IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and LES LABORATOIRES SERVIER, Plaintiffs, v. ALEMBIC PHARMACEUTICALS LIMITED and ALEMBIC PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 1:21-cv-00061-CFC **JURY TRIAL DEMANDED**

DEFENDANTS ALEMBIC PHARMACEUTICALS LIMITED AND ALEMBIC PHARMACEUTICALS, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS AMGEN INC. AND LES LABORATOIRES SERVIER'S COMPLAINT FOR PATENT INFRINGEMENT

Defendants Alembic Pharmaceuticals Limited ("Alembic Ltd.") and Alembic Pharmaceuticals, Inc. ("Alembic Inc.") (collectively, "Defendants" or "Counterclaim Plaintiffs"), by and through their undersigned counsel, file this Answer, Affirmative Defenses, and Counterclaims to Plaintiffs Amgen Inc. ("Amgen") and Les Laboratoires Servier's ("Servier") (collectively, "Plaintiffs" or "Counterclaim Defendants") Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in Plaintiffs' Complaint except those specifically admitted below.

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").

ANSWER: Defendants admit that Plaintiffs purport to bring this action alleging infringement 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"), and that Plaintiffs' cause of action arises under 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271. Defendants admit that they seek FDA-approval for the ivabradine (5 mg and 7.5 mg) tablet products described in Abbreviated New Drug Application ("ANDA") No. 215238 ("Alembic's ANDA Products") before the expiration dates of the Patents-in-Suit, but deny that Alembic's ANDA Products have infringed or will infringe any valid and enforceable claim of the Patents-in-Suit. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 1.

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.

ANSWER: On information and belief, Defendants admit that 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. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 2, and on that basis deny said allegations.

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.

ANSWER: On information and belief, Defendants admit that 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. Defendants lack knowledge or information sufficient to form a belief

about the truth of the remaining allegations in Paragraph 3, and on that basis deny said allegations.

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.

ANSWER: Admitted.

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.

ANSWER: Admitted.

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

ANSWER: Defendants admit that Alembic Inc. is a subsidiary of Alembic Ltd. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 6.

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

ANSWER: Aaron S. Lukas was designated as Alembic Ltd.'s agent for service of process in the United States for the purposes of any complaint for patent infringement filed against ANDA No. 215238. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 7.

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.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that Alembic Ltd. develops and/or manufactures high-quality generic drug products, some of which are distributed and/or sold within the United States by Alembic Inc.. Except as expressly admitted, Defendants deny the remaining

allegations of Paragraph 8.

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.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that Defendants seek FDA-approval for ANDA No. 215238. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 9.

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.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 215238 seeks FDA-approval of Alembic's ANDA Products prior to the expiration of the Patents-in-Suit. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 10.

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.

ANSWER: Paragraph 11 contains speculative allegations to which no answer is required. To the extent an answer is required, Defendants admit that Defendants seek FDA-approval for ANDA No. 215238 but that it has not yet been tentatively or finally approved by FDA. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 11.

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.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is

required. To the extent an answer is required, Defendants admit that Plaintiffs purport to bring this action under Title 35 of the United States Code. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 12.

> 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*.

ANSWER: Admitted.

> 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.

ANSWER: Defendants deny that Alembic Inc. is subject to personal jurisdiction in this District, but does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 14.

> 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).

ANSWER: Defendants deny that Alembic Ltd. is subject to personal jurisdiction in this District, but does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 15.

> 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.

ANSWER: The allegations of Paragraph 15 are wholly speculative, as ANDA No. 215238 is

not yet tentatively or finally approved. To the extent an answer is required, Defendants admit that ANDA No. 215238 was filed at FDA and seeks FDA-approval for Alembic's ANDA Products. For purposes of this action only, Alembic Ltd. does not contest personal jurisdiction or venue in this District for the limited purposes of this Action only. To the extent a further response is required, Defendants deny the remaining allegations of Paragraph 16.

> 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.).

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction or venue in this District for the limited purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 17.

> 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.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 18.

> 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.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is

required. To the extent an answer is required, Defendants admit that venue is proper as to Alembic Inc. under 28 U.S.C. § 1400(b). Solely for the purposes of this action, Alembic Inc. does not contest venue in this District. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 19.

> 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.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that venue is proper as to Alembic Ltd. under 28 U.S.C. § 1391(c). Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 20.

THE PATENTS-IN-SUIT

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

ANSWER: Defendants admit that, according to the U.S. Patent Office's electronic assignment database, Servier is the Assignee of the Patents-in-Suit and that Servier is named as Assignee on the face of the Patents-in-Suit. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 21, and on that basis deny said allegations.

> 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.

ANSWER: Defendants admit that the '649 Patent is entitled "β-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," and that the '649 Patent issued on or about April 22, 2008. Defendants further admit that what appears

to be an uncertified copy of the '649 Patent was attached to Plaintiffs' Complaint (D.I. 1) as Exhibit A. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 22.

> 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.

ANSWER: Defendants admit that the '650 Patent is entitled "γ-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," and that the '650 Patent issued on or about April 22, 2008. Defendants further admit that what appears to be an uncertified copy of the '650 Patent was attached to Plaintiffs' Complaint (D.I. 1) as Exhibit B. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 23.

> 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.

ANSWER: Defendants admit that the '996 Patent is entitled "γ-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," and that the '996 Patent issued on or about January 11, 2011. Defendants further admit that what appears to be an uncertified copy of the '996 Patent was attached to Plaintiffs' Complaint (D.I. 1) as Exhibit C. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 24.

> 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.

ANSWER: Defendants admit that the '842 Patent is entitled "Beta-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," and that the '842 Patent issued on or about February 1, 2011. Defendants further

admit that what appears to be an uncertified copy of the '842 Patent was attached to Plaintiffs' Complaint (D.I. 1) as Exhibit D. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 25.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26, and on that basis deny these allegations.

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.

ANSWER: Defendants admit that, according to FDA's electronic publication "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (the "Orange Book"), Amgen Inc. is the holder of New Drug Application ("NDA") No. 20-6143 for Corlanor® (ivabradine) tablets (5 mg and 7.5 mg). Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 27, and on that basis deny these allegations.

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."

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs have chosen to list the Patents-in-Suit in FDA's *Orange Book* in association with NDA No. 20-6143. Defendants lack knowledge or information sufficient to know whether the Patents-in-Suit in fact cover the

active pharmaceutical ingredient ivabradine in Corlanor®, its method of manufacture, and/or its FDA-approved use. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 28.

Defendants' ANDA No. 215238

29. In a letter dated December 7, 2020 (the "Notice Letter"), Defendants stated that they had submitted ANDA No. 215238 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. 215238 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.

ANSWER: Alembic admits that it sent a letter dated December 7, 2020 to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), the content of which speaks for itself. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 29.

30. Defendants were aware of the Patents-in-Suit when they submitted ANDA No. 215238 with a Paragraph IV Certification.

ANSWER: Defendants admit awareness of the Patents-in-Suit as of the date that ANDA No. 215238 was submitted to the FDA. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 30.

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

ANSWER: The content of ANDA No. 215238 speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 31.

32. On information and belief, ANDA No. 215238 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).

ANSWER: The content of ANDA No. 215238 speaks for itself. To the extent an answer to

Paragraph 32 is require, Defendants admit that ANDA No. 215238 complies with the statutory requirements of 21 U.S.C. § 355(j) *et seq*. and FDA's regulations under 21 C.F.R. § 314 *et seq*. Except as expressly admitted, Defendants deny the allegations of Paragraph 32.

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

ANSWER: Denied.

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.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, the content of ANDA No. 215238, including the proposed labeling information, is intended to comply with FDA regulatory requirements. Further, FDA has not yet finally approved ANDA No. 215238, and the label for which Defendants seek FDA approval may change during the course of FDA review. The allegations of Paragraph 34 are wholly speculative. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 34.

35. On information and belief, the FDA has not yet approved ANDA No. 215238.

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

38. Between December 11, 2020 and January 8, 2021, Amgen and the Defendants negotiated and reached an agreement to modify the Offer of Confidential Access.

ANSWER: Admitted.

39. On January 13, 2021, Defendants produced documents purportedly from their ANDA No. 215238.

ANSWER: Admitted.

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.

ANSWER: Defendants incorporate and reallege each of their responses to the foregoing Paragraphs 1-39 as if fully set forth herein.

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.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 41.

42. Defendants' submission of ANDA No. 215238 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).

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 42.

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. 215238 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of ANDA No. 215238 speaks for itself, ANDA No. 215238 is not yet finally approved by FDA, and the allegations of Paragraph 43 are

wholly speculative. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 43.

> 44. On information and belief, upon FDA approval of ANDA No. 215238, 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).

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 44.

> 45. On information and belief, Defendants had knowledge of the '649 Patent when they submitted ANDA No. 215238 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.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they had knowledge of the '649 Patent as of the date on which ANDA No. 215238 was submitted to FDA. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 45.

> 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.

ANSWER: Denied.

> 47. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 215238, 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.

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 47.

> 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.

ANSWER: The allegations of Paragraph 48 lack any basis in fact or the law and are wholly contradicted by Plaintiffs' own allegations in their complaint, and in particular their allegations set forth in Paragraph 47. To the extent an answer is required, Defendants deny the allegations in Paragraph 48.

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.

ANSWER: Defendants incorporate and reallege each of their responses to the foregoing Paragraphs 1-48 as if fully set forth herein.

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.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 50.

51. Defendants' submission of ANDA No. 215238 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).

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 51.

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. 215238 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of ANDA No. 215238 speaks for itself, ANDA No. 215238 is not yet finally approved by FDA, and the allegations of Paragraph 52 are

wholly speculative. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 52.

> 53. On information and belief, upon FDA approval of ANDA No. 215238, 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).

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 53.

> 54. On information and belief, Defendants had knowledge of the '650 Patent when they submitted ANDA No. 215238 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.

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they had knowledge of the '650 Patent as of the date on which ANDA No. 215238 was submitted to FDA. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 54.

> 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.

ANSWER: Denied.

> 56. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 215238, 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.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 56.

> 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.

ANSWER: The allegations of Paragraph 57 lack any basis in fact or the law and are wholly contradicted by Plaintiffs' own allegations in their complaint, and in particular their allegations set forth in Paragraph 56. To the extent an answer is required, Defendants deny the allegations in Paragraph 57.

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.

ANSWER: Defendants incorporate and reallege each of their responses to the foregoing Paragraphs 1-57 as if fully set forth herein.

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.

ANSWER: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 59.

60. Defendants' submission of ANDA No. 215238 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).

ANSWER: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 60.

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. 215238 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of ANDA No. 215238 speaks for itself, ANDA No. 215238 is not yet finally approved by FDA, and the allegations of Paragraph 61 are

wholly speculative. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 61.

> 62. On information and belief, upon FDA approval of ANDA No. 215238, 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).

ANSWER: Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 62.

> 63. On information and belief, Defendants had knowledge of the '996 Patent when they submitted ANDA No. 215238 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.

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they had knowledge of the '996 Patent as of the date on which ANDA No. 215238 was submitted to FDA. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 63.

> 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.

ANSWER: Denied.

> 65. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 215238, 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.

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 65.

> 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.

ANSWER: The allegations of Paragraph 66 lack any basis in fact or the law and are wholly contradicted by Plaintiffs' own allegations in their complaint, and in particular their allegations set forth in Paragraph 65. To the extent an answer is required, Defendants deny the allegations in Paragraph 66.

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.

ANSWER: Defendants incorporate and reallege each of their responses to the foregoing Paragraphs 1-66 as if fully set forth herein.

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.

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 68.

69. Defendants' submission of ANDA No. 215238 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).

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 69.

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. 215238 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of ANDA No. 215238 speaks for itself, ANDA No. 215238 is not yet finally approved by FDA, and the allegations of Paragraph 70 are

wholly speculative. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 70.

> 71. On information and belief, upon FDA approval of ANDA No. 215238, 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).

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 71.

> 72. On information and belief, Defendants had knowledge of the '842 Patent when they submitted ANDA No. 215238 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.

ANSWER: Paragraph 72 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they had knowledge of the '842 Patent as of the date on which ANDA No. 215238 was submitted to FDA. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 72.

> 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.

ANSWER: Denied.

> 74. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 215238, 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.

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 74.

> 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.

ANSWER: The allegations of Paragraph 75 lack any basis in fact or the law and are wholly contradicted by Plaintiffs' own allegations in their complaint, and in particular their allegations set forth in Paragraph 74. To the extent an answer is required, Defendants deny the allegations in Paragraph 75.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requested in its Prayer for Relief.

ALEMBIC'S AFFIRMATIVE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Defendants reserve the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST AFFIRMATIVE DEFENSE
(Non-Infringement of U.S. Patent No. 7,361,649)

Defendants do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '649 Patent, and Defendants' Proposed ANDA Product that is the subject of ANDA No. 215238 does not infringe any valid and enforceable claim of the '649 Patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,361,649)

The '649 Patent and each of the claims therein is invalid and/or unenforceable for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, or other judicially-created bases for invalidity.

THIRD AFFIRMATIVE DEFENSE
(Non-Infringement of U.S. Patent No. 7,361,650)

Defendants do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '650 Patent, and Defendants' Proposed ANDA Product that is the subject of ANDA No. 215238 does not infringe any valid and enforceable claim of the '650 Patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,361,650)

The '650 Patent and each of the claims therein is invalid and/or unenforceable for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, or other judicially-created bases for invalidity.

FIFTH AFFIRMATIVE DEFENSE
(Non-Infringement of U.S. Patent No. 7,867,996)

Defendants do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '996 Patent, and Defendants' Proposed ANDA Product that is the subject of ANDA No. 215238 does not infringe any valid and enforceable claim of the '996 Patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,867,996)

The '996 Patent and each of the claims therein is invalid and/or unenforceable for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, or other judicially-created bases for invalidity.

SEVENTH AFFIRMATIVE DEFENSE
(Non-Infringement of U.S. Patent No. 7,879,842)

Defendants do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '842 Patent, and Defendants' Proposed ANDA Product that is the subject of ANDA No. 215238 does not infringe any valid and enforceable claim of the '842 Patent.

EIGHTH AFFIRMATIVE DEFENSE

(Invalidity of U.S. Patent No. 7,879,842)

The '842 Patent and each of the claims therein is invalid and/or unenforceable for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, or other judicially-created bases for invalidity.

NINTH AFFIRMATIVE DEFENSE
(Failure to State a Claim for Exceptional Case)

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to Defendants. Plaintiffs' Complaint fails to set forth any facts supporting the conclusion that it has suffered or will suffer irreparable injury or harm, that this is an exceptional case, or that there has been or will be any willful infringement of the Patents-in-Suit by Defendants under 35 U.S.C. § 285, and/or 21 U.S.C. § 271(e)(4)(A).

TENTH AFFIRMATIVE DEFENSE
(Failure to Adequately Plead a Claim for Injunctive Relief)

Plaintiffs fail to claim entitlement to injunctive relief against Defendants because Plaintiffs alleged injury is not immediate or irreparable, because Plaintiffs have an adequate remedy at law, and because public policy concerns weigh against any injunctive relief.

ELEVENTH AFFIRMATIVE DEFENSE
(Reservation of Defenses)

Defendants hereby reserve any and all defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation, including that Plaintiffs have failed to support the conclusion that this is an exceptional case or that an award of attorney's fees under 35 U.S.C. § 285 is warranted.

ALEMBIC PHARMACEUTICALS LIMITED AND ALEMBIC PHARMACEUTICALS, INC.'S COUNTERCLAIMS

Counterclaim-Plaintiffs Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. (collectively, "Alembic"), for their counterclaims against Counterclaim Defendants Amgen Inc. ("Amgen") and Les Laboratoires Servier ("Servier") (collectively, "Counterclaim Defendants"), allege as follows:

1. Counterclaim Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of Alembic's Answer and Affirmative Defenses to the Complaint.

2. This is a counterclaim for declaratory judgment of non-infringement of one or more claims of the '649, '650, '996, and '842 patents (the "Patents-in-Suit") under 28 U.S.C. §§ 2201 and 2202. On information and belief, true and correct uncertified copies of the '649, '650, '996, and '842 patents were attached to Counterclaim-Defendants' Complaint (D.I. 1) as Exhibits A-D, respectively.

THE PARTIES

3. Counterclaim Plaintiff Alembic Limited 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.

4. Counterclaim Plaintiff 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.

5. On information and belief, Counterclaim Defendant 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.

6. On information and belief, Counterclaim Defendant 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.

JURISDICTION AND VENUE

7. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and this Court has subject matter jurisdiction over Counterclaim Plaintiffs declaratory judgment claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. There is an actual and justiciable controversy between the parties as to whether the ivabradine tablet products described in ANDA No. 215238 infringe any valid and enforceable claim of the Patents-in-Suit.

9. This court has personal jurisdiction over Counterclaim Defendants because, among other reasons, Counterclaim Defendants have voluntarily subjected themselves to the jurisdiction of this Court by filing their Complaint here and because Counterclaim Defendants are doing business in this jurisdiction.

10. Venue is proper in this judicial district for Servier under 28 U.S.C. § 1391(c) and by Counterclaim Defendants' choice of forum.

11. Venue is proper in this judicial district for Amgen under 28 U.S.C. § 1400(b) and by Counterclaim Defendants' choice of forum.

ORANGE BOOK LISTING OF THE '649, '650, '996, AND '842 PATENTS

12. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to file with FDA "the patent number and expiration date of any patent which claims the drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

13. On information and belief, Amgen is the approval holder for New Drug Application ("NDA") No. 20-6143 for Corlanor® (ivabradine) tablets, 5 mg and 7.5 mg.

14. On information and belief, Amgen and/or Servier have listed the Patents-in-Suit in the FDA's publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book"), in connection with NDA No. 20-6143 for Corlanor® (ivabradine) tablets, 5 mg and 7.5 mg.

15. On information and belief, the '649 Patent, which is titled "β-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," issued on or about April 22, 2008. According to the PTO's electronic records and the face of the '649 Patent, Counterclaim Defendant Servier is the Assignee of the '649 Patent. According to Paragraph 21 of Counterclaim Defendants' Complaint (D.I. 1), Amgen is the exclusive licensee of the '649 Patent.

16. On information and belief, the '650 Patent, which is titled "γ-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," issued on or about April 22, 2008. According to the PTO's electronic records and the face of the '650 Patent, Counterclaim Defendant Servier is the Assignee of the '650 Patent. According to Paragraph 21 of Counterclaim Defendants' Complaint (D.I. 1), Amgen is the exclusive licensee of the '650 Patent.

17. On information and belief, the '996 Patent, which is titled "γ-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," issued on or about January 11, 2011. The '996 Patent indicates on its face that it is assigned to Servier. According to Paragraph 21 of Counterclaim Defendants' Compaint (D.I. 1), Amgen is the exclusive licensee of the '996 Patent.

18. On information and belief, the ’842 Patent, which is titled “Beta-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It,” issued on or about February 1, 2011. The ’842 Patent indicates on its face that it is assigned to Servier. According to Paragraph 21 of Counterclaim Defendants’ Complaint (D.I. 1), Amgen is the exclusive licensee of the ’842 Patent.

19. On information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), one or more of Counterclaim Defendants caused the FDA to list the Patents-in-Suit in the Orange Book in association with NDA No. 20-6143.

ALEMBIC’S ABBREVIATED NEW DRUG APPLICATION

20. Alembic Inc. submitted ANDA No. 215238 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the Alembic’s ANDA Products. ANDA No. 215238 includes a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) indicating that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Alembic’s ANDA Products.

THE PRESENT CASE OR CONTROVERSY

21. On information and belief, one or more of Amgen and/or Servier caused the Patents-in-Suit to be listed in FDA’s Orange Book in association with NDA No. 20-6143.

22. By maintaining the listing of the Patents-in-Suit in the Orange Book in association with NDA No. 20-6143, Counterclaim Defendants represent that the Patents-in-Suit “could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug” without a license from Servier and/or Amgen. 21 U.S.C. § 355(b)(1)(G).

23. Counterclaim Defendants have filed an infringement action under 35 U.S.C.

§ 271(a), (b), (c), and/or (e) asserting the Patents-in-Suit against Alembic. There has been and is now an actual and justiciable controversy between Counterclaim Plaintiffs and Alembic as to whether the Alembic's ANDA Product infringes the Patents-in-Suit.

24. Alembic submitted ANDA No. 215238 to obtain FDA approval to engage in the commercial manufacture, use, offer to sell, sale, and importation of the Proposed ANDA Product prior to expiration of the Patents-in-Suit.

25. Counterclaim Plaintiffs' ANDA No. 215238 contains Paragraph IV certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the Proposed ANDA Product.

26. On January 20, 2021, Counterclaim Defendants filed a Complaint (D.I. 1) alleging infringement of the Patents-in-Suit.

27. If it is shown that Alembic's ANDA Products does not infringe the Patents-in-Suit, such judgment will remove any uncertainty that may exist by virtue of Counterclaim Defendants' maintenance of the listing of the Patents-in-Suit in the Orange Book in connection with the NDA No. 20-6143.

28. In sum, an actual and substantial controversy between, on the one hand, Amgen and Servier, and on the other hand, Alembic exists as to whether the claims of the Patents-in-Suit are infringed by Alembic's ANDA Products, warranting the issuance of a declaration of rights by the Court. The nature of the controversy between Alembic and Counterclaim Defendants can be redressed by judicial relief and is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT I
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,361,649)

29. Alembic repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1-28.

30. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

31. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the products described in ANDA No. 215238 infringe, and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of such products, will infringe any valid and enforceable claim of the '649 Patent. The actual, substantial, continuing, and justiciable controversy between parties with adverse legal interests of sufficient immediacy and reality warrants the issuance of a declaration of rights by this Court concerning the infringement of the '649 Patent.

32. Counterclaim Defendants bear the burden of proving infringement by Alembic of one or more claims of the '649 Patent and will not be able to meet their burden.

33. Alembic is entitled to a declaration that its proposed ivabradine tablet products described in ANDA No. 215238 do not infringe any valid and enforceable claim of the '649 Patent, and their commercial manufacture, use, offer for sale, sale, and/or importation will not infringe, either directly or indirectly, any valid and enforceable claim of the '649 Patent.

COUNT II
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,361,650)

34. Alembic repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1-33.

35. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

36. There is an actual, substantial, continuing, and justiciable controversy between the

parties regarding whether the products described in ANDA No. 215238 infringe, and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of such products, will infringe any valid and enforceable claim of the '650 Patent. The actual, substantial, continuing, and justiciable controversy between parties with adverse legal interests of sufficient immediacy and reality warrants the issuance of a declaration of rights by this Court concerning the infringement of the '650 Patent.

37. Counterclaim Defendants bear the burden of proving infringement by Alembic of one or more claims of the '650 Patent and will not be able to meet their burden.

38. Alembic is entitled to a declaration that its proposed ivabradine tablet products described in ANDA No. 215238 do not infringe any valid and enforceable claim of the '650 Patent, and their commercial manufacture, use, offer for sale, sale, and/or importation will not infringe, either directly or indirectly, any valid and enforceable claim of the '650 Patent.

COUNT III
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,867,996)

39. Alembic repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1-38.

40. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

41. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the products described in ANDA No. 215238 infringe, and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of such products, will infringe any valid and enforceable claim of the '996 Patent. The actual, substantial, continuing, and justiciable controversy between parties with adverse legal interests of sufficient immediacy and reality warrants the issuance of a declaration of rights by this Court concerning the

infringement of the ’996 Patent.

42. Counterclaim Defendants bear the burden of proving infringement by Alembic of one or more claims of the ’996 Patent and will not be able to meet their burden.

43. Alembic is entitled to a declaration that its proposed ivabradine tablet products described in ANDA No. 215238 do not infringe any valid and enforceable claim of the ’996 Patent, and their commercial manufacture, use, offer for sale, sale, and/or importation will not infringe, either directly or indirectly, any valid and enforceable claim of the ’996 Patent.

COUNT IV
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,879,842)

44. Alembic repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1-43.

45. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

46. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the products described in ANDA No. 215238 infringe, and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of such products, will infringe any valid and enforceable claim of the ’842 Patent. The actual, substantial, continuing, and justiciable controversy between parties with adverse legal interests of sufficient immediacy and reality warrants the issuance of a declaration of rights by this Court concerning the infringement of the ’842 Patent.

47. Counterclaim Defendants bear the burden of proving infringement by Alembic of one or more claims of the ’842 Patent and will not be able to meet their burden.

48. Alembic is entitled to a declaration that its proposed ivabradine tablet products described in ANDA No. 215238 do not infringe any valid and enforceable claim of the ’842 Patent,

and their commercial manufacture, use, offer for sale, sale, and/or importation will not infringe, either directly or indirectly, any valid and enforceable claim of the '842 Patent.

DEMAND FOR JURY TRIAL

Counterclaim Plaintiffs demand a trial by jury on all issues so triable in this Action.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim Plaintiffs respectfully request the Court enter judgment in their favor and against Counterclaim Defendants, and grant the following relief:

A. Dismissing Counterclaim Defendants complaint with prejudice;

B. Denying Counterclaim Defendants any of the relief requested in their Complaint;

C. Declaring that the filing of ANDA No. 215238 and the products described in ANDA No. 215238 do not infringe and will not infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit;

D. Declaring that the manufacture, use, offer to sell, sale, and/or importation of the products described in ANDA No. 215238 does not and will not infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

E. Granting Counterclaim Plaintiffs judgment in their favor;

F. Declaring that the 30-month time period referred to in 21 U.S.C. § 355(j)(5)(B)(iii) be shortened to expire immediately upon entry of judgment in Counterclaim Plaintiffs' favor;

G. Declaring this case exceptional in favor of Counterclaim Plaintiffs under 35 U.S.C. § 285 and awarding Counterclaim Plaintiffs their reasonable attorneys' fees incurred in connection with this Action;

H. Awarding Counterclaim Plaintiffs their costs and expenses incurred in this Action; and

I. Awarding all other and further relief as the Court deems just and proper.

Respectfully submitted,

Dated: February 1, 2021

COZEN O'CONNOR, P.C.

/s/ Marla S. Benedek

Marla S. Benedek (# 6638)
1201 N. Market Street, Suite 1001
Wilmington, DE 19801
Tel: (302) 295-2024
Fax: (302) 250-4498
E-mail: mbenedek@cozen.com

Attorneys for Defendants and Counterclaim Plaintiffs Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc.

Of Counsel:

COZEN O'CONNOR, P.C.
W. Blake Coblentz (*pro hac vice* motion to be filed)
Aaron S. Lukas (*pro hac vice* motion to be filed)
Eric Levi (*pro hac vice* motion to be filed)
1200 Nineteenth Street, NW,
Washington, DC 20036
Tel: (202) 912-4800
E-mail: wcoblentz@cozen.com
alukas@cozen.com
elevi@cozen.com