

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
AUROBINDO PHARMA LIMITED and)
AUROBINDO PHARMA USA, INC.,)
)
Defendants.)

COMPLAINT

Plaintiff AbbVie Inc. (“AbbVie”) by way of complaint against Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, “Aurobindo”) states as follows:

THE PARTIES

1. AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

AbbVie is a global biopharmaceutical company engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. On information and belief, Defendant Aurobindo Pharma Limited (“Aurobindo Limited”) is a corporation organized and existing under the laws of India having a registered office at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India, and having a principal place of business at Unit-VII, Sy.No. 411/P, 425/P, 434/P, 435/P & 458/P, Plot No. S1 (Part), SEZ (Pharma), APIIC, Green Industrial Park, Polepally, Mahaboob Nagar (DT), Jedcherla – 509 302, Andhra Pradesh, India.

3. On information and belief, Defendant Aurobindo Pharma USA, Inc. (“Aurobindo USA”) is a Delaware corporation having a registered office, or place of business, at 6 Wheeling

Road, Dayton, New Jersey 08810, and having a principal place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

4. On information and belief, Aurobindo USA is registered to transact business in Delaware and has appointed a registered agent for service of process (The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801).

5. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Limited.

6. On information and belief, Aurobindo USA holds a Pharmacy – Wholesale License from the State of Delaware under License No. A4-0001240.

7. On information and belief, Aurobindo USA holds a Distributor/Manufacturer CSR License from the State of Delaware under License No. DM-0006550.

NATURE OF THE ACTION

8. This is a civil action for patent infringement of U.S. Patent No. 7,148,359 B2 (“the ’359 Patent”), U.S. Patent No. 7,364,752 B1 (“the ’752 Patent”), U.S. Patent No. 8,399,015 B2 (“the ’015 Patent”), and U.S. Patent No. 8,691,878 B2 (“the ’878 Patent”), arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et. seq.*, and in particular 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application (“ANDA”) No. 206614, which Aurobindo filed or caused to be filed under 21 U.S.C. § 355(j) with the U.S. Food and Drug Administration (“FDA”), for approval to market a generic copy of AbbVie’s successful Norvir[®] (ritonavir) tablets that are sold in the United States.

JURISDICTION AND VENUE

9. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment

Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. On information and belief, this Court has personal jurisdiction over Aurobindo because of, among other things, its marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products in this judicial district, and the fact that it has availed itself of the rights afforded in this judicial district.

11. On information and belief, Aurobindo Limited develops, formulates, manufactures, imports, markets, and sells various generic pharmaceutical drug products, and regularly conducts business, throughout the United States, including in the State of Delaware, through various directly or indirectly-owned subsidiaries, including for example Aurobindo USA.

12. On information and belief, Aurobindo USA imports, markets, and sells various generic pharmaceutical drug products, and regularly conducts business, through the United States, including in the State of Delaware, for example on behalf of and at the direction of Aurobindo Limited.

13. On information and belief, Aurobindo has purposefully conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantially revenue.

14. Upon information and belief, Aurobindo Limited has, directly or through its agent Aurobindo USA, filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of the generic drug product described in ANDA No. 206614 in the United States, including Delaware.

15. Upon information and belief, Aurobindo USA has filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, on behalf of Aurobindo Limited for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic drug product described in ANDA No. 206614 in the United States, including Delaware.

16. On information and belief, Aurobindo will act in concert, and intends to offer to sell and sell in this judicial district, the generic drug product that will be manufactured as a result of any FDA approval of Aurobindo's ANDA No. 206614, and this judicial district is a likely destination of products that will be manufactured and sold as a result of any FDA approval of Aurobindo's ANDA No. 206614.

17. On information and belief, Aurobindo USA is qualified and registered to do business in the State of Delaware, has appointed a registered agent in Delaware, and holds current and valid "Pharmacy-Wholesale" and "Distributor/Manufacturer CSR" Licenses in Delaware.

18. On information and belief, Aurobindo Limited and/or Aurobindo USA have previously submitted to the jurisdiction of this Court and asserted counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this Court. *See, e.g.,* Answer at 5 & 16–23, *UCB, Inc. v. Aurobindo Pharma Ltd. & Aurobindo Pharma USA, Inc.*, No. 13-cv-1210 (D. Del. Oct. 4, 2013), ECF No. 14; Answer at 2–3 & 10–16, *Helsinn Healthcare S.A. v. Aurobindo Pharma Ltd.*, No. 13-cv-688 (D. Del. Nov. 1, 2013), ECF No. 19.

19. This Court also has personal jurisdiction over Aurobindo by virtue of the fact that, among other things, Aurobindo has committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to AbbVie, a Delaware corporation.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

21. AbbVie is the holder of approved New Drug Application (“NDA”) No. 22-417 for ritonavir tablets, which AbbVie markets and sells under the trademark Norvir[®]. AbbVie manufactures and sells Norvir[®] 100mg tablets in the United States under NDA No. 22-417.

22. Aurobindo filed with the FDA ANDA No. 206614 under 21 U.S.C. §355(j)(2)(B), seeking FDA approval to market ritonavir tablets 100mg (“Aurobindo’s generic ritonavir tablets”), which are generic copies of AbbVie’s Norvir[®] tablets.

23. Upon information and belief, Aurobindo’s ANDA No. 206614 seeks FDA approval of a pharmaceutical composition comprising ritonavir in a 100mg dosage strength.

24. Upon information and belief, Aurobindo’s ANDA No. 206614 seeks FDA approval to market Aurobindo’s generic ritonavir tablets in the United States.

25. On June 6, 2014, AbbVie received a letter on behalf of Aurobindo, dated June 5, 2014, purporting to be a “Notice of Paragraph IV Certification” for ANDA No. 206614 pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 314.94(a)(12)(A)(i)(4) and 314.95(a) (“Notice Letter”). Aurobindo’s Notice Letter notified AbbVie that Aurobindo had filed ANDA No. 206614, seeking approval to market Aurobindo’s generic ritonavir tablets prior to the expiration of the ’359, ’752, and ’015 Patents.

THE PATENTS-IN-SUIT

26. The '359 Patent was duly and legally issued by the U.S. Patent and Trademark Office ("USPTO") on December 12, 2006. AbbVie is the owner by assignment of the '359 Patent and has the right to sue for infringement thereof. AbbVie lists the '359 Patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 22-417, with an expiration date of January 19, 2020 (including pediatric exclusivity). The '359 Patent is currently the subject of a reexamination proceeding pending at the USPTO. A true and correct copy of the '359 Patent is attached as Exhibit A.

27. The '752 Patent was duly and legally issued by the USPTO on April 29, 2008. AbbVie is the owner by assignment of the '752 Patent and has the right to sue for infringement thereof. AbbVie lists the '752 Patent in the Orange Book for NDA No. 22-417, with an expiration date of May 10, 2021 (including pediatric exclusivity). The '752 Patent is currently the subject of a reexamination proceeding pending at the USPTO. A true and correct copy of the '752 Patent is attached as Exhibit B.

28. The '015 Patent was duly and legally issued by the USPTO on March 19, 2013. AbbVie is the owner by assignment of the '015 Patent and has the right to sue for infringement thereof. AbbVie lists the '015 Patent in the Orange Book for NDA No. 22-417, with an expiration date of February 25, 2025 (including pediatric exclusivity). A true and correct copy of the '015 Patent is attached as Exhibit C.

29. The '878 Patent was duly and legally issued by the USPTO on April 8, 2014. AbbVie is the owner by assignment of the '878 Patent and has the right to sue for infringement thereof. AbbVie lists the '878 Patent in the Orange Book for NDA No. 22-417, with an expiration date of February 25, 2025 (including pediatric exclusivity). A true and correct copy of the '878 Patent is attached as Exhibit D.

FIRST COUNT FOR PATENT INFRINGEMENT
U.S. PATENT NO. 7,148,359 B2

30. Paragraphs 1–29 are incorporated herein by reference.

31. On information and belief, Aurobindo filed ANDA No. 206614 in order to obtain approval to market Aurobindo’s generic ritonavir tablets in the United States prior to the expiration of the ’359 Patent. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the ’359 Patent are purportedly invalid and/or not infringed.

32. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 206614 seeking approval for the commercial marketing of Aurobindo’s generic ritonavir tablets before the expiration date of the ’359 Patent constitutes infringement of one or more claims of the ’359 Patent, either literally or under the doctrine of equivalents.

33. Upon FDA approval of ANDA No. 206614, Aurobindo will infringe one or more claims of the ’359 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Aurobindo’s generic ritonavir tablets, and by actively inducing others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 206614 shall be no earlier than the expiration date of the ’359 Patent and any additional periods of exclusivity.

34. The offering to sell, sale, making, and/or importation of Aurobindo’s generic ritonavir tablets would actively induce infringement of at least one of the claims of the ’359 Patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of AbbVie’s ’359 Patent, as evidenced by Aurobindo’s Notice Letter.

35. Aurobindo USA is jointly and severally liable for infringement of at least one claim of the ’359 Patent. On infringement and belief, Aurobindo USA participated in,

contributed to, aided, abetted, and/or induced the submission of ANDA No. 206614 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

36. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '359 Patent. Pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT
U.S. PATENT NO. 7,364,752 B1

37. Paragraphs 1–36 are incorporated herein by reference.

38. On information and belief, Aurobindo filed ANDA No. 206614 in order to obtain approval to market Aurobindo's generic ritonavir tablets in the United States prior to the expiration of the '752 Patent. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '752 Patent are purportedly invalid and/or not infringed.

39. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 206614 seeking approval for the commercial marketing of Aurobindo's generic ritonavir tablets before the expiration date of the '752 Patent constitutes infringement of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

40. Upon FDA approval of ANDA No. 206614, Aurobindo will infringe one or more claims of the '752 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Aurobindo's generic ritonavir tablets, and by actively inducing others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 206614 shall be no earlier than the expiration date of the '752 Patent and any additional periods of exclusivity.

41. On information and belief, Aurobindo knows and intends that medical practitioners will prescribe, and patients will take, Aurobindo's generic ritonavir tablets for which approval is sought in ANDA No. 206614 to treat HIV infection, and therefore will infringe at least one claim in the '752 Patent. The use of Aurobindo's generic ritonavir tablets in accordance with and as directed by Aurobindo's proposed labeling would infringe at least one claim of the '752 Patent.

42. On information and belief, Aurobindo had knowledge of the '752 Patent and, by its promotional activities and proposed package insert for Aurobindo's generic ritonavir tablets, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '752 Patent, either literally or under the doctrine of equivalents.

43. The offering to sell, sale, making, and/or importation of Aurobindo's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '752 Patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of AbbVie's '752 Patent, as evidenced by Aurobindo's Notice Letter.

44. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and actively inducing infringement of at least one claim of the '752 Patent. Pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

THIRD COUNT FOR PATENT INFRINGEMENT
U.S. PATENT NO. 8,399,015 B2

45. Paragraphs 1–44 are incorporated herein by reference.

46. On information and belief, Aurobindo filed ANDA No. 206614 in order to obtain approval to market Aurobindo's generic ritonavir tablets in the United States prior to the expiration of the '015 Patent. On information and belief, Aurobindo filed with the FDA,

pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '015 Patent are purportedly invalid and/or not infringed.

47. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 206614 seeking approval for the commercial marketing of Aurobindo's generic ritonavir tablets before the expiration date of the '015 Patent constitutes infringement of one or more claims of the '015 Patent, either literally or under the doctrine of equivalents.

48. Upon FDA approval of ANDA No. 206614, Aurobindo will infringe one or more claims of the '015 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Aurobindo's generic ritonavir tablets, and by actively inducing others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 206614 shall be no earlier than the expiration date of the '015 Patent and any additional periods of exclusivity.

49. The offering to sell, sale, making, and/or importation of Aurobindo's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '015 Patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of AbbVie's '015 Patent, as evidenced by Aurobindo's Notice Letter.

50. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '015 Patent. Pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

FOURTH COUNT FOR DECLARATORY JUDGMENT
AS TO THE '359 PATENT

51. Paragraphs 1–50 are incorporated herein by reference.

52. On information and belief, Aurobindo is actively seeking FDA approval to sell its generic ritonavir tablets labeled for the same indications, and the same dosage and methods of use, as the Norvir[®] product sold by AbbVie.

53. On information and belief, Aurobindo intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

54. The manufacture, importation, sale, and offer for sale of Aurobindo's generic ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '359 Patent, either literally or under the doctrine of equivalents.

55. Aurobindo's threatened actions in actively aiding, abetting, encouraging, and inducing sales of its generic ritonavir tablets would infringe one or more claims of the '359 Patent, either literally or under the doctrine of equivalents.

56. A case or controversy exists between AbbVie and Aurobindo regarding the infringement and validity of the '359 Patent.

57. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Aurobindo having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Aurobindo's threatened infringement of the '359 Patent.

58. AbbVie will be substantially and irreparably damaged and harmed if Aurobindo's threatened infringement is not enjoined. AbbVie does not have an adequate remedy at law.

FIFTH COUNT FOR DECLARATORY JUDGMENT
AS TO THE '752 PATENT

59. Paragraphs 1–58 are incorporated herein by reference.

60. On information and belief, Aurobindo is actively seeking FDA approval to sell its generic ritonavir tablets labeled for the same indications, and the same dosage and methods of use, as the Norvir[®] product sold by AbbVie.

61. On information and belief, Aurobindo intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

62. The manufacture, importation, sale, and offer for sale of Aurobindo's generic ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

63. The offering to sell, sale, making, and/or importation of Aurobindo's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '752 Patent, under the doctrine of equivalents.

64. On information and belief, Aurobindo knows and intends that medical practitioners will prescribe, and patients will take, Aurobindo's generic ritonavir tablets for which approval is sought in ANDA No. 206614 to treat HIV, and therefore will infringe at least one claim in the '752 Patent, under the doctrine of equivalents.

65. On information and belief, Aurobindo has knowledge of the '752 Patent and, by its promotional activities and proposed package insert for Aurobindo's generic ritonavir tablets, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '752 Patent, under the doctrine of equivalents.

66. On information and belief, Aurobindo intends to actively induce infringement of at least one claim of the '752 Patent.

67. Aurobindo's threatened actions in actively aiding, abetting, encouraging, and inducing sales of its generic ritonavir tablets would infringe one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

68. A case or controversy exists between AbbVie and Aurobindo regarding the infringement and validity of the '752 Patent.

69. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Aurobindo having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Aurobindo's threatened infringement of the '752 Patent.

70. AbbVie will be substantially and irreparably damaged and harmed if Aurobindo's threatened infringement is not enjoined. AbbVie does not have an adequate remedy at law.

SIXTH COUNT FOR DECLARATORY JUDGMENT
AS TO THE '015 PATENT

71. Paragraphs 1–70 are incorporated herein by reference.

72. On information and belief, Aurobindo is actively seeking FDA approval to sell its generic ritonavir tablets labeled for the same indications, and the same dosage and methods of use, as the Norvir[®] product sold by AbbVie.

73. On information and belief, Aurobindo intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

74. The manufacture, importation, sale, and offer for sale of Aurobindo's generic ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '015 Patent, either literally or under the doctrine of equivalents.

75. Aurobindo's threatened actions in actively aiding, abetting, encouraging, and inducing sales of its generic ritonavir tablets would infringe one or more claims of the '015 Patent, either literally or under the doctrine of equivalents.

76. A case or controversy exists between AbbVie and Aurobindo regarding the infringement and validity of the '015 Patent.

77. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Aurobindo having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Aurobindo's threatened infringement of the '015 Patent.

78. AbbVie will be substantially and irreparably damaged and harmed if Aurobindo's threatened infringement is not enjoined. AbbVie does not have an adequate remedy at law.

SEVENTH COUNT FOR DECLARATORY JUDGMENT
AS TO THE '878 PATENT

79. Paragraphs 1–78 are incorporated herein by reference.

80. On information and belief, Aurobindo is actively seeking FDA approval to sell its generic ritonavir tablets labeled for the same indications, and the same dosage and methods of use, as the Norvir[®] product sold by AbbVie.

81. On information and belief, Aurobindo filed ANDA No. 206614 in order to obtain approval to market Aurobindo's generic ritonavir tablets in the United States prior to the expiration of the '878 Patent.

82. On information and belief, Aurobindo intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

83. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 206614 seeking approval for the commercial marketing of Aurobindo's generic ritonavir tablets before the expiration date of the '878 Patent constitutes infringement of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

84. Upon FDA approval of ANDA No. 206614, Aurobindo will infringe one or more claims of the '878 Patent, under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Aurobindo's generic ritonavir tablets, and by actively inducing others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 206614 shall be no earlier than the expiration date of the '878 Patent and any additional periods of exclusivity.

85. The offering to sell, sale, making, and/or importation of Aurobindo's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '878 Patent, under the doctrine of equivalents.

86. On information and belief, Aurobindo knows and intends that medical practitioners will prescribe, and patients will take, Aurobindo's generic ritonavir tablets for which approval is sought in ANDA No. 206614 to treat HIV, and therefore will infringe at least one claim in the '878 Patent, under the doctrine of equivalents.

87. On information and belief, Aurobindo has knowledge of the '878 Patent and, by its promotional activities and proposed package insert for Aurobindo's generic ritonavir tablets, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '878 Patent, under the doctrine of equivalents.

88. The offering to sell, sale, making, and/or importation of Aurobindo's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '878 Patent, under the doctrine of equivalents.

89. On information and belief, Aurobindo intends to actively induce infringement of at least one claim of the '878 Patent.

90. Aurobindo's threatened actions in actively aiding, abetting, encouraging, and inducing sales of its generic ritonavir tablets would infringe one or more claims of the '878 Patent, under the doctrine of equivalents.

91. A case or controversy exists between AbbVie and Aurobindo regarding the infringement and validity of the '878 Patent.

92. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Aurobindo having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Aurobindo's threatened infringement of the '878 Patent.

93. AbbVie will be substantially and irreparably damaged and harmed if Aurobindo's threatened infringement is not enjoined. AbbVie does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that this Court enter judgment in its favor as follows:

1. declaring that, under 35 U.S.C. § 271(e)(2)(A), Aurobindo's submission to the FDA of ANDA No. 206614 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Aurobindo's generic ritonavir tablets before the expiration of the '359 Patent was an act of infringement of the '359 Patent;

2. declaring that Aurobindo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Aurobindo's generic ritonavir tablets would constitute infringement of the '359 Patent;

3. ordering that the effective date of any FDA approval or Aurobindo's generic ritonavir tablets shall be no earlier than the expiration date of the '359 Patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

4. enjoining Aurobindo, and all persons acting in concert with Aurobindo, from commercially manufacturing, using, offering for sale, or selling Aurobindo's generic ritonavir tablets within the United States, or importing into the United States Aurobindo's generic ritonavir tablets, until the expiration of the '359 Patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

5. enjoining Aurobindo, and all persons acting in concert with Aurobindo, from seeking, obtaining, or maintaining approval of ANDA No. 206614 until the expiration of the '359 Patent, and any additional periods of exclusivity;
6. declaring the '359 Patent to be valid and enforceable;
7. declaring that, under 35 U.S.C. § 271(e)(2)(A), Aurobindo's submission to the FDA of ANDA No. 206614 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Aurobindo's generic ritonavir tablets before the expiration of the '752 Patent was an act of infringement of the '752 Patent;
8. declaring that Aurobindo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Aurobindo's generic ritonavir tablets would constitute infringement of the '752 Patent;
9. ordering that the effective date of any FDA approval or Aurobindo's generic ritonavir tablets shall be no earlier than the expiration date of the '752 Patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);
10. enjoining Aurobindo, and all persons acting in concert with Aurobindo, from commercially manufacturing, using, offering for sale, or selling Aurobindo's generic ritonavir tablets within the United States, or importing into the United States Aurobindo's generic ritonavir tablets, until the expiration of the '752 Patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);
11. enjoining Aurobindo, and all persons acting in concert with Aurobindo, from seeking, obtaining, or maintaining approval of ANDA No. 206614 until the expiration of the '752 Patent, and any additional periods of exclusivity;
12. declaring the '752 Patent to be valid and enforceable;

13. declaring that, under 35 U.S.C. § 271(e)(2)(A), Aurobindo's submission to the FDA of ANDA No. 206614 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Aurobindo's generic ritonavir tablets before the expiration of the '015 Patent was an act of infringement of the '015 Patent;

14. declaring that Aurobindo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Aurobindo's generic ritonavir tablets would constitute infringement of the '015 Patent;

15. ordering that the effective date of any FDA approval or Aurobindo's generic ritonavir tablets shall be no earlier than the expiration date of the '015 Patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

16. enjoining Aurobindo, and all persons acting in concert with Aurobindo, from commercially manufacturing, using, offering for sale, or selling Aurobindo's generic ritonavir tablets within the United States, or importing into the United States Aurobindo's generic ritonavir tablets, until the expiration of the '015 Patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

17. enjoining Aurobindo, and all persons acting in concert with Aurobindo, from seeking, obtaining, or maintaining approval of ANDA No. 206614 until the expiration of the '015 Patent, and any additional periods of exclusivity;

18. declaring the '015 Patent to be valid and enforceable;

19. declaring that, under 35 U.S.C. § 271(e)(2)(A), Aurobindo's submission to the FDA of ANDA No. 206614 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Aurobindo's generic ritonavir tablets before the expiration of the '878 Patent was an act of infringement of the '878 Patent;

20. declaring that, by Aurobindo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Aurobindo's generic ritonavir tablets, Aurobindo will induce infringement of the '878 Patent;

21. ordering that the effective date of any FDA approval or Aurobindo's generic ritonavir tablets shall be no earlier than the expiration date of the '878 Patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

22. enjoining Aurobindo, and all persons acting in concert with Aurobindo, from commercially manufacturing, using, offering for sale, or selling Aurobindo's generic ritonavir tablets within the United States, or importing into the United States Aurobindo's generic ritonavir tablets, until the expiration of the '878 Patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

23. enjoining Aurobindo, and all persons acting in concert with Aurobindo, from seeking, obtaining, or maintaining approval of ANDA No. 206614 until the expiration of the '878 Patent, and any additional periods of exclusivity;

24. declaring the '878 Patent to be valid and enforceable;

25. declaring this to be an exceptional case and awarding AbbVie its attorney fees under 35 U.S.C. §285;

26. awarding AbbVie its costs and expenses in this Action;

27. awarding AbbVie any further and additional relief as this Court deems just and proper.

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