

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ADVERIO PHARMA GMBH, BAYER AG, )  
and BAYER HEALTHCARE )  
PHARMACEUTICALS INC., )

Plaintiffs, )

v. )

C.A. No. \_\_\_\_\_

ALEMBIC PHARMACEUTICALS )  
LIMITED, ALEMBIC GLOBAL HOLDING )  
SA, ALEMBIC PHARMACEUTICALS, INC., )  
and INC RESEARCH, LLC, )

Defendants. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Adverio Pharma GmbH, Bayer AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, “Bayer” or “Plaintiffs”) bring this Complaint for patent infringement against Defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, Alembic Pharmaceuticals, Inc., and INC Research, LLC (collectively “Alembic” or “Defendants”) and allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement by Alembic of U.S. Patent No. 6,743,798 (“the ’798 Patent”), arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly 35 U.S.C. § 271. This action relates to the Abbreviated New Drug Application (“ANDA”) No. 211127, filed by Alembic with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of Bayer’s Adempas<sup>®</sup> (riociguat tablets) drug product (0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg) prior to the expiration of the ’798 Patent.

**PARTIES**

2. Plaintiff Adverio Pharma GmbH (“Adverio”) is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Willy-Brandt-Platz 2, 12529 Schönefeld, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. (“Bayer HealthCare”) is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 100 Bayer Boulevard, Whippany, New Jersey, 07981.

5. On information and belief, Defendant Alembic Pharmaceuticals Limited (“APL”) is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390 003, Gujarat, India. On information and belief, APL is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market.

6. On information and belief, Defendant Alembic Global Holding SA (“Alembic Global”) is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland. On information and belief, Alembic Global is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market.

7. On information and belief, Defendant Alembic Pharmaceuticals, Inc. (“Alembic Pharma”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Highway 202, Bridgewater, NJ 08807. On information and

belief, Alembic Pharma is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market.

8. On information and belief, Defendant INC Research, LLC (“INC Research”) is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 3201 Beechleaf Court, Suite 600, Raleigh, North Carolina 27604. On information and belief, INC Research is in the business of, among other things, performing contract research for pharmaceutical companies.

9. On information and belief, Alembic Global is a wholly owned subsidiary of APL, and is controlled and dominated by APL.

10. On information and belief, Alembic Pharma is a wholly owned subsidiary of Alembic Global, and is controlled and dominated by Alembic Global and APL.

11. On information and belief, Alembic Pharma and/or INC Research are designated U.S. FDA agent(s) for APL.

12. On information and belief, Defendants acted in concert to prepare and submit ANDA No. 211127 to the FDA.

13. On information and belief, and consistent with their practice with respect to other generic products, Defendants will act to distribute and sell the generic riociguat tablet drug product (0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg) that is the subject of ANDA No. 211127 (“Defendants’ ANDA Product”) throughout the United States, including within Delaware. On information and belief, Alembic knows and intends that Defendants’ ANDA Product will be distributed and sold in the United States, including within Delaware.

#### **JURISDICTION AND VENUE**

14. This action arises under the patent laws of the United States. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

15. On information and belief, this Court has personal jurisdiction over Defendants because Defendants have purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court in Delaware.

16. On information and belief, Defendants have had persistent and continuous contacts within this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

17. On information and belief, Alembic Pharma and INC Research are organized under the laws of the State of Delaware and are therefore "at home" in Delaware and subject to suit in this judicial district.

18. On information and belief, Alembic Pharma is registered to do business in Delaware (File Number 5197177), and has thereby consented to suit in Delaware.

19. On information and belief, Alembic Pharma has appointed National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware 19904, as its registered agent for receipt and service of process.

20. On information and belief, INC Research is registered to do business in Delaware (File Number 2656930), and has thereby consented to suit in Delaware.

21. On information and belief, INC Research has appointed Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808, as its registered agent for receipt and service of process.

22. On information and belief, Defendants are in the business of, among other things, formulating, developing, manufacturing, packaging, marketing, and selling generic copies of branded pharmaceutical products for the United States market, including in Delaware. On information and belief, Defendants, directly or through their affiliates and agents, formulate,

manufacture, package, market, and/or sell pharmaceutical products throughout the United States and in Delaware.

23. On information and belief, Defendants derive substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

24. On information and belief, Defendants either sell their generic pharmaceuticals directly into Delaware or have a network of independent wholesalers and distributors with which they contract to market generic pharmaceuticals products in Delaware.

25. Defendants also engaged in Delaware-related activities in connection with their efforts to obtain FDA approval to market Defendants' ANDA Product. On information and belief, Defendants sent a letter dated December 1, 2017 to Plaintiff Bayer HealthCare, a corporation organized under the laws of the State of Delaware, stating that Alembic had submitted ANDA No. 211127 seeking approval to commercially manufacture, use, import, offer for sale, and sell Defendants' ANDA Product prior to the expiration of the '798 Patent. If Defendants succeed in obtaining FDA approval, they would sell Defendants' ANDA Product in Delaware and other states, causing injury to Bayer in Delaware.

26. On information and belief, Defendants have previously invoked this Court's jurisdiction, or has stipulated and/or consented to personal jurisdiction in this district, including in prior patent cases.

27. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

### **BACKGROUND**

28. On June 1, 2004, the United States Patent and Trademark Office issued the '798 Patent, entitled "Substituted Pyrazole Derivatives Condensed with Six-Membered Heterocyclic Rings." A true and correct copy of the '798 Patent is attached hereto as Exhibit A.

29. The '798 Patent claims compounds (along with their stereoisomers) and their associated salts and compositions, as well as methods preparing the compounds and methods for using the compounds. Riociguat is one of the compounds claimed in the '798 Patent.

30. Adverio is the assignee of the '798 Patent and holds title to the '798 Patent.

31. Bayer AG is the exclusive licensee of the '798 Patent in the United States.

32. Plaintiff Bayer HealthCare is the holder of approved New Drug Application (“NDA”) No. 204819 for 0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg tablets of riociguat, which are sold under the trade name Adempas<sup>®</sup>. Adempas<sup>®</sup> is a soluble guanylate cyclase (sGC) stimulator indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension or pulmonary arterial hypertension. Bayer HealthCare markets Adempas<sup>®</sup> in the United States under Bayer AG’s exclusive license.

33. Adempas<sup>®</sup> is included in the FDA’s list of “Approved Drug Products With Therapeutic Equivalence Evaluations,” also known as the “Orange Book.” The '798 Patent is listed in the Orange Book in association with Adempas<sup>®</sup>. The '798 Patent claims cover Adempas<sup>®</sup>.

34. On information and belief, Alembic submitted ANDA No. 211127 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA Product—a generic version of Adempas<sup>®</sup>.

35. On information and belief, Alembic continues to seek approval of ANDA No. 211127 from the FDA and intends to engage in the marketing, commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA Product if the FDA approves ANDA No. 211127.

36. On or about December 4, 2017, Plaintiffs received a letter dated December 1, 2017 (Alembic's "Paragraph IV Letter") purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto, and stating that Alembic had submitted ANDA No. 211127 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Defendants' ANDA Product prior to the expiration of the '798 Patent.

37. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), Alembic's Paragraph IV Letter shall contain "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."

38. Alembic's Paragraph IV Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that the '798 Patent is invalid and that Defendants' ANDA Product will not infringe claims 3-6 of the '798 Patent (Alembic's "Paragraph IV Certification").

39. Alembic's Paragraph IV Letter does not contend that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product would not infringe claims 1, 2, 7, and 8 of the '798 Patent, if valid. For those claims, Alembic's only statement of non-infringement is based on a presumed finding of invalidity.

40. On information and belief, Alembic had actual and constructive notice of the '798 Patent prior to the filing of ANDA No. 211127.

41. Plaintiffs are commencing this action within forty-five days of the date on which they received Alembic's Paragraph IV Letter.

**CLAIM FOR INFRINGEMENT**

(Infringement of the '798 Patent under 35 U.S.C. § 271(e))

42. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

43. On information and belief, Alembic submitted ANDA No. 211127 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '798 Patent.

44. On information and belief, Alembic made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '798 Patent is invalid, unenforceable, and/or not infringed.

45. Under 35 U.S.C. § 271(e)(2), Alembic has infringed the '798 Patent by submitting ANDA No. 211127 with its Paragraph IV Certification and seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the '798 Patent.

46. Upon information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product prior to the expiration of the '798 Patent would infringe, contribute to the infringement of, and/or induce the infringement of claims 1-8 of the '798 Patent.

47. Alembic's Paragraph IV Letter does not contend that Defendants' ANDA Product, or its use, will not infringe claims 1, 2, 7, and 8 of the '798 Patent, if valid.

48. Alembic had actual and constructive notice of the '798 Patent prior to filing ANDA No. 211127.

49. Plaintiffs have no adequate remedy at law to redress the infringement by Alembic.

50. Plaintiffs will be irreparably harmed if Alembic is not enjoined from infringing, actively inducing, or contributing to the infringement of the '798 Patent, either literally or under the doctrine of equivalents.

51. Plaintiffs respectfully request the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Alembic's



ANDA No. 211127 shall be a date that is not earlier than the current expiration date of the '798 Patent and any additional periods of exclusivity.

52. Alembic has proceeded with knowledge of the '798 Patent and no reasonable basis to conclude that it has not infringed the '798 Patent. This is an exceptional case.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

A. a judgment that Alembic has infringed one or more claims of the '798 Patent under 35 U.S.C. § 271(e)(2)(A);

B. a judgment pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Alembic's ANDA No. 211127 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration date of the '798 Patent, including any additional exclusivity period applicable to that patent;

C. a judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product described in ANDA No. 211127 would constitute infringement by Alembic of the '798 Patent, or actively induce and/or contribute to infringement by others, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

D. a judgment permanently enjoining Alembic and each of its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' ANDA Product until the day after the expiration of the '798 Patent, including any additional exclusivity period applicable to that patent, and from otherwise infringing one or more claims of the '798 Patent, either literally or under the doctrine of equivalents;

E. damages from Alembic if it engages in any commercial activity constituting infringement of the '798 Patent, or inducing or contributing to such infringement, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

F. a declaration that this case is exceptional;

G. an award of Plaintiffs' costs, expenses, reasonable attorneys' fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

H. such other and further relief as the Court may deem just and proper.

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January 9, 2018