

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AGIOS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ANNORA PHARMA PRIVATE LIMITED,	)	
HETERO LABS LIMITED, AND HETERO	)	
USA INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Agios Pharmaceuticals, Inc. (“Agios”) by its attorneys, hereby alleges 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 Defendants Annora Pharma Private Limited (“Annora”), Hetero Labs Limited (“Hetero Labs”), and Hetero USA Inc. (“Hetero USA”) (collectively “Defendants”) of Abbreviated New Drug Application (“ANDA”) No. 221270 to the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of Pyrukynd® (mitapivat) in 5, 20, and 50 mg strength tablets (“Annora’s Proposed ANDA Product”) prior to the expiration of U.S. Patent Nos. 11,234,976 (“the ’976 Patent”); 11,254,652 (“the ’652 Patent”); and 11,878,049 (“the ’049 Patent”) (collectively, “the Asserted Patents”). Defendants notified Agios that they had submitted ANDA No. 221270 by a letter dated April 16, 2026 (the “Notice Letter”). Upon information and belief, if approved by the FDA, Annora’s Proposed ANDA Product will be marketed as a competing product to Pyrukynd®, a product developed and marketed by Agios for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

PARTIES

2. Agios is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 88 Sidney Street, Cambridge, Massachusetts 02139-4169.

3. On information and belief, Defendant Annora is a corporation organized and existing under the laws of India, having its principal place of business at Sy. No. 261, Plot No. 13 to 14, Annaram Village, Gummadidala Mandal, Sangareddy District, Telangana State, 502313, India.

4. On information and belief, Defendant Hetero Labs is a corporation organized and existing under the laws of India, having a principal place of business at #7-2-A2, Industrial Estates, Sanath Nagar Hyderabad - 500018, Telangana, India.

5. On information and belief, Defendant Hetero USA is a corporation organized and existing under the laws of the State of Delaware (File No. 4837317), having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

6. On information and belief, Hetero Labs is the parent company of Annora and Hetero USA. *See, e.g., Mirum Pharmaceuticals, Inc., et al., v. Annora Pharma Private Limited, et al.*, C.A. No. 25-1537-MN, D.I. 14 at 5, ¶ 11 (D. Del. Feb. 20, 2026). On information and belief, Annora is a wholly owned subsidiary of Hetero Labs. *See, e.g., id.*

7. On information and belief, Hetero Labs ultimately owns all of Annora's ANDAs, including ANDA No. 221270.

8. On information and belief, Hetero USA is the regulatory agent for Annora and Hetero Labs with respect to ANDA No. 221270. The Notice Letter Agios received from Annora was signed by "Somaraju Indukuri," as the "U.S. Agent for Annora Pharma Private Limited," and represented the same individual as "authorized to accept service of process for any patent

infringement complaint” against Annora. On information and belief, Somaraju Indukuri is the Vice President, Regulatory Affairs, U.S. Agent, for Hetero USA. The letter packaging for the Notice Letter identified the sender as “Hetero USA” and the address of the sender as “1035 Centennial Ave[,], Piscataway[,], NJ 08854.”

9. On information and belief, Defendants collaborate with respect to, among other things, the development, regulatory approval, marketing, sale, and/or distribution of generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware. For example, Defendants have admitted that Hetero Labs ultimately owns all of Annora’s ANDAs. *See, e.g., Harmony Biosciences, LLC v. AET Pharma US, Inc.*, C.A. No. 23-1340-MN, D.I. 38 at 6, ¶ 21 (D. Del. Mar. 4, 2024). Hetero USA, the agent for Annora, has stated that it is the U.S. sales and marketing arm of Hetero Labs. *See Presence*, Hetero, <https://www.hetero.com/presence> (last visited May 26, 2026) (listing Hetero USA as “the sales and marketing arm of Hetero [Labs’] Active Pharmaceutical Ingredients (API) and Custom Pharmaceutical Services (CPS) business in USA”). On further information and belief, Defendants are agents of one another and/or operate in concert as integrated parts of the same business group, including with respect to the preparation and submission of ANDA No. 221270 and the development, manufacturing, marketing, sale, and distribution of Annora’s Proposed ANDA Product.

10. On information and belief, Hetero Labs and Hetero USA were, are, and will be actively involved in the preparation, submission, maintenance, and further prosecution of ANDA No. 221270, together with Annora, and they intend to directly or indirectly benefit from the preparation, submission, maintenance, and further prosecution of ANDA No. 221270, such that

Hetero Labs and Hetero USA should be deemed submitters of ANDA No. 221270 together with Annora.

JURISDICTION AND VENUE

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

12. This Court has personal jurisdiction over Defendant Hetero USA because, on information and belief, Hetero USA is a corporation organized and existing under the laws of the State of Delaware.

13. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, themselves and through their subsidiaries, agents, and/or affiliates, have purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. Upon information and belief, Defendants, themselves and through their subsidiaries, agents, and/or affiliates, develop, manufacture, import, market, offer to sell, sell, and/or distribute a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transact business within Delaware relating to Plaintiff's claims, and/or have engaged in systematic and continuous business contacts within Delaware.

14. In addition, this Court has personal jurisdiction over Defendants because, among other things, upon information and belief: (1) Defendants acted in concert with respect to the development, preparation, and filing of Annora's Proposed ANDA product that is the subject of ANDA No. 221270 and submitted ANDA No. 221270 for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in the United States of Annora's Proposed ANDA Product, including in Delaware; (2) upon approval of Annora's ANDA, Defendants will act in concert to market, distribute, offer for sale, and sell in the United States,

and/or import into the United States, including in Delaware, Annora's Proposed ANDA Product, and will derive substantial revenue from the use or consumption of Annora's Proposed ANDA Product in Delaware; (3) upon approval of Annora's ANDA, Annora's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, and sold in Delaware, and/or imported into Delaware; prescribed by physicians practicing in Delaware and administered to patients in Delaware, all of which would have substantial effects on Delaware. By submitting Annora's ANDA, Defendants have shown they will use distribution channels to direct sales of Annora's Proposed ANDA Product into Delaware.

15. In addition, this Court has personal jurisdiction over Defendants because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Agios, a Delaware corporation.

16. Furthermore, this Court has personal jurisdiction over Defendants because they have regularly engaged in patent litigation concerning Annora's ANDA products in this District and have consented to jurisdiction in Delaware in prior cases arising out of the filing of ANDAs. *Sumitomo Pharma Switzerland GmbH, et al., v. Annora Pharma Private Limited, et al.*, 25-380-MN (D. Del.), *Mirum Pharmaceuticals, Inc., et al., v. Annora Pharma Private Limited, et al.*, No. 25-1537-MN (D. Del.), *Sumitomo Pharma Switzerland GmbH, et al., v. Annora Pharma Private Limited, et al.*, C.A. No. 25-380-MN (D. Del.), *Azurity Pharmaceuticals, Inc., et al., v. Annora Pharma Private Ltd.*, C.A. No. 25-1493-MN (D. Del.), *Azurity Pharmaceuticals, Inc. v. Annora Pharma Private Ltd.*, C.A. No. 25-1139-CFC (D. Del.).

17. In the alternative, this Court has personal jurisdiction over Annora and Hetero Labs under Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiff's claims arise under federal

law; (b) Annora and Hetero Labs are foreign companies not subject to jurisdiction in any state's courts of general jurisdiction; and (c) Annora and Hetero Labs have sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Annora and Hetero Labs satisfies due process.

18. Venue is proper in this judicial district as to Annora and Hetero Labs under 28 U.S.C. § 1391(c)(3) at least because, upon information and belief, Annora and Hetero Labs are foreign corporations that may be sued in any judicial district in the United States.

19. Venue is proper in this judicial district as to Hetero USA under 28 U.S.C. § 1400(b) because, *inter alia*, Hetero US is incorporated in Delaware and therefore resides in Delaware.

BACKGROUND

PYRUKYND[®] (MITAPIVAT)

20. Pyrukynd[®] is a pyruvate kinase activator indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

21. Agios sells Pyrukynd[®] in the United States pursuant to New Drug Application (“NDA”) No. 216196, which has been approved by the FDA.

22. Agios is the holder of approved NDA No. 216196 for Pyrukynd[®].

23. The Asserted Patents are listed for NDA No. 216196 for Pyrukynd[®] in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.”

24. The '976 Patent, titled “Methods of Using Pyruvate Kinase Activators,” was duly and legally issued on February 1, 2022. A copy of the '976 Patent is attached as Exhibit A.

25. Agios is the assignee of the '976 Patent.

26. There is an actual case or controversy between the parties regarding Defendants' liability for their infringement of the '976 Patent.

27. The '652 Patent, titled "Crystalline Forms of N-(4-(4-(Cyclopropylmethyl)piperazine-1-carbonyl)phenyl)quinoline-8-sulfonamide," was duly and legally issued on February 22, 2022. A copy of the '652 Patent is attached as Exhibit B.

28. Agios is the assignee of the '652 Patent.

29. There is an actual case or controversy between the parties regarding Defendants' liability for their infringement of the '652 Patent.

30. The '049 Patent, titled "Mitapivat Therapy and Modulators of Cytochrome P450," was duly and legally issued on January 23, 2024. A copy of the '049 Patent is attached as Exhibit C.

31. Agios is the assignee of the '049 Patent.

32. There is an actual case or controversy between the parties regarding Defendants' liability for their infringement of the '049 Patent.

33. This action is being filed within 45 days of Plaintiff's receipt of Annora's Notice Letter.

ANNORA'S ANDA

34. According to Annora's Notice Letter, ANDA No. 221270 includes a certification pursuant to the Food, Drug, & Cosmetic Act ("FDCA") 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of Annora's Proposed ANDA Product.

35. Defendants were aware of the Asserted Patents when ANDA No. 221270 was filed with a Paragraph IV Certification.

36. Upon information and belief, mitapivat, present as mitapivat sulfate, is the active ingredient in Annora's Proposed ANDA Product.

37. Upon information and belief, ANDA No. 221270 refers to and relies upon the NDA for Pyrukynd[®] and contains data that, according to Defendants, demonstrate bioequivalence of Annora's Proposed ANDA Product and Pyrukynd[®], *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7), or Defendants have sought a waiver of the requirement to demonstrate bioequivalence of their Proposed ANDA Product and Pyrukynd[®].

38. Upon information and belief, Defendants intend to have healthcare professionals administer Annora's Proposed ANDA Product, if approved, as set forth in Annora's proposed label for this ANDA product. Upon information and belief, Annora's proposed label will instruct healthcare professionals to prescribe and administer Annora's Proposed ANDA Product in the manner set forth in the label.

COUNT I
(Infringement of the '976 Patent)

39. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

40. Claim 1 of the '976 Patent covers "A method for treating pyruvate kinase deficiency (PKD) in a subject in need thereof, comprising orally administering to the subject once or twice daily a dose of about 10 mg to about 60 mg or about 60 mg to about 200 mg of (1) Compound 1 or a pharmaceutically acceptable salt or hydrate thereof; or (2) a pharmaceutical composition comprising Compound 1 or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier, to thereby treat PKD in the subject, wherein Compound 1 is N-(4-(4-(cyclopropylmethyl)piperazine-1-carbonyl)phenyl)quinoline-8-sulfonamide."

41. Upon information and belief, Annora's Proposed ANDA Product and its use are covered by one or more of the claims of the '976 Patent, including at least claim 1.

42. Upon information and belief, the commercial manufacture, sale, offer for sale, and/or importation of Annora's Proposed ANDA Product, and/or the use of Annora's Proposed ANDA Product in accordance with and as directed by Annora's proposed label for that product, will infringe one or more claims of the '976 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

43. Upon information and belief, Defendants submitted as part of ANDA No. 221270 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that the claims of the '976 Patent are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Annora's Proposed ANDA Product.

44. Defendants did not contend in Annora's Notice Letter that Annora's Proposed ANDA Product, or the use of Annora's Proposed ANDA Product in accordance with and as directed by Annora's proposed label for that product, would not infringe the '976 Patent.

45. The purpose of submitting ANDA No. 221270 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's Proposed ANDA Product prior to the expiration of the '976 Patent.

46. Defendants' submission of ANDA No. 221270 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's Proposed ANDA Product prior to the expiration of the '976 Patent was an act of infringement of the '976 Patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's Proposed ANDA Product and the proposed label immediately and imminently upon the approval

of ANDA No. 221270 and any amendments thereto, i.e., prior to the expiration of the '976 Patent, in violation of 35 U.S.C. § 271(a).

48. Upon information and belief, Defendants have knowledge of the '976 Patent at least because the '976 Patent is listed in the FDA's Orange Book for Plaintiff's Pyrukynd[®] drug product. Notwithstanding this knowledge, Defendants continue to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's Proposed ANDA Product and the proposed label therefor immediately and imminently upon the approval of ANDA No. 221270.

49. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '976 Patent when ANDA No. 221270 is approved, and will do so with specific intent to induce infringement of the '976 Patent, in violation of 35 U.S.C. § 271(b). Further upon information and belief, Defendants plan and intend to, and will, do so immediately and imminently upon approval.

50. Upon information and belief, Defendants know that Annora's Proposed ANDA Product is especially made or adapted for use in patented methods of the '976 Patent, and that Annora's Proposed ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '976 Patent immediately and imminently upon approval of ANDA No. 221270, in violation of 35 U.S.C. 271(c).

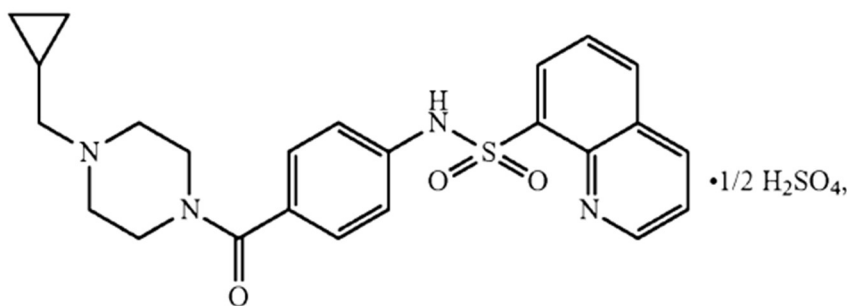
51. The foregoing actions by Defendants constitute and/or will constitute infringement of the '976 Patent, active inducement of infringement of the '976 Patent, and contribution to the infringement by others of the '976 Patent, either literally or under the doctrine of equivalents.

52. Unless Defendants are enjoined from infringing the '976 Patent, actively inducing infringement of the '976 Patent, and contributing to the infringement by others of the '976 Patent, Agios will suffer irreparable injury. Agios has no adequate remedy at law.

COUNT II
(Infringement of the '652 Patent)

53. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

54. Claim 1 of the '652 Patent covers “A crystalline form of a compound having the formula:



wherein the crystalline form is crystalline form A characterized by x-ray powder diffraction peaks at 2 Θ angles ($\pm 0.2^\circ$) 9.9°, 15.8°, and 22.6°.”

55. Upon information and belief, Annora’s Proposed ANDA Product and its use are covered by one or more of the claims of the '652 Patent, including at least claim 1.

56. Upon information and belief, the commercial manufacture, sale, offer for sale, and/or importation of Annora’s Proposed ANDA Product, and/or the use of Annora’s Proposed ANDA Product in accordance with and as directed by Annora’s proposed label for that product, will infringe one or more claims of the '652 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

57. Upon information and belief, Defendants submitted as part of ANDA No. 221270 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), asserting that the claims of the '652 Patent are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Annora's Proposed ANDA Product.

58. The purpose of submitting ANDA No. 221270 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's Proposed ANDA Product prior to the expiration of the '652 Patent.

59. Defendants' submission of ANDA No. 221270 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's Proposed ANDA Product prior to the expiration of the '652 Patent was an act of infringement of the '652 Patent under 35 U.S.C. § 271(e)(2)(A).

60. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's Proposed ANDA Product and the proposed label immediately and imminently upon the approval of ANDA No. 221270 and any amendments thereto, i.e., prior to the expiration of the '652 Patent, in violation of 35 U.S.C. § 271(a).

61. Upon information and belief, Defendants have knowledge of the '652 Patent at least because the '652 Patent is listed in the FDA's Orange Book for Plaintiff's Pyrukynd[®] drug product. Notwithstanding this knowledge, Defendants continue to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's Proposed ANDA Product and the proposed label therefor immediately and imminently upon the approval of ANDA No. 221270.

62. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '652 Patent when ANDA No. 221270 is approved, and will do so with

specific intent to induce infringement of the '652 Patent, in violation of 35 U.S.C. § 271(b). Further upon information and belief, Defendants plan and intend to, and will, do so immediately and imminently upon approval.

63. Upon information and belief, Defendants know that Annora's Proposed ANDA Product is especially made or adapted for use in patented methods of the '652 Patent, and that Annora's Proposed ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '652 Patent immediately and imminently upon approval of ANDA No. 221270, in violation of 35 U.S.C. § 271(c).

64. The foregoing actions by Defendants constitute and/or will constitute infringement of the '652 Patent, active inducement of infringement of the '652 Patent, and contribution to the infringement by others of the '652 Patent, either literally or under the doctrine of equivalents.

65. Unless Defendants are enjoined from infringing the '652 Patent, actively inducing infringement of the '652 Patent, and contributing to the infringement by others of the '652 Patent, Agios will suffer irreparable injury. Agios has no adequate remedy at law.

COUNT III
(Infringement of the '049 Patent)

66. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

67. Claim 1 of the '049 Patent covers "A method of treating hemolytic anemia in a subject, comprising administering to the subject about 10 mg/day, about 40 mg/day, about 100 mg/day, or about 200 mg/day of mitapivat or a pharmaceutically acceptable salt thereof and a moderate inducer of cytochrome P450 3A4/5 (CYP3A4/5)."

68. Upon information and belief, Annora's Proposed ANDA Product and its use are covered by one or more of the claims of the '049 Patent, including at least claim 1.

69. Upon information and belief, the commercial manufacture, sale, offer for sale, and/or importation of Annora's Proposed ANDA Product, and/or the use of Annora's Proposed ANDA Product in accordance with and as directed by Annora's proposed label for that product, will infringe one or more claims of the '049 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

70. Upon information and belief, Defendants submitted as part of ANDA No. 221270 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that the claims of the '049 Patent are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Annora's Proposed ANDA Product.

71. The purpose of submitting ANDA No. 221270 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's Proposed ANDA Product prior to the expiration of the '049 Patent.

72. Defendants' submission of ANDA No. 221270 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's Proposed ANDA Product prior to the expiration of the '049 Patent was an act of infringement of the '049 Patent under 35 U.S.C. § 271(e)(2)(A).

73. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's Proposed ANDA Product and the proposed label immediately and imminently upon the approval of ANDA No. 221270 and any amendments thereto, i.e., prior to the expiration of the '049 Patent, in violation of 35 U.S.C. § 271(a).

74. Upon information and belief, Defendants have knowledge of the '049 Patent at least because the '049 Patent is listed in the FDA's Orange Book for Plaintiff's Pyrukynd[®] drug product. Notwithstanding this knowledge, Defendants continue to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's Proposed ANDA Product and the proposed label therefor immediately and imminently upon the approval of ANDA No. 221270.

75. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '049 Patent when ANDA No. 221270 is approved, and will do so with specific intent to induce infringement of the '049 Patent, in violation of 35 U.S.C. § 271(b). Further upon information and belief, Defendants plan and intend to, and will, do so immediately and imminently upon approval.

76. Upon information and belief, Defendants know that Annora's Proposed ANDA Product is especially made or adapted for use in patented methods of the '049 Patent, and that Annora's Proposed ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '049 Patent immediately and imminently upon approval of ANDA No. 221270, in violation of 35 U.S.C. § 271(c).

77. The foregoing actions by Defendants constitute and/or will constitute infringement of the '049 Patent, active inducement of infringement of the '049 Patent, and contribution to the infringement by others of the '049 Patent, either literally or under the doctrine of equivalents.

78. Unless Defendants are enjoined from infringing the '049 Patent, actively inducing infringement of the '049 Patent, and contributing to the infringement by others of the '049 Patent, Agios will suffer irreparable injury. Agios has no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that Defendants have infringed the Asserted Patents under 35 U.S.C. § 271(e)(2)(A);

(b) A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Defendants to make, use, offer for sale, sell, market, distribute, or import Annora's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the latest expiration date among the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining Defendants, and all persons and entities acting in concert with Defendants, from making, using, selling, offering for sale, marketing, distributing, or importing Annora's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the latest-expiring of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Annora's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, prior to the expiration date of the latest-expiring of the Asserted Patents, infringes, will infringe, will actively induce infringement of, and/or will contribute to the infringement by others of the Asserted Patents under 35 U.S.C. §§ 271(a), (b) and (c);

(e) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in making, using, selling, offering for same, marketing, distributing, or importing of Annora's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, or induces or contributes to such conduct, prior to the expiration date of the

latest-expiring of the Asserted Patents, including of any extension(s) and additional period(s) of exclusivity;

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

(g) An award of Plaintiff's costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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