

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and)
LES LABORATOIRES SERVIER,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
ALEMBIC PHARMACEUTICALS)
LIMITED and ALEMBIC)
PHARMACEUTICALS, INC.,)
)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amgen Inc. (“Amgen”) and Les Laboratoires Servier (“Servier,” and collectively with Amgen, “Plaintiffs”) bring this action for patent infringement against Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. (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. 215238, filed by and for the benefit of Defendants with the United States Food and Drug Administration (“FDA”). Through ANDA No. 215238, Defendants seek approval to market generic versions of Corlanor[®] (ivabradine) 5 mg and 7.5 mg tablets (the “Proposed ANDA Product”), prior to the expiration of U.S. Patent Nos. 7,361,649 (“the ’649 Patent”), 7,361,650 (“the ’650 Patent”), 7,867,996 (“the ’996 Patent”), and 7,879,842 (“the ’842 Patent”) (collectively, “the Patents-in-Suit”).

THE PARTIES

2. Plaintiff Amgen is a corporation organized and existing under the laws of Delaware, having a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

3. Plaintiff Servier is a corporation organized and existing under the laws of France, having a principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France. Servier is part of the Servier Group. Servier Group discovers, develops, manufactures, and sells innovative therapeutic products and is governed by a non-profit foundation.

4. On information and belief, Defendant Alembic Pharmaceuticals Limited (“Alembic Ltd.”) is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

5. On information and belief, Defendant Alembic Pharmaceuticals, Inc. (“Alembic Inc.”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807.

6. On information and belief, Alembic Inc. is a wholly owned-subsiary of Alembic Ltd.

7. On information and belief, Aaron S. Lukas is the agent for service of process in the United States for Alembic Ltd.

8. 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.

9. On information and belief, Defendants acted in concert to develop the Proposed ANDA Product that is the subject of ANDA No. 215238 and to seek regulatory approval from the FDA to market and sell the Proposed ANDA Product throughout the United States, including within this District.

10. Defendants' ANDA No. 215238 seeks approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of Amgen's Corlanor[®] (ivabradine) tablets prior to the expiration of the Patents-in-Suit.

11. On information and belief, Defendants intend to act collaboratively to obtain approval for Defendants' ANDA No. 215238, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product.

JURISDICTION AND VENUE

12. 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. 215238 to the FDA.

13. 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.

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

15. This Court has personal jurisdiction over Alembic Ltd. because, *inter alia*, it has maintained continuous and systematic contacts with this District and availed itself of the privilege of doing business in this District. On information and belief, Alembic Ltd. has acted in concert with Alembic Inc.: (1) to file ANDA No. 215238 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product in the United States, including

in this District; (2) regularly and continuously transacted business within this District, including by selling pharmaceutical products in this District either on its own or through its affiliates; and (3) derived substantial revenue from the sale of those products in this District. Alternatively, this Court has personal jurisdiction over Alembic Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

16. On information and belief, if ANDA No. 215238 is approved, the Proposed ANDA Product charged with 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.

17. This Court also has personal jurisdiction over Alembic Inc. and Alembic Ltd. because they have affirmatively availed themselves 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., Pfizer Inc., et al. v. Alembic Pharmaceuticals, Inc., et al.*, Civil Action No. 20-1392 (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc., et al. v. Mankind Pharma Ltd., et al.*, Civil Action No. 18-1689 (D. Del.); *H. Lundbeck A/S, et al. v. Alembic Pharmaceuticals Limited, et al.*, Civil Action No. 18-0113 (D. Del.); *Adverio Pharma GmbH, et al. v. MSN Laboratories Private Limited, et al.*, Civil Action No. 18-0073 (D. Del.).

18. For the reasons set forth above, and for additional reasons which will be supplied if Defendants challenge personal jurisdiction in this action, Defendants are subject to personal jurisdiction in this District.

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

20. Venue is proper in this District for Alembic Ltd. pursuant to 28 U.S.C. § 1391(c) because, *inter alia*, Alembic Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this District.

THE PATENTS-IN-SUIT

21. The Patents-in-Suit are assigned to Servier and exclusively licensed to Amgen.

22. The '649 Patent, entitled “ β -Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It,” was duly and legally issued on April 22, 2008. A copy of the '649 Patent is attached as Exhibit A.

23. The '650 Patent, entitled “ γ -Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It,” was duly and legally issued on April 22, 2008. A copy of the '650 Patent is attached as Exhibit B.

24. The '996 Patent, entitled “ γ -Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It,” was duly and legally issued on January 11, 2011. A copy of the '996 Patent is attached as Exhibit C.

25. The '842 Patent, entitled “Beta-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It,” was duly and legally issued on February 1, 2011. A copy of the '842 Patent is attached as Exhibit D.

FACTUAL BACKGROUND

Corlanor[®] (ivabradine)

26. Corlanor[®] (ivabradine) is a drug used to treat certain cases of chronic heart failure. In chronic heart failure, a person's heart does not adequately supply the body with blood, causing fatigue and weakness. Corlanor[®] can reduce a patient's risk of being hospitalized due to heart failure.

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