies upon the FASLODEX® (fulvestrant injection) NDA and contains data that, according to Sandoz,

demonstrate the bioequivalence of Sandoz's ANDA Product and FASLODEX® (fulvestrant injection).

30. On information and belief, Sandoz's ANDA Product will have instructions for use that substantially copy the instructions for FASLODEX® (fulvestrant injection), including instructions for administering Sandoz's ANDA Product by intramuscular injection to treat breast cancer. The instructions accompanying Sandoz's ANDA Product will induce and/or contribute others to use Sandoz's ANDA Product in the manner set forth in the instructions.

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

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

32. The use of Sandoz's ANDA Product is covered by one or more claims of the '122 patent.

33. Sandoz Inc.'s submission of ANDA No. 205935 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 Sandoz's 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).

34. 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 Sandoz's ANDA Product immediately upon approval of ANDA No. 205935 and will direct physicians and patients on the use of Sandoz's ANDA Product through product labeling.

35. Sandoz's 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).

36. Upon FDA approval of ANDA No. 205935, Defendants will infringe the '122 patent by making, using, offering to sell, selling, and/or importing Sandoz's 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).

37. On information and belief, Defendants had knowledge of the '122 patent when Sandoz Inc. submitted its ANDA 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.

38. The Notice Letter lacks any legal or factual basis for non-infringement of any claims of the '122 patent.

39. Defendants have knowledge of the '122 patent and are knowingly and willfully infringing the '122 patent.

40. 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.

41. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the '122 patent when it filed its Paragraph IV Certification. Accordingly, Sandoz Inc.'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

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

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

44. 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 Sandoz's ANDA No. 205935 is approved.

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

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

46. The use of Sandoz's ANDA Product is covered by one or more claims of the '160 patent.

47. Sandoz Inc.'s submission of ANDA No. 205935 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 Sandoz's 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).

48. 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 Sandoz's ANDA Product immediately upon approval of ANDA No. 205935 and will direct physicians and patients on the use of Sandoz's ANDA Product through product labeling.

49. On information and belief, Sandoz's 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).

50. Upon FDA approval of ANDA No. 205935, Defendants will infringe the '160 patent by making, using, offering to sell, selling, and/or importing Sandoz's 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).

51. On information and belief, Defendants had knowledge of the '160 patent when Sandoz Inc. submitted its ANDA 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.

52. The Notice Letter lacks any legal or factual basis for non-infringement of any claims of the '160 patent.

53. Defendants have knowledge of the '160 patent and are knowingly and willfully infringing the '160 patent.

54. 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.

55. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the '160 patent when it filed its Paragraph IV Certification. Accordingly, Sandoz Inc.'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

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

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

58. 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 Sandoz's ANDA No. 205935 is approved.

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

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

60. The use of Sandoz's ANDA Product is covered by one or more claims of the '680 patent.

61. Sandoz Inc.'s submission of ANDA No. 205935 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 Sandoz's 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).

62. 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 Sandoz's ANDA Product immediately upon approval of ANDA No. 205935 and will direct physicians and patients on the use of Sandoz's ANDA Product through product labeling.

63. On information and belief, Sandoz's 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).

64. Upon FDA approval of ANDA No. 205935, Defendants will infringe the '680 patent by making, using, offering to sell, selling, and/or importing Sandoz's 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).

65. On information and belief, Defendants had knowledge of the '680 patent when Sandoz Inc. submitted its ANDA 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.

66. The Notice Letter lacks any legal or factual basis for non-infringement of any claims of the ’680 patent.

67. Defendants had knowledge of the ’680 patent and are knowingly and willfully infringing the ’680 patent.

68. 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.

69. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the ’680 patent when it filed its Paragraph IV Certification. Accordingly, Sandoz Inc.’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

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

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

72. 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 Sandoz’s ANDA No. 205935 is approved.

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

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

74. The use of Sandoz's ANDA Product is covered by one or more claims of the '139 patent.

75. Sandoz Inc.'s submission of ANDA No. 205935 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 Sandoz's 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).

76. 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 Sandoz's ANDA Product immediately upon approval of ANDA No. 205935 and will direct physicians and patients on the use of Sandoz's ANDA Product through product labeling.

77. On information and belief, Sandoz's 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).

78. Upon FDA approval of ANDA No. 205935, Defendants will infringe the '139 patent by making, using, offering to sell, selling, and/or importing Sandoz's 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).

79. On information and belief, Defendants had knowledge of the '139 patent when Sandoz Inc. submitted its ANDA 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.

80. The Notice Letter lacks any legal or factual basis for non-infringement of any claims of the '139 patent.

81. Defendants have knowledge of the '139 patent and are knowingly and willfully infringing the '139 patent.

82. 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.

83. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the '139 patent when it filed its Paragraph IV Certification. Accordingly, Sandoz Inc.'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

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

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

86. 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 Sandoz's ANDA No. 205935 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 Sandoz Inc.'s submission of ANDA No. 205935 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 Sandoz's making, using, offering to sell, selling, or importing into the United States of Sandoz's 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 Sandoz's ANDA No. 205935 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 Sandoz, its affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Sandoz, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States Sandoz's 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 Sandoz is willful should Sandoz commercially manufacture, use, offer to sell, sell, or import into the United States Sandoz's 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: June 3, 2014

Respectfully submitted,

By: s/John E. Flaherty

John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys For Plaintiffs, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB

OF COUNSEL:

Lisa B. Pensabene
Filko Prugo
Will C. Autz
O'MELVENY & MYERS LLP
7 Times Square
New York, New York 10036
(212) 326-2000

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: June 3, 2014

Respectfully submitted,

By: s/John E. Flaherty

John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys For Plaintiffs, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB

OF COUNSEL:

Lisa B. Pensabene
Filko Prugo
Will C. Autz
O'MELVENY & MYERS LLP
7 Times Square
New York, New York 10036
(212) 326-2000