IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIONOGI & CO., LTD., HOFFMANN-LA ROCHE INC., and GENENTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
NORWICH PHARMACEUTICALS, INC. and ALVOGEN PB RESEARCH & DEVELOPMENT LLC,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Shionogi & Co., Ltd. ("Shionogi"), Hoffmann-La Roche Inc. ("HLR"), and Genentech, Inc. ("Genentech") (collectively, "Plaintiffs") bring this action for patent infringement against Norwich Pharmaceuticals, Inc. ("Norwich") and Alvogen PB Research & Development LLC ("Alvogen") (collectively, "Defendants").

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 217449, filed by and for the benefit of Defendants with the United States Food and Drug Administration ("FDA"). Through ANDA No. 217449, Defendants seek approval to market generic versions of 40 mg and 80 mg XOFLUZA® (baloxavir marboxil) tablets, for oral use (the "Proposed ANDA Products"), prior to the expiration of U.S. Patent Nos. 8,927,710 ("the '710 Patent"), 8,987,441 ("the '441 Patent"), 9,815,835 ("the '835 Patent"), 10,392,406 ("the '406 Patent"), 10,633,397 ("the '397 Patent"), 10,759,814 ("the

’814 Patent”), 11,261,198 (“the ’198 Patent”), and 11,306,106 (“the ’106 Patent”) (collectively, “the Patents-in-Suit”).

THE PARTIES

2. Plaintiff Shionogi is a corporation organized and existing under the laws of Japan, having a principal place of business in Osaka, Japan.

3. Plaintiff HLR is a corporation organized and existing under the laws of New Jersey, having a principal place of business in Little Falls, New Jersey.

4. Plaintiff Genentech is a corporation organized and existing under the laws of Delaware, having a principal place of business in South San Francisco, California.

5. On information and belief, Defendant Norwich is a corporation organized and existing under the laws of Delaware, having a principal place of business at 6826 State Highway 12, Norwich, New York 13815.

6. On information and belief, Defendant Alvogen is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058.

7. On information and belief, Norwich and Alvogen are owned in their entirety by Alvogen Pharma US, Inc.

8. Defendants’ Notification Pursuant to Section 505(j)(2)(B)(iv), dated December 29, 2022 (“Notice Letter”) states that “Norwich has submitted . . . Abbreviated New Drug Application No. 217449.”

9. Defendants’ Notice Letter states that “Alvogen will provide confidential access to its application . . . ” and refers to “Alvogen’s Paragraph IV certification.”

10. Defendants' Notice Letter is signed by the Executive Director, Regulatory Affairs for Alvogen PB Research & Development LLC (Regulatory Agent for Norwich Pharmaceuticals, Inc.).

11. On information and belief, Defendants collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group.

12. On information and belief, Defendants acted in concert to develop the Proposed ANDA Products that are the subject of ANDA No. 217449 and to seek regulatory approval from the FDA to market and sell the Proposed ANDA Products throughout the United States, including within this District.

13. Defendants' ANDA No. 217449 seeks approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Plaintiffs' 40 mg and 80 mg XOFLUZA® (baloxavir marboxil) tablets, for oral use into the United States prior to the expiration of the Patents-in-Suit.

14. On information and belief, Defendants intend to act collaboratively to obtain approval for Defendants' ANDA No. 217449, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States.

JURISDICTION AND VENUE

15. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of the submission of Defendants' ANDA No. 217449 to the FDA.

16. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1, et seq.

17. This Court has personal jurisdiction over Norwich because, on information and belief, Norwich is a corporation organized and existing under the laws of Delaware.

18. This Court also has personal jurisdiction over Norwich because it has affirmatively availed itself of the jurisdiction of this Court through the assertion of counterclaims in suits brought in this District and/or by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *Takeda Pharm. Co. Ltd. et al. v. Norwich Pharms., Inc. et al.*, 20-953 (D. Del.); *Salix Pharms., Ltd. et al. v. Norwich Pharms., Inc. et al.*, 20-430 (D. Del.).

19. This Court has personal jurisdiction over Alvogen because, on information and belief, Alvogen is a corporation organized and existing under the laws of Delaware.

20. This Court also has personal jurisdiction over Alvogen because it has affirmatively availed itself of the jurisdiction of this Court through the assertion of counterclaims in suits brought in this District and/or by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *Salix Pharms., Ltd. et al. v. Norwich Pharms., Inc. et al.*, 20-430 (D. Del.); *BioDelivery Sciences International, Inc. et al. v. Alvogen PB Research & Development LLC et al.*, 18-1395 (D. Del.).

21. On information and belief, if ANDA No. 217449 is approved, the Proposed ANDA Products accused of infringing the Patents-in-Suit will be marketed, distributed, offered for sale, and/or sold in this District, prescribed by physicians practicing in this District, dispensed by pharmacies located within this District, and/or used by patients in this District, all of which would have a substantial effect on this District.

22. For the reasons set forth above, Defendants are subject to personal jurisdiction in this District.

23. Venue is proper in this District for Norwich pursuant to 28 U.S.C. § 1400(b) because Norwich is a corporation organized and existing under the laws of Delaware.

24. Venue is proper in this District for Alvogen pursuant to 28 U.S.C. § 1400(b) because Alvogen is a corporation organized and existing under the laws of Delaware.

THE PATENTS-IN-SUIT

25. The Patents-in-Suit are assigned to Shionogi.

26. HLR is the exclusive licensee of the Patents-in-Suit.

27. Genentech is the exclusive sublicensee of the Patents-in-Suit.

28. The '710 Patent, entitled "Substituted Polycyclic Carbamoylpyridone Derivative," was duly and legally issued on January 6, 2015. A copy of the '710 Patent, including certificates of correction, is attached as Exhibit A.

29. The '441 Patent, entitled "Substituted Polycyclic Carbamoyl Pyridone Derivative Prodrug," was duly and legally issued on March 24, 2015. A copy of the '441 Patent, including certificates of correction, is attached as Exhibit B.

30. The '835 Patent, entitled "Substituted Polycyclic Carbamolypyridone Derivative," was duly and legally issued on November 14, 2017. A copy of the '835 Patent, including certificate of correction, is attached as Exhibit C.

31. The '406 Patent, entitled "Substituted Polycyclic Pyridone Derivatives and Prodrugs Thereof," was duly and legally issued on August 27, 2019. A copy of the '406 Patent is attached as Exhibit D.

32. The '397 Patent, entitled "Substituted Polycyclic Pyridone Derivatives and Prodrugs Thereof," was duly and legally issued on April 28, 2020. A copy of the '397 Patent is attached as Exhibit E.

33. The '814 Patent, entitled "Pharmaceutical Compositions Containing Substituted Polycyclic Pyridone Derivatives and Prodrug Thereof," was duly and legally issued on September 1, 2020. A copy of the '814 Patent is attached as Exhibit F.

34. The '198 Patent, entitled "Process for Preparing Substituted Polycyclic Pyridone Derivative and Crystal Thereof," was duly and legally issued on March 1, 2022. A copy of the '198 Patent is attached as Exhibit G.

35. The '106 Patent, entitled "Pharmaceutical Compositions Containing Substituted Polycyclic Pyridone Derivatives and Prodrug Thereof," was duly and legally issued on April 19, 2022. A copy of the '106 Patent is attached as Exhibit H.

FACTUAL BACKGROUND

XOFLUZA® (baloxavir marboxil)

36. XOFLUZA® (baloxavir marboxil) is a drug used for the treatment of influenza and for the post-exposure prophylaxis of influenza. XOFLUZA® (baloxavir marboxil) is an influenza virus polymerase acidic (PA) endonuclease inhibitor.

37. Genentech is the holder of approved New Drug Application ("NDA") No. 210854 for XOFLUZA® (baloxavir marboxil) tablets, for oral use. Pursuant to NDA No. 210854, Genentech markets and distributes XOFLUZA® (baloxavir marboxil) tablets, for oral use in the United States.

38. XOFLUZA® (baloxavir marboxil) tablets, for oral use, baloxavir marboxil, baloxavir, their method of manufacture, and/or their use are covered by one or more claims of the

Patents-in-Suit. The Patents-in-Suit have been listed for NDA No. 210854 in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is also known as the "Orange Book."

Defendants' ANDA No. 217449

39. In the Notice Letter, Defendants stated that they had submitted ANDA No. 217449 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States prior to the expiration of the Patents-in-Suit. The Notice Letter further stated that ANDA No. 217449 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products.

40. Defendants were aware of the Patents-in-Suit when they submitted ANDA No. 217449 with a Paragraph IV Certification.

41. On information and belief, the baloxavir marboxil claimed in one or more of the Patents-in-Suit is present in the Proposed ANDA Products.

42. On information and belief, baloxavir marboxil is present in the Proposed ANDA Products in the form or forms claimed in one or more of the Patents-in-Suit.

43. On information and belief, the baloxavir claimed in one or more of the Patents-in-Suit is present in the Proposed ANDA Products.

44. On information and belief, baloxavir is present in the Proposed ANDA Products in the form or forms claimed in one or more of the Patents-in-Suit.

45. On information and belief, baloxavir marboxil is manufactured by the use of one or more of the processes, by using one or more of the compounds, and/or with the presence of one or more of the compounds claimed in one or more of the Patents-in-Suit.

46. On information and belief, upon patient use of the Proposed ANDA Products, the baloxavir claimed in one or more of the Patents-in-Suit will be formed from baloxavir marboxil.

47. On information and belief, ANDA No. 217449 refers to and relies upon the NDA for XOFLUZA® (baloxavir marboxil) tablets, for oral use and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Products and 40 mg and 80 mg XOFLUZA® (baloxavir marboxil) tablets, for oral use. *See* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

48. On information and belief, Defendants intend to have healthcare providers use the Proposed ANDA Products, if approved, as set forth in the Proposed ANDA Product labels. On further information and belief, Defendants' Proposed ANDA Product labels will instruct healthcare providers to prescribe the Proposed ANDA Products in the manner set forth in the label.

49. On information and belief, the FDA has not yet approved ANDA No. 217449.

50. Plaintiffs commenced this action within 45 days of receipt of the Notice Letter.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,927,710

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

52. On information and belief, the Proposed ANDA Products infringe one or more claims of the '710 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Products of the baloxavir of one or more of the claims of the '710 Patent.

53. Defendants' submission of ANDA No. 217449 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or

import the Proposed ANDA Products into the United States before the expiration of the '710 Patent constitutes infringement of the '710 Patent under 35 U.S.C. § 271(e)(2).

54. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States immediately upon approval of ANDA No. 217449 and will instruct healthcare providers to use the Proposed ANDA Products in accordance with their labels.

55. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '710 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States, by actively inducing infringement by others under 35 U.S.C. § 271(b), and/or by offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use under 35 U.S.C. § 271(c).

56. On information and belief, Defendants had knowledge of the '710 Patent when they submitted ANDA No. 217449 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '710 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '710 Patent.

57. To date, Plaintiffs have not received sufficient information, materials, and things from Defendants to enable Plaintiffs to meaningfully evaluate the bases for Defendants' assertion of non-infringement of the '710 Patent.

58. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 217449, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Defendants infringe one or more claims of the '710 Patent.

59. In the Notice Letter, Defendants do not dispute that using the Proposed ANDA Products in accordance with their labels will result in the conversion of baloxavir marboxil into baloxavir that infringes one or more claims of the '710 Patent.

60. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 8,987,441

61. Plaintiffs hereby reallege and incorporate the allegations of paragraphs 1 – 60 of this Complaint.

62. On information and belief, the Proposed ANDA Products infringe one or more claims of the '441 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Products of the baloxavir marboxil of one or more of the claims of the '441 Patent.

63. Defendants' submission of ANDA No. 217449 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States before the expiration of the '441 Patent constitutes infringement of the '441 Patent under 35 U.S.C. § 271(e)(2).

64. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States immediately upon approval of ANDA No. 217449 and will instruct healthcare providers to use the Proposed ANDA Products in accordance with their labels.

65. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '441 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States, by actively inducing infringement by others under 35 U.S.C. § 271(b), and/or by offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use under 35 U.S.C. § 271(c).

66. On information and belief, Defendants had knowledge of the '441 Patent when they submitted ANDA No. 217449 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '441 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '441 Patent.

67. In the Notice Letter, Defendants do not dispute that the Proposed ANDA Products infringe one or more claims of the '441 Patent.

68. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 9,815,835

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

70. On information and belief, the Proposed ANDA Products infringe one or more claims of the '835 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Products of the baloxavir of one or more of the claims of the '835 Patent.

71. Defendants' submission of ANDA No. 217449 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States before the expiration of the '835 Patent constitutes infringement of the '835 Patent under 35 U.S.C. § 271(e)(2).

72. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States immediately upon approval of ANDA No. 217449 and will instruct healthcare providers to use the Proposed ANDA Products in accordance with their labels.

73. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '835 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States, by actively inducing infringement by others under 35 U.S.C. § 271(b), and/or by offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for

use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use under 35 U.S.C. § 271(c).

74. On information and belief, Defendants had knowledge of the '835 Patent when they submitted ANDA No. 217449 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '835 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '835 Patent.

75. To date, Plaintiffs have not received sufficient information, materials, and things from Defendants to enable Plaintiffs to meaningfully evaluate the bases for Defendants' assertion of non-infringement of the '835 Patent.

76. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 217449, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Defendants infringe one or more claims of the '835 Patent.

77. In the Notice Letter, Defendants do not dispute that using the Proposed ANDA Products in accordance with their labels will result in the conversion of baloxavir marboxil into baloxavir that infringes one or more claims of the '835 Patent.

78. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 10,392,406

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

80. On information and belief, the Proposed ANDA Products infringe one or more claims of the '406 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Products of the baloxavir marboxil of one or more of the claims of the '406 Patent.

81. Defendants' submission of ANDA No. 217449 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States before the expiration of the '406 Patent constitutes infringement of the '406 Patent under 35 U.S.C. § 271(e)(2).

82. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States immediately upon approval of ANDA No. 217449 and will instruct healthcare providers to use the Proposed ANDA Products in accordance with their labels.

83. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '406 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States, by actively inducing infringement by others under 35 U.S.C. § 271(b), and/or offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use under 35 U.S.C. § 271(c).

84. On information and belief, Defendants had knowledge of the '406 Patent when they submitted ANDA No. 217449 to the FDA, Defendants knew or should have known that they will

induce or contribute to another's direct infringement of the '406 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '406 Patent.

85. In the Notice Letter, Defendants do not dispute that the Proposed ANDA Products infringe one or more claims of the '406 Patent.

86. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 10,633,397

87. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 86 of this Complaint.

88. On information and belief, the Proposed ANDA Products infringe one or more claims of the '397 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Products of the baloxavir marboxil of one or more of the claims of the '397 Patent.

89. Defendants' submission of ANDA No. 217449 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States before the expiration of the '397 Patent constitutes infringement of the '397 Patent under 35 U.S.C. § 271(e)(2).

90. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States immediately upon approval of ANDA No. 217449 and will instruct healthcare providers to use the Proposed ANDA Products in accordance with their labels.

91. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '397 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States, by actively inducing infringement by others under 35 U.S.C. § 271(b), and/or offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use under 35 U.S.C. § 271(c).

92. On information and belief, Defendants had knowledge of the '397 Patent when they submitted ANDA No. 217449 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '397 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '397 Patent.

93. In the Notice Letter, Defendants do not dispute that using the Proposed ANDA Products in accordance with their labels infringes one or more claims of the '397 Patent.

94. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 10,759,814

95. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 94 of this Complaint.

96. On information and belief, the Proposed ANDA Products infringe one or more claims of the '814 Patent, either literally or under the doctrine of equivalents, by the use and/or

presence in the Proposed ANDA Products of the baloxavir marboxil in the form or forms of one or more of the claims of the '814 Patent.

97. Defendants' submission of ANDA No. 217449 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States before the expiration of the '814 Patent constitutes infringement of the '814 Patent under 35 U.S.C. § 271(e)(2).

98. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States immediately upon approval of ANDA No. 217449 and will instruct healthcare providers to use the Proposed ANDA Products in accordance with their labels.

99. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '814 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States, by actively inducing infringement by others under 35 U.S.C. § 271(b), and/or offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use under 35 U.S.C. § 271(c).

100. On information and belief, Defendants had knowledge of the '814 Patent when they submitted ANDA No. 217449 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '814 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '814 Patent.

101. In the Notice Letter, Defendants do not dispute that the Proposed ANDA Products infringe one or more claims of the '814 Patent.

102. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 11,261,198

103. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 102 of this Complaint.

104. On information and belief, the Proposed ANDA Products infringe one or more claims of the '198 Patent, either literally or under the doctrine of equivalents, by the use of one or more of the processes, by using one or more of the compounds, and/or by the presence of one or more of the compounds of one or more of the claims of the '198 Patent.

105. Defendants' submission of ANDA No. 217449 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States before the expiration of the '198 Patent constitutes infringement of the '198 Patent under 35 U.S.C. § 271(e)(2).

106. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States immediately upon approval of ANDA No. 217449 and will instruct healthcare providers to use the Proposed ANDA Products in accordance with their labels.

107. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '198 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States, by actively inducing infringement by others

under 35 U.S.C. § 271(b), and/or offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use under 35 U.S.C. § 271(c).

108. On information and belief, Defendants had knowledge of the '198 Patent when they submitted ANDA No. 217449 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '198 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '198 Patent.

109. To date, Plaintiffs have not received sufficient information, materials, and things from Defendants to enable Plaintiffs to meaningfully evaluate the bases for Defendants' assertion of non-infringement of the '198 Patent.

110. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 217449, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Defendants infringe one or more claims of the '198 Patent.

111. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT VIII: INFRINGEMENT OF U.S. PATENT NO. 11,306,106

112. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 111 of this Complaint.

113. On information and belief, the Proposed ANDA Products infringe one or more claims of the '106 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Products of the baloxavir marboxil in the form or forms of one or more of the claims of the '106 Patent.

114. Defendants' submission of ANDA No. 217449 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States before the expiration of the '106 Patent constitutes infringement of the '106 Patent under 35 U.S.C. § 271(e)(2).

115. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States immediately upon approval of ANDA No. 217449 and will instruct healthcare providers to use the Proposed ANDA Products in accordance with their labels.

116. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '106 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States, by actively inducing infringement by others under 35 U.S.C. § 271(b), and/or offering to sell or selling within the United States or importing into the United States a component of a patented machine, manufacture, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use under 35 U.S.C. § 271(c).

117. On information and belief, Defendants had knowledge of the '106 Patent when they submitted ANDA No. 217449 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '106 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '106 Patent.

118. In the Notice Letter, Defendants do not dispute that using the Proposed ANDA Products in accordance with their labels infringes one or more claims of the '106 Patent.

119. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a) Judgment that Defendants' submission of ANDA No. 217449 to the FDA was an act of infringement of one or more claims of the '710, '441, '835, '406, '397, '814, '198, and '106 Patents under 35 U.S.C. § 271(e)(2);

b) Judgment that Defendants' making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Products prior to the expiration of the '710, '441, '835, '406, '397, '814, '198, and '106 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of those patents;

c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217449 shall be a date that is not earlier than the expiration of the '710, '441, '835, '406, '397, '814, '198, and '106 Patents plus any other extensions or exclusivity to which Plaintiffs are or become entitled;

d) An Order permanently enjoining Defendants, Defendants' 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, or importing into the United States the Proposed ANDA Products until after the expiration of the '710, '441, '835, '406, '397, '814, '198, and '106 Patents plus any other extensions or exclusivity to which Plaintiffs are or become entitled;

e) A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

f) An award of Plaintiffs' reasonable costs and expenses in this action; and

Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs

Jack B. Blumenfeld (#1014)
Karen Jacobs (#2881)
Cameron P. Clark (#6647)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
kjacobs@morrisnichols.com
cclark@morrisnichols.com

Attorneys for Plaintiffs Shionogi & Co., Ltd., Hoffmann-La Roche Inc., and Genentech, Inc.

OF COUNSEL:

Lisa B. Pensabene
Hassen A. Sayeed
Daniel O'Boyle
Nancy Schroeder
Carolyn Wall
O'MELVENY & MYERS LLP
7 Times Square
New York, New York 10036
(212) 326-2000

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