IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs, v. SAGENT PHARMACEUTICALS, INC. Defendant.	Civil Action No. 1:14-cv-07358 Judge: Magistrate Judge: **Complaint for Patent Infringement**

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 Defendant Sagent Pharmaceuticals, Inc. ("Defendant" or "Sagent").

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 Sagent is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 1901 N. Roselle Road, Ste. 700, Schaumburg, IL 60195.

5. On information and belief, Defendant Sagent 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 Illinois.

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 the filing by Sagent of Abbreviated New Drug Application ("ANDA") No. 205871 with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use and sale of its Fulvestrant Injection, 50 mg/mL, 5 mL syringes ("Sagent'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

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. This Court has personal jurisdiction over Sagent because of its continuous and systematic contacts with the State of Illinois and, in particular, this Judicial District. On

information and belief, Sagent: (1) maintains its principal place of business in Cook County, Illinois, within this Judicial District; (2) is registered with the Illinois Department of Financial & Professional Regulation as a licensed "Drug Distributor" (License No. 004003580); (3) intentionally markets and provides its generic pharmaceutical products to residents of this Judicial District; (4) maintains a broad distributorship network within this Judicial District; and (5) enjoys substantial income from sales in this Judicial District.

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

10. On September 2, 2014, Plaintiffs filed a complaint against Defendant Sagent for patent infringement in the United States District Court for the District of New Jersey. The resulting action, Civ. Action No. 1: l 4-cv-05539-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 Appendix A. The New Jersey complaint alleges essentially the same acts of infringement as the present complaint.

11. Based on Sagent's continuous and systematic business contacts with New Jersey, it should be subject to personal jurisdiction in the District of New Jersey; however, Sagent may assert that it is not subject to such jurisdiction.

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

THE PATENTS-IN-SUIT

13. 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 B.

14. 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 C.

15. 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 D.

16. 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 E.

FACTUAL BACKGROUND

FASLODEX® (fulvestrant injection)

17. 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.

18. 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.

19. 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."

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

SAGENT'S ANDA

21. By letter dated August 7, 2014 (the "Notice Letter"), Sagent notified AstraZeneca that it submitted to the FDA ANDA No. 205871 seeking approval to engage in the commercial manufacture, use and sale of Sagent'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 Sagent's ANDA Product.

22. On information and belief, Defendant was necessarily aware of the patents-in-suit when it filed ANDA No. 205871 with a Paragraph IV Certification.

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

24. On information and belief, Sagent's ANDA No. 205871 refers to and relies upon the FASLODEX® (fulvestrant injection) NDA and contains data that, according to Sagent,

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

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

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

26. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 25 of this Complaint.

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

28. Sagent's submission of ANDA No. 205871 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 Sagent'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).

29. 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 Sagent's ANDA Product immediately upon approval of ANDA No. 205871 and will direct physicians and patients on the use of Sagent's ANDA Product through product labeling.

30. Sagent'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).

31. Upon FDA approval of ANDA No. 205871, Defendant will infringe the '122 patent by making, using, offering to sell, selling, and/or importing Sagent'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).

32. On information and belief, Defendant had knowledge of the '122 patent when Sagent submitted its ANDA to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '122 patent.

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

34. Defendant has knowledge of the '122 patent and is knowingly and willfully infringing the '122 patent.

35. 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.

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

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

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

39. 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 the ’122 patent under 35 U.S.C. § 271(b) and/or § 271(c), after Sagent’s ANDA No. 205871 is approved.

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

40. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 39 of this Complaint.

41. The use of Sagent’s ANDA Product is covered by one or more claims of the ’160 patent.

42. Sagent’s submission of ANDA No. 205871 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 Sagent’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).

43. 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 Sagent’s ANDA Product immediately upon approval of ANDA No. 205871 and will direct physicians and patients on the use of Sagent’s ANDA Product through product labeling.

44. On information and belief, Sagent’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).

45. Upon FDA approval of ANDA No. 205871, Defendant will infringe the ’160 patent by making, using, offering to sell, selling, and/or importing Sagent’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).

46. On information and belief, Defendant had knowledge of the ’160 patent when Sagent submitted its ANDA to the FDA and Defendant knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’160 patent.

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

48. Defendant has knowledge of the ’160 patent and is knowingly and willfully infringing the ’160 patent.

49. 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.

50. On information and belief, Sagent lacked a good faith basis for alleging invalidity of the ’160 patent when it filed its Paragraph IV Certification. Accordingly, Sagent’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

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

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

53. 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 the ’160 patent under 35 U.S.C. § 271(b) and/or § 271(c), after Sagent’s ANDA No. 205871 is approved.

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

54. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 53 of this Complaint.

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

56. Sagent's submission of ANDA No. 205871 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 Sagent'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).

57. 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 Sagent's ANDA Product immediately upon approval of ANDA No. 205871 and will direct physicians and patients on the use of Sagent's ANDA Product through product labeling.

58. On information and belief, Sagent'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).

59. Upon FDA approval of ANDA No. 205871, Defendant will infringe the '680 patent by making, using, offering to sell, selling, and/or importing Sagent'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).

60. On information and belief, Defendant had knowledge of the '680 patent when Sagent submitted its ANDA to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '680 patent.

61. Defendant had knowledge of the ’680 patent and is knowingly and willfully infringing the ’680 patent.

62. 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.

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

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

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

66. 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 the ’680 patent under 35 U.S.C. § 271(b) and/or § 271(c), after Sagent’s ANDA No. 205871 is approved.

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

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

68. The use of Sagent’s ANDA Product is covered by one or more claims of the ’139 patent.

69. Sagent’s submission of ANDA No. 205871 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 Sagent'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).

70. 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 Sagent's ANDA Product immediately upon approval of ANDA No. 205871 and will direct physicians and patients on the use of Sagent's ANDA Product through product labeling.

71. On information and belief, Sagent'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).

72. Upon FDA approval of ANDA No. 205871, Defendant will infringe the '139 patent by making, using, offering to sell, selling, and/or importing Sagent'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).

73. On information and belief, Defendant had knowledge of the '139 patent when Sagent submitted its ANDA to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '139 patent.

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

75. Defendant has knowledge of the '139 patent and is knowingly and willfully infringing the '139 patent.

76. 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.

77. On information and belief, Sagent lacked a good faith basis for alleging invalidity of the ’139 patent when it filed its Paragraph IV Certification. Accordingly, Sagent’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

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

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

80. 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 the ’139 patent under 35 U.S.C. § 271(b) and/or § 271(c), after Sagent’s ANDA No. 205871 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 Sagent’s submission of ANDA No. 205871 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 Sagent’s making, using, offering to sell, selling, or importing into the United States of Sagent’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 Sagent’s ANDA No. 205871 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 Sagent, its affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Sagent, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States Sagent’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 Sagent is willful should Sagent commercially manufacture, use, offer to sell, sell, or import into the United States Sagent’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: September 22, 2014

Respectfully submitted,

s/ David C. Van Dyke

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