

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

ADVERIO PHARMA GMBH, BAYER AG, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	:	Civil Action No.: _____
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, and ALEMBIC PHARMACEUTICALS, INC.,	:	
	:	
Defendants.	:	

COMPLAINT

Plaintiffs Adverio Pharma GmbH, Bayer AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, “Bayer” or “Plaintiffs”), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively, “Alembic” or “Defendants”) of an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs’ 0.5 mg, 1.0 mg, 1.5 mg, 2.0 mg, and 2.5 mg ADEMPAS® tablet products prior to the expiration of U.S. Patent Nos. 10,662,188 (“the ’188 patent”) and 11,203,593 (“the ’593 patent”).

THE PARTIES

Plaintiffs

2. Plaintiff Adverio Pharma GmbH (“Adverio”) is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, D-51373 Leverkusen, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a 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. Bayer HealthCare is the holder of New Drug Application No. 204819 for ADEMPAS®, which has been approved by the FDA.

Alembic

6. On information and belief, Defendant Alembic Pharmaceuticals Limited (“APL”) is a corporation organized and existing under the laws of India, with a place of business at Alembic Road, Vadodara 390 003, Gujarat, India.

7. On information and belief, Defendant Alembic Global Holding SA (“Alembic Global”) is a corporation organized and existing under the laws of Switzerland, with a place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

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

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. On information and belief, Alembic Pharma is the U.S. agent for APL.

11. On information and belief, APL is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, APL, acting in concert with Alembic Global and Alembic Pharma, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, APL, acting in concert with Alembic Global and Alembic Pharma, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“Paragraph IV Certifications”) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

12. On information and belief, APL, Alembic Global, and Alembic Pharma acted in concert to prepare and submit ANDA No. 216967 for APL’s 0.5 mg, 1.0 mg, 1.5 mg, 2.0 mg, and 2.5 mg riociguat tablets (“Alembic’s ANDA Products”), which was done at the direction of, under the control of, and for the direct benefit of APL.

13. On information and belief, APL, Alembic Global, and Alembic Pharma are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm’s length, including with respect to

the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Alembic's ANDA Products at issue.

14. On information and belief, following any FDA approval of ANDA No. 216967, APL, Alembic Global, and Alembic Pharma will act in concert to market, distribute, offer for sale, and sell Alembic's ANDA Products throughout the United States and within New Jersey. These three entities are hereafter collectively referred to as "Alembic."

15. On information and belief, following any FDA approval of ANDA No. 216967, Alembic knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

JURISDICTION

16. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

17. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

18. This Court has personal jurisdiction over Alembic Pharma because, among other things, on information and belief: (1) Alembic Pharma maintains regular and established, physical places of business in Bridgewater, New Jersey and in Bedminster, New Jersey; (2) Alembic Pharma is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 101031141; (3) Alembic Pharma is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5004785. Accordingly, Alembic Pharma is, on information and belief, physically present in New Jersey.

19. On information and belief, Alembic Pharma is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in New Jersey, and relies on contributions from APL and Alembic Global.

20. On information and belief, Alembic Pharma, acting as the agent of APL and Alembic Global, markets, distributes, offers for sale, and/or sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by APL or for which APL is the named applicant on approved ANDAs.

21. In addition, this Court has personal jurisdiction over APL, Alembic Global, and Alembic Pharma because, among other things, on information and belief: (1) APL, acting in concert with Alembic Global and Alembic Pharma, has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic ANDA Products in the United States, including in New Jersey; and (2) APL, Alembic Global, and Alembic Pharma, acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Alembic's ANDA Products in the United States, including in New Jersey, upon approval of ANDA No. 216967, and will derive substantial revenue from the use or consumption of Alembic's ANDA Products in New Jersey. On information and belief, if ANDA No. 216967 is approved, the generic Alembic products charged with infringing the '188 and '593 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

22. Alternatively, if APL's connections with New Jersey, including its connections with Alembic Pharma, are found to be insufficient to confer personal jurisdiction, then, on information and belief, APL is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over APL in New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

23. Alternatively, if Alembic Global's connections with New Jersey, including its connections with Alembic Pharma, are found to be insufficient to confer personal jurisdiction, then, on information and belief, Alembic Global is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Alembic Global in New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

24. Alembic has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and APL and Alembic Pharma have filed counterclaims in at least one such case.

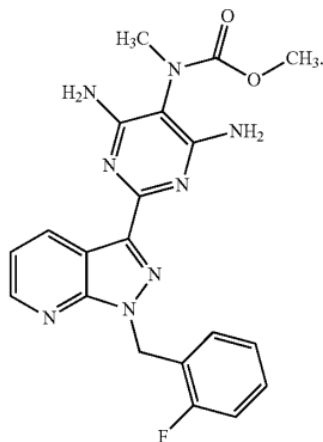
VENUE

25. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

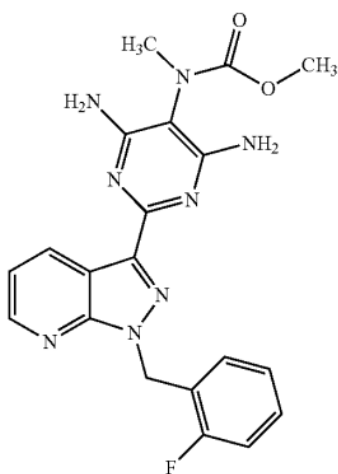
THE '188 PATENT

26. The '188 patent, entitled "Forms of Methyl {4,6-diamino-2-[1(2-fluorobenzyl)-1H-pyrazolo[3-4-b]pyridino-3-yl]pyrimidino-5-yl} Methyl Carbamate," was duly and legally issued on May 26, 2020. The '188 patent is attached as Exhibit A.

27. As set forth in greater detail in the '188 patent, the claims of the '188 patent, incorporated by reference herein, cover certain forms of methyl {4,6-diamino-2-[1(2-fluorobenzyl)-1H-pyrazolo[3-4-b]pyridino-3-yl]pyrimidino-5-yl}methylcarbamate of the following formula:



The '188 patent also covers pharmaceutical compositions and methods of using pharmaceutical compositions comprising such forms. For example, claim 1 recites, “A pharmaceutical composition comprising a sesqui-DMSO solvate of a compound of formula (I)



wherein the sesqui-DMSO solvate of the compound of formula (I) is characterized by an X-Ray powder diffractogram comprising peak maxima of the 2 Theta angel [sic] of 8.3, 13.7, 15.7, and further wherein the pharmaceutical composition contains more than 90 percent by weight of the sesqui-DMSO solvate of the compound of formula (I) related to the total amount of all forms of the compound of formula (I) present in the pharmaceutical composition.”

28. In addition, as set forth in greater detail in the claim itself, claim 8 of the '188 patent is directed to a pharmaceutical composition comprising a 1/4-ethyl acetate solvate of a compound of formula (I).

29. Further, as set forth in greater detail in the claim itself, claim 15 of the '188 patent is directed to a compound of formula (I) in the form of modification I, as 1/4-ethyl acetate solvate, or a mixture thereof.

30. Adverio is the assignee of the '188 patent.

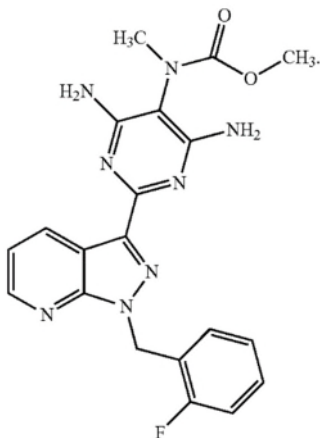
31. Bayer AG is an exclusive licensee under the '188 patent.

32. Pursuant to 21 U.S.C. § 355, the '188 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with ADEMPAS® in 0.5 mg, 1.0 mg, 1.5 mg, 2.0 mg, and 2.5 mg dosage strengths.

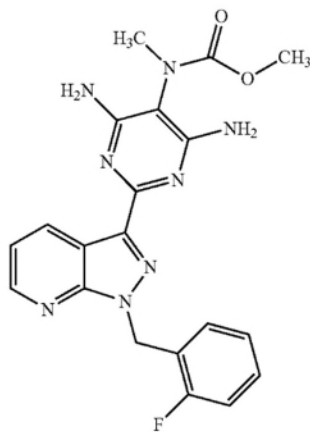
THE '593 PATENT

33. The '593 patent, entitled "Forms of Methyl {4,6-diamino-2-[1(2-fluorobenzyl)-1H-pyrazolo[3-4-b]pyridino-3-yl]pyrimidino-5-yl} Methyl Carbamate," was duly and legally issued on December 21, 2021. The '593 patent is attached as Exhibit B.

34. As set forth in greater detail in the '593 patent, the claims of the '593 patent, incorporated by reference herein, cover certain forms of methyl {4,6-diamino-2-[1(2-fluorobenzyl)-1H-pyrazolo[3-4-b]pyridino-3-yl]pyrimidino-5-yl}methylcarbamate of the following formula:



The '593 patent also covers pharmaceutical compositions and methods of using pharmaceutical compositions comprising such forms. For example, claim 1 recites, “A compound of the formula (I)



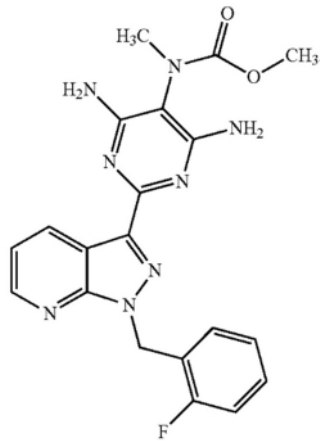
in crystalline form having an X-Ray powder diffractogram comprising at least three peak maxima of the 2 Theta angle selected from 6.7, 9.1, 14.3, 14.4, 17.8, 19.8, 20.2, 24.8, 25.6 and 27.3.”

35. Adverio is the assignee of the '593 patent.
36. Bayer AG is an exclusive licensee under the '593 patent.
37. Pursuant to 21 U.S.C. § 355, the '593 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) in connection with ADEMPAS® in 0.5 mg, 1.0 mg, 1.5 mg, 2.0 mg, and 2.5 mg dosage strengths.

Infringement by Alembic

38. By letter dated September 2, 2022, (the “Alembic Notice Letter”), Alembic notified Bayer HealthCare and Adverio that APL had submitted to the FDA ANDA No. 216967 for Alembic’s ANDA Products. These products are generic versions of ADEMPAS®.

39. In the Alembic Notice Letter, Alembic stated that Alembic’s ANDA Products contain a crystalline form of riociguat, which is a compound of the following formula:



40. On information and belief, the manufacture, use (including in accordance with and as directed by Alembic’s proposed labeling for Alembic’s ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Alembic’s ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claims 1, 8 and/or 15 of the ’188 patent.

41. On information and belief, the manufacture, use (including in accordance with and as directed by Alembic’s proposed labeling for Alembic’s ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Alembic’s ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the ’593 patent.

42. On information and belief, Alembic’s ANDA Products are not publicly available, nor is ANDA No. 216967 accessible to the public.

43. In Alembic's Notice Letter, Alembic included an Offer of Confidential Access to portions of ANDA No. 216967. The offer, however, was subject to various unreasonably restrictive conditions.

44. On September 29, 2022, counsel for Plaintiffs sent a letter to counsel for Alembic attempting to negotiate access to Alembic's ANDA and other materials, including samples, and proposing that the parties use a draft protective order that was based on protective orders previously used in Hatch-Waxman litigation.

45. On October 4, 2022, counsel for Plaintiffs and counsel for Alembic had a meet-and-confer call to discuss access to Alembic's ANDA and other materials on confidential terms. However, the parties were unable to reach agreement on such confidential terms.

46. In the Alembic Notice Letter, Alembic indicated that, in connection with its ANDA No. 216967, Alembic had filed Paragraph IV Certifications with respect to the '188 and '593 patents.

47. In the Alembic Notice Letter, Alembic also indicated that the FDA had received an ANDA from Alembic seeking approval for generic versions of the 0.5 mg, 1.0 mg, 1.5 mg, 2.0 mg, and 2.5 mg strengths of Plaintiffs' ADEMPAS® products.

48. The purpose of ANDA No. 216967 was to obtain approval under the Food Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products, including with their proposed labeling, prior to the expiration of the '188 and '593 patents.

49. Alembic intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Products with their proposed

labeling immediately and imminently upon approval of ANDA No. 216967, *i.e.*, prior to the expiration of the '188 and '593 patents.

50. Alembic has knowledge of the claims of the '188 and '593 patents. Notwithstanding this knowledge, Alembic has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 216967. On information and belief, by such activities, Alembic specifically intends infringement of the '188 and '593 patents.

51. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '188 and '593 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

52. On information and belief, Alembic knows that Alembic's ANDA Products are especially made or adapted for use in infringing the '188 and '593 patents, and that Alembic's ANDA Products are not suitable for substantial noninfringing use. Alembic's ANDA Products are a material part of the claimed invention. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '188 and '593 patents immediately and imminently upon approval of ANDA No. 216967.

53. On information and belief, the foregoing actions by Alembic constitute and/or will constitute infringement of each of the '188 and '593 patents, active inducement of infringement of each of the '188 and '593 patents, and/or contribution to the infringement by others of each of the '188 and '593 patents.

54. An actual case or controversy exists between Plaintiffs and Alembic with respect to infringement of each of the '188 and '593 patents.

55. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Alembic Notice Letter.

COUNT I
(Infringement of the '188 Patent)

56. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

57. Alembic's submission of ANDA No. 216967 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products was an act of infringement of the '188 patent under 35 U.S.C. § 271(e)(2).

58. On information and belief, Alembic has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Alembic's ANDA Products, including with their proposed labeling, prior to the expiration of the '188 patent.

59. Alembic intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Products, including with their proposed labeling, immediately and imminently upon approval of ANDA No. 216967, *i.e.*, prior to the expiration of the '188 patent.

60. On information and belief, the foregoing actions by Alembic constitute and/or will constitute infringement of the '188 patent, active inducement of infringement of the '188 patent, and/or contribution to the infringement by others of the '188 patent.

61. Unless Alembic is enjoined from infringing the '188 patent, actively inducing infringement of the '188 patent, and contributing to the infringement by others of the '188 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Declaratory Judgment of Infringement of the '188 Patent)

62. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

63. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Alembic on the other regarding Alembic's liability for infringement, active inducement of, and contribution to infringement of the '188 patent.

64. An actual case or controversy exists between Plaintiffs and Alembic with respect to Alembic's liability for infringement of the '188 patent.

65. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Alembic's ANDA Products will infringe, induce the infringement of, and contribute to the infringement of the '188 patent.

COUNT III
(Infringement of the '593 Patent)

66. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

67. Alembic's submission of ANDA No. 216967 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products was an act of infringement of the '593 patent under 35 U.S.C. § 271(e)(2).

68. On information and belief, Alembic has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Alembic's ANDA Products, including with their proposed labeling, prior to the expiration of the '593 patent.

69. Alembic intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Products, including with their proposed labeling, immediately and imminently upon approval of ANDA No. 216967, *i.e.*, prior to the expiration of the '593 patent.

70. On information and belief, the foregoing actions by Alembic constitute and/or will constitute infringement of the '593 patent, active inducement of infringement of the '188 patent, and/or contribution to the infringement by others of the '593 patent.

71. Unless Alembic is enjoined from infringing the '593 patent, actively inducing infringement of the '593 patent, and contributing to the infringement by others of the '593 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV
(Declaratory Judgment of Infringement of the '593 Patent)

72. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

73. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Alembic on the other regarding Alembic's liability for infringement, active inducement of, and contribution to infringement of the '593 patent.

74. An actual case or controversy exists between Plaintiffs and Alembic with respect to Alembic's liability for infringement of the '593 patent.

75. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Alembic's ANDA Products will infringe, induce the infringement of, and contribute to the infringement of the '593 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

- (a) A judgment that Alembic has infringed the '188 patent;
- (b) A judgment that Alembic has infringed the '593 patent
- (c) A judgment ordering that the effective date of any FDA approval for Alembic to make, use, offer for sale, sell, market, distribute, or import Alembic's ANDA Products, or any product or compound the use of which infringes the '188 patent, be no earlier than the expiration date of the '188 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) A judgment ordering that the effective date of any FDA approval for Alembic to make, use, offer for sale, sell, market, distribute, or import Alembic's ANDA Products, or any product or compound the use of which infringes the '593 patent, be no earlier than the expiration date of the '593 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (e) A preliminary and permanent injunction enjoining Alembic, and all persons acting in concert with Alembic, from making, using, selling, offering for sale, marketing, distributing, or importing Alembic's ANDA Products, or any product or compound the use of which infringes the '188 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '188 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (f) A preliminary and permanent injunction enjoining Alembic, and all persons acting in concert with Alembic, from making, using, selling, offering for sale, marketing, distributing, or importing Alembic's ANDA Products, or any product or compound the use of which infringes the '593 patent, or the inducement of or the contribution to any of the foregoing,

prior to the expiration date of the '593 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Alembic's ANDA Products prior to the expiration of the '188 patent will infringe and induce the infringement of the '188 patent;

(h) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Alembic's ANDA Products prior to the expiration of the '593 patent will infringe and induce the infringement of the '593 patent;

(i) A declaration that this is an exceptional case and an award of attorneys' fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(j) An award of Plaintiffs' costs and expenses in this action; and

(k) Such further and other relief as this Court may deem just and proper.

Dated: October 17, 2022

s/ David E. De Lorenzi

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