IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and LES LABORATOIRES SERVIER Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD. Defendants,	Civil Action No. _____

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 Zydus Pharmaceuticals (USA) Inc. ("Zydus") and Cadila Healthcare Ltd. ("Cadila," and collectively with Zydus, "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. 213442, filed by and for the benefit of Defendants with the United States Food and Drug Administration ("FDA"). Through ANDA No. 213442, 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 Zydus is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

5. On information and belief, Defendant Cadila is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380 015, Gujarat, India.

6. On information and belief, Zydus is a wholly owned-subsidiary of Cadila.

7. 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.

8. On information and belief, Zydus acts as the U.S. agent for Cadila for the purposes of regulatory submissions to the FDA in seeking approval for regulatory drugs.

9. On information and belief, Defendants acted in concert to develop the Proposed ANDA Product that is the subject of ANDA No. 213442 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. 213442 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. 213442, 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. 213442 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 Zydus because, on information and belief, Zydus is a corporation organized and existing under the laws of New Jersey.

15. This Court has personal jurisdiction over Cadila 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, Cadila has acted in concert with Zydus: (1) to file ANDA No. 213442 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 Cadila pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

16. On information and belief, if ANDA No. 213442 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 Defendants because they have affirmatively availed themselves of the jurisdiction of this Court through the assertions of counterclaims in suits brought in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g., Takeda Pharmaceutical Company Limited et al. v. Zydus Pharmaceuticals (USA) Inc. et al.,* Civil Action No. 18-11792 (D.N.J.); *Celgene Corporation v. Zydus Pharmaceuticals (USA) Inc. et al.,* Civil Action No. 17-2528 (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.,* Civil Action No. 17-2754 (D.N.J.); *Helsinn Healthcare S.A. v. Zydus Pharmaceuticals (USA) Inc. et al.,* Civil Action No. 16-4239 (D.N.J).

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 Zydus pursuant to 28 U.S.C. § 1400(b) because Zydus is a corporation organized and existing under the laws of New Jersey.

20. Venue is proper in this District for Cadila pursuant to 28 U.S.C. § 1391(c) because, *inter alia*, Cadila 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.

27. Amgen is the holder of approved New Drug Application ("NDA") No. 20-6143 for Corlanor® (ivabradine) tablets. Pursuant to NDA No. 20-6143, Amgen markets and distributes Corlanor® (ivabradine) tablets in the United States. Corlanor® is available in 5 mg and 7.5 mg tablets.

28. Corlanor® (ivabradine) tablets, the active pharmaceutical ingredient ivabradine, the 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. 20-6143 in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is also known as the "Orange Book."

Defendants' ANDA No. 213442

29. In a letter dated December 5, 2019 (the "Notice Letter"), Defendants stated that they had submitted ANDA No. 213442 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product prior to the expiration of the Patents-in-Suit. The Notice Letter further stated that ANDA No. 213442 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 of the Proposed ANDA Product.

30. Defendants were aware of the Patents-in-Suit when they submitted ANDA No. 213442 with a Paragraph IV Certification.

31. On information and belief, ivabradine is the active ingredient in the Proposed ANDA Product.

32. On information and belief, ANDA No. 213442 refers to and relies upon the NDA for Corlanor® (ivabradine) and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and Corlanor® (ivabradine). *See* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

33. On information and belief, the active ingredient in the Proposed ANDA Product—ivabradine—exhibits a patented crystalline form.

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

35. On information and belief, the FDA has not yet approved ANDA No. 213442.

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

37. Defendants' Notice Letter included an Offer of Confidential Access.

38. Between December 26, 2019 and January 7, 2020, Amgen and the Defendants negotiated and reached an agreement to modify the Offer of Confidential Access.

39. On January 8, 2020, Defendants produced documents purportedly from their ANDA No. 213442.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 7,361,649

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

41. On information and belief, the Proposed ANDA Product infringes one or more claims of the '649 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of an ivabradine crystalline form as covered by one or more of the claims of the '649 Patent.

42. Defendants' submission of ANDA No. 213442 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 Product before the expiration of the '649 Patent constitutes infringement of the '649 Patent under 35 U.S.C. § 271(e)(2).

43. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 213442 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

44. On information and belief, upon FDA approval of ANDA No. 213442, Defendants will infringe the '649 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

45. On information and belief, Defendants had knowledge of the '649 Patent when they submitted ANDA No. 213442 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '649 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '649 Patent.

46. 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 '649 Patent.

47. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 213442, 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 '649 Patent.

48. 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. 7,361,650

49. Plaintiffs hereby reallege and incorporate the allegations of paragraphs 1 – 48 of this Complaint.

50. On information and belief, the Proposed ANDA Product infringes one or more claims of the '650 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of an ivabradine crystalline form as covered by one or more of the claims of the '650 Patent.

51. Defendants' submission of ANDA No. 213442 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 Product before the expiration of the '650 Patent constitutes infringement of the '650 Patent under 35 U.S.C. § 271(e)(2).

52. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 213442 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

53. On information and belief, upon FDA approval of ANDA No. 213442, Defendants will infringe the '650 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

54. On information and belief, Defendants had knowledge of the '650 Patent when they submitted ANDA No. 213442 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '650 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '650 Patent.

55. 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 '650 Patent.

56. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 213442, 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 '650 Patent.

57. 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. 7,867,996

58. Plaintiffs hereby reallege and incorporate the allegations of paragraphs 1 – 57 of this Complaint.

59. On information and belief, the Proposed ANDA Product infringes one or more claims of the '996 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of an ivabradine crystalline form as covered by one or more of the claims of the '996 Patent.

60. Defendants' submission of ANDA No. 213442 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 Product before the expiration of the '996 Patent constitutes infringement of the '996 Patent under 35 U.S.C. § 271(e)(2).

61. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 213442 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

62. On information and belief, upon FDA approval of ANDA No. 213442, Defendants will infringe the '996 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

63. On information and belief, Defendants had knowledge of the '996 Patent when they submitted ANDA No. 213442 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '996 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '996 Patent.

64. 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 '996 Patent.

65. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 213442, 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 '996 Patent.

66. 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. 7,879,842

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

68. On information and belief, the Proposed ANDA Product infringes one or more claims of the '842 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of an ivabradine crystalline form as covered by one or more of the claims of the '842 Patent.

69. Defendants' submission of ANDA No. 213442 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 Product before the expiration of the '842 Patent constitutes infringement of the '842 Patent under 35 U.S.C. § 271(e)(2).

70. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 213442 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

71. On information and belief, upon FDA approval of ANDA No. 213442, Defendants will infringe the '842 Patent by making, using, offering to sell, selling, and/or importing the

Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

72. On information and belief, Defendants had knowledge of the '842 Patent when they submitted ANDA No. 213442 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '842 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '842 Patent.

73. 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 '842 Patent.

74. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 213442, 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 '842 Patent.

75. 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. 213442 to the FDA was an act of infringement of one or more claims of the '649, '650, '996, and '842 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 Product prior to the expiration of the '649, '650, '996, and '842 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. 213442 shall be a date that is not earlier than the expiration of the '649, '650, '996, and '842 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

d) An Order permanently enjoining Defendants, Defendants' affiliates and subsidiaries, each of its 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 Product until after the expiration of the '649, '650, '996, and '842 Patents plus any other 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

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

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Dated: January 21, 2020

RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

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Dated: January 21, 2020

RULE 11.2 CERTIFICATION

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") are the subject of the pending action in the United States District Court for the District of Delaware: *Amgen Inc. et al v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 20-cv-00075.

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

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