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 No. 12,064,438 ("the '438 Patent").

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. 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. 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. Norwich and Alvogen are owned in their entirety by Alvogen Pharma US, Inc.

8. In a Notification Pursuant to Section 505(j)(2)(B)(iv), dated December 29, 2022 ("Notice Letter"), Defendants state that "Norwich has submitted . . . Abbreviated New Drug Application No. 217449," and that the "ANDA identifies Xofluza (NDA No. 210854) as the Reference Listed Drug."

9. The Notice Letter identifies Alvogen PB Research & Development LLC as the Regulatory Agent for Norwich Pharmaceuticals, Inc.

10. 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.

11. 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.

12. 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 '438 Patent.

13. 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

14. 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.

15. 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.

16. This Court has personal jurisdiction over Norwich because Norwich is a corporation organized and existing under the laws of Delaware.

17. 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, including in Plaintiffs' related, previously-filed civil action regarding Defendants' ANDA No. 217449. *See, e.g.*, *Shionogi & Co., Ltd. et al. v. Norwich Pharms., Inc. et al.*, 23-161 (D. Del.); *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.).

18. This Court has personal jurisdiction over Alvogen because Alvogen is a corporation organized and existing under the laws of Delaware.

19. 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, including in Plaintiffs' related, previously-filed civil action regarding Defendants' ANDA No. 217449. *See, e.g.*, *Shionogi & Co., Ltd. et al. v. Norwich Pharms., Inc. et al.*, 23-161 (D. Del.); *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.).

20. On information and belief, if ANDA No. 217449 is approved, the Proposed ANDA Products accused of infringing the '438 Patent 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.

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

22. 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.

23. 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 '438 PATENT

24. The '438 Patent is assigned to Shionogi.

25. HLR is the exclusive licensee of the '438 Patent.

26. Genentech is the exclusive sublicensee of the '438 Patent.

27. The '483 Patent, entitled "Pharmaceutical Preparation Excellent in Light Stability and Dissolution Property," was duly and legally issued on August 20, 2024. A copy of the '438 Patent is attached as Exhibit A.

FACTUAL BACKGROUND

XOFLUZA® (baloxavir marboxil)

28. 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.

29. 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.

30. The formulation of XOFLUZA® (baloxavir marboxil) tablets, for oral use, is covered by one or more claims of the '438 Patent. The '438 Patent has 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

31. 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 U.S. Patent Nos. 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"), which are listed in the Orange Book for XOFLUZA® (baloxavir marboxil) tablets. The '710 Patent, the '441 Patent, the '835 Patent, the '406 Patent, the '397 Patent, the '814 Patent, the '198 Patent, and the '106 Patent are all currently due to expire before the '438 Patent.

32. Plaintiffs have not yet received any notification pursuant to Section 505(j)(2)(B)(iv) for the '438 Patent.

33. On information and belief, the Proposed ANDA Products uses a formulation that is covered by the formulation claimed in the '438 Patent.

34. 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).

35. On information and belief, Defendants intend to have healthcare providers prescribe 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.

36. The FDA has not yet approved ANDA No. 217449. The FDA tentatively approved ANDA No. 217449 on September 13, 2023.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 12,064,438

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

38. On information and belief, the Proposed ANDA Products infringe one or more claims of the '438 Patent, either literally or under the doctrine of equivalents, by the Proposed ANDA Products' use of the formulation of at least claims 1-8 and 10-14 of the '438 Patent.

39. 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 '438 Patent constitutes infringement of one or more claims of the '438 Patent under 35 U.S.C. § 271(e)(2).

40. 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.

41. On information and belief, upon FDA approval of ANDA No. 217449, Defendants will infringe the '438 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Products into the United States under 35 U.S.C. § 271(a), 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).

42. 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 '438 Patent 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 '438 Patent, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of the '438 Patent;

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 '438 Patent 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 '438 Patent plus any other extensions or exclusivity to which Plaintiffs are or become entitled;

e) If, prior to the expiration of the '438 Patent (including any extensions, adjustments, or exclusivities), Defendants commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Products into the United States, a judgment pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284 awarding Plaintiffs monetary relief, together with interest;

f) 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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