IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACACIA PHARMA LIMITED, PAION UK LIMITED, and EAGLE PHARMACEUTICALS, INC., Plaintiffs, v. GALENICUM HEALTH S.L.U., Defendant.	)))))))))))	C.A. No. _____

COMPLAINT

Plaintiffs Acacia Pharma Limited, PAION UK Limited, and Eagle Pharmaceuticals, Inc. (collectively, "Plaintiffs") by their attorneys, 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 Defendant Galenicum Health S.L.U. ("Defendant" or "Galenicum") of Abbreviated New Drug Application ("ANDA") No. 219794 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of BYFAVO® (remimazolam) for injection 2.5 mg/mL ("Galenicum's Proposed ANDA Product"), prior to the expiration of U.S. Patent Nos. 9,561,236 (the "'236 Patent") and 9,827,251 (the "'251 Patent") (collectively the "Asserted Patents").

2. Galenicum notified Plaintiffs that it had submitted ANDA No. 219794 by a letter dated November 20, 2024 and received November 21, 2024 ("Notice Letter"). Upon information and belief, Galenicum's Proposed ANDA Product will be marketed as a competing product to BYFAVO® (remimazolam), a product developed for induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

PARTIES

3. Plaintiff Acacia Pharma Limited ("Acacia") is a private limited company organized and existing under the laws of the United Kingdom, having its corporate offices and a place of business at One Ashley Road, Third Floor, Altrincham, Cheshire, United Kingdom, WA14 2DT. Acacia Pharma Limited is a wholly owned subsidiary of Plaintiff Eagle Pharmaceuticals, Inc.

4. Plaintiff PAION UK Limited ("PAION") is a private limited company organized and existing under the laws of the United Kingdom, with a principal place of business at 5 Kew Road, Parkshot House, Richmond, London, United Kingdom, TW9 2PR.

5. Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle") is a corporation organized and existing under the laws of Delaware, with its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

6. Upon information and belief, Defendant Galenicum Health S.L.U. is a sociedad limitada unipersonal company organized and existing under the laws of Spain, having its principal place of business at St. Gabriel, 50, Esplugues de Llobregat, 08950, Spain. Upon information and belief, Galenicum is in the business of, among other things, developing, manufacturing, obtaining regulatory approval, marketing, selling, importing, and distributing generic copies of branded pharmaceutical products, throughout the United States, including in Delaware.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Galenicum because, *inter alia*, Galenicum has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hauled into court here. On information and belief, Galenicum

develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

9. In addition, this Court has personal jurisdiction over Galenicum because, among other things, on information and belief: (1) Galenicum, filed Galenicum's ANDA No. 219794 for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Galenicum's Proposed ANDA Product in the United States, including in Delaware; and (2) upon approval of Galenicum's ANDA, Galenicum will market, distribute, offer for sale, sell, and/or import Galenicum's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Galenicum's Proposed ANDA Product in Delaware. On information and belief, upon approval of Galenicum's ANDA, Galenicum's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware.

10. In addition, this Court has personal jurisdiction over Galenicum because it has 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 Eagle, a Delaware corporation.

11. In addition, to the extent personal jurisdiction does not exist over Galenicum in Delaware, this Court has personal jurisdiction over it under Federal Rule of Civil Procedure 4(k)(2)

because Galenicum is not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over it is consistent with the United States Constitution and laws.

12. For at least the above reasons, it would not be unfair or unreasonable for Galenicum to litigate this action in this District, and Galenicum is subject to personal jurisdiction in this District.

13. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to Galenicum, at least because, on information and belief, Galenicum is a foreign corporation that may be sued in any judicial district.

BACKGROUND

BYFAVO® (REMIMAZOLAM)

14. On July 2, 2020, the FDA approved ("NDA") No. 212295 (the "BYFAVO® NDA") for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

15. The active pharmaceutical ingredient in BYFAVO® is remimazolam. Remimazolam is an ultra-short acting benzodiazepine. Its chemical description is 4H-imidazol[1,2-a][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4S)-, methyl ester, benzenesulfonate (1:1).

16. BYFAVO® (remimazolam) is FDA approved for intravenous injection. It is a white to off-white lyophilized powder in a single-patient-use vial containing 20 mg remimazolam, equivalent to 27.2 mg remimazolam besylate. Each vial is formulated with 82 mg dextran 40 and 55 mg lactose monohydrate as bulking agents/stabilizers, and adjusted to pH of 2.9 to 3.9 with hydrochloride/sodium hydroxide. It is reconstituted prior to administration. The reconstituted product has a final concentration of 2.5 mg/mL solution of remimazolam.

17. Eagle, itself or through a subsidiary, markets BYFAVO® (remimazolam) in the United States pursuant to the BYFAVO® NDA.

18. Acacia, a wholly owned subsidiary of Eagle, is the holder of the BYFAVO® NDA.

19. The Asserted Patents are among the patents listed for the BYFAVO® NDA for BYFAVO® (remimazolam) in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

THE ASSERTED PATENTS

20. On February 7, 2017, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '236 Patent entitled "Dosing Regimen for Sedation with CNS 7056 (Remimazolam)." A copy of the '236 Patent is attached as Exhibit A.

21. Plaintiffs own and have rights to the '236 Patent.

22. There is an actual case or controversy between the parties regarding Galenicum's liability for its infringement of the '236 Patent.

23. On November 28, 2017, the USPTO duly and legally issued the '251 Patent entitled "Dosing Regimen for Sedation with CNS 7056 (Remimazolam)." A copy of the '251 Patent is attached as Exhibit B.

24. Plaintiffs own and have rights to the '251 Patent.

25. There is an actual case or controversy between the parties regarding Galenicum's liability for its infringement of the '251 Patent.

GALENICUM'S ANDA

26. On November 21, 2024, Plaintiffs received Galenicum's Notice Letter, which informed Plaintiffs that Galenicum filed ANDA No. 219794 seeking FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of Galenicum's Proposed ANDA Product

prior to the expiration of the Asserted Patents. According to the Notice Letter, included within ANDA No. 219794 is a certification pursuant to 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 Galenicum's Proposed ANDA Product.

27. This action is being filed within 45 days of Plaintiffs' receipt of Galenicum's Notice Letter.

28. Galenicum was aware of the Asserted Patents when it filed ANDA No. 219794 with a Paragraph IV Certification.

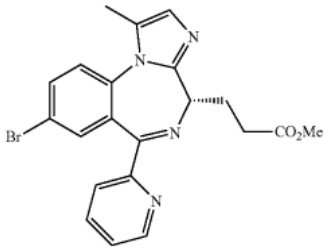
29. On information and belief, remimazolam is the active ingredient in Galenicum's Proposed ANDA Product. On information and belief, Galenicum's Proposed ANDA Product is remimazolam for injection, for intravenous use, 20 mg per vial, lyophilized powder for reconstitution (2.5 mg/mL).

30. On information and belief, Galenicum's ANDA No. 219794 refers to and relies upon the BYFAVO® NDA and contains data that, according to Galenicum, demonstrate bioequivalence of Galenicum's Proposed ANDA Product and BYFAVO® (remimazolam), *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7), or Galenicum has sought a waiver of the requirement to demonstrate bioequivalence of its Proposed ANDA Product and BYFAVO® (remimazolam).

31. On information and belief, Galenicum intends to have healthcare providers use its Proposed ANDA Product, if approved, as set forth in its Proposed ANDA Product label. On information and belief, Galenicum's Proposed ANDA Product label will instruct healthcare providers to prescribe Galenicum's Proposed ANDA Product in the manner set forth in the label.

COUNT I
(Infringement of the '236 Patent)

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

33. Claim 1 of the '236 Patent covers "[a] method of sedating a subject comprising administering to the subject an initial dose of the besylate salt of 3-[(4S)-8-bromo-1-methyl-6-(2-pyridinyl)-4H-imidazo[1,2-a][1,4]benzodiazepin-4-yl]-propionic methyl ester (CNS 7056) of formula (I)  wherein the initial dose is a fixed dose of between about 2 mg and about 10 mg and is irrespective of the body weight of the subject, in combination with one or more doses of an opioid."

34. Upon information and belief, Galenicum's Proposed ANDA Product is covered by one or more claims of the '236 Patent, including at least claim 1, because the use of Galenicum's Proposed ANDA Product in accordance with and as directed by Galenicum's proposed labeling for that product involves sedating a subject by administering, irrespective of the body weight of the subject, an initial fixed dose of between about 2 mg and about 10 mg of the besylate salt of 3-[(4S)-8-bromo-1-methyl-6-(2-pyridinyl)-4H-imidazo[1,2-a][1,4]benzodiazepin-4-yl]-propionic methyl ester (CNS 7056) of formula (I), which is the chemical name for remimazolam, in combination with one or more doses of an opioid, in particular fentanyl.

35. Upon information and belief, Galenicum intends to sell its Proposed ANDA Product with a label that includes instructions to administer remimazolam besylate to sedate patients in a manner that will infringe claim 1 of the '236 Patent.

36. Upon information and belief, the use of Galenicum's Proposed ANDA Product in accordance with and as directed by Galenicum's proposed labeling for that product will infringe claim 1 of the '236 Patent, either literally or under the doctrine of equivalents.

37. Upon information and belief, Galenicum submitted as part of ANDA No. 219794 a Paragraph IV Certification, asserting that the claims of the '236 Patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Galenicum's Proposed ANDA Product.

38. Galenicum did not contend or make any non-infringement arguments in its Notice Letter that Galenicum's Proposed ANDA Product, or the use of Galenicum's Proposed ANDA Product in accordance with and as directed by Galenicum's proposed labeling for that product would not infringe the claims of the '236 Patent.

39. The purpose of submitting ANDA No. 219794 to the FDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Galenicum's Proposed ANDA Product prior to the expiration of the '236 Patent.

40. Galenicum's submission of ANDA No. 219794 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of Galenicum's Proposed ANDA Product prior to the expiration of the '236 Patent was an act of infringement of the '236 Patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon information and belief, Galenicum intends to engage in the commercial manufacture, use, sale and/or offer for sale of Galenicum's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 219794 and any amendments thereto, *i.e.*, prior to the expiration of the '236 Patent.

42. Upon information and belief, Galenicum has knowledge of the '236 Patent at least because the '236 Patent is listed in the Orange Book for BYFAVO® (remimazolam) drug product. Notwithstanding this knowledge, Galenicum continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of Galenicum's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 219794 and any amendments thereto.

43. Upon information and belief, Galenicum plans and intends to, and will, actively induce infringement of the '236 Patent when ANDA No. 219794 and any amendments thereto are approved by selling its Proposed ANDA Product with a label that provides instructions to administer remimazolam besylate to sedate patients in a manner that infringes claims of the '236 Patent, and will do so with specific intent to induce infringement of the '236 Patent. Further, upon information and belief, Galenicum plans and intends to, and will, do so immediately and imminently upon approval.

44. Upon information and belief, Galenicum knows that its Proposed ANDA Product is especially made or adapted for use in infringing the '236 Patent, and that its Proposed ANDA Product is not a staple article of commerce suitable for substantial non-infringing use. Upon information and belief, Galenicum plans and intends to, and will, contribute to infringement of the '236 Patent immediately and imminently upon approval of ANDA No. 219794 and any amendments thereto.

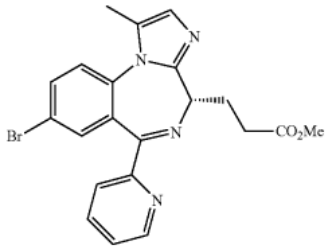
45. The foregoing actions by Galenicum constitute and/or will constitute infringement of the '236 Patent, active inducement of infringement of the '236 Patent, and contribution to the infringement of the '236 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and (c).

46. Unless Galenicum is enjoined from infringing the ’236 Patent and actively inducing and contributing to infringement of the ’236 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the ’251 Patent)

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

48. Claim 1 of the ’251 Patent covers “[a] method of sedating a subject undergoing a procedure, comprising administering intravenously to the subject one or more fixed doses of a composition comprising the besylate salt of 3-[(4S)-8-bromo-1-methyl-6-(2-pyridinyl)-4H-imidazo[1,2-a][1,4]benzodiazepin-4-yl]-propionic methyl ester (CNS 7056) of formula (I)



wherein the amount of the besylate salt of the compound of formula (I) administered to the subject does not depend on the body weight of the subject.”

49. Upon information and belief, Galenicum’s Proposed ANDA Product is covered by one or more claims of the ’251 Patent, including at least claim 1, because the use of Galenicum’s Proposed ANDA Product in accordance with and as directed by Galenicum’s proposed labeling for that product involves sedating a subject undergoing a procedure by administering intravenously to the subject one or more fixed doses of the besylate salt of 3-[(4S)-8-bromo-1-methyl-6-(2-pyridinyl)-4H-imidazo[1,2-a][1,4]benzodiazepin-4-yl]-propionic methyl ester (CNS 7056) of formula (I), which is the chemical name for remimazolam, in an amount that does not depend on the body weight of the subject.

50. Upon information and belief, Galenicum intends to sell its Proposed ANDA Product with a label that includes instructions to administer remimazolam besylate to sedate patients in a manner that will infringe claim 1 of the ’251 Patent.

51. Upon information and belief, the use of Galenicum’s Proposed ANDA Product in accordance with and as directed by Galenicum’s proposed labeling for that product will infringe claim 1 of the ’251 Patent, either literally or under the doctrine of equivalents.

52. Upon information and belief, Galenicum submitted as part of ANDA No. 219794 a Paragraph IV Certification, asserting that the claims of the ’251 Patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Galenicum’s Proposed ANDA Product.

53. Galenicum did not contend or make any non-infringement arguments in its Notice Letter that Galenicum’s Proposed ANDA Product, or the use of Galenicum’s Proposed ANDA Product in accordance with and as directed by Galenicum’s proposed labeling for that product would not infringe the claims of the ’251 Patent.

54. The purpose of submitting ANDA No. 219794 to the FDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Galenicum’s Proposed ANDA Product prior to the expiration of the ’251 Patent.

55. Galenicum’s submission of ANDA No. 219794 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of Galenicum’s Proposed ANDA Product prior to the expiration of the ’251 Patent was an act of infringement of the ’251 Patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, Galenicum intends to engage in the commercial manufacture, use, sale and/or offer for sale of Galenicum’s Proposed ANDA Product and the

proposed labeling therefor immediately and imminently upon the approval of ANDA No. 219794 and any amendments thereto, *i.e.*, prior to the expiration of the '251 Patent.

57. Upon information and belief, Galenicum has knowledge of the '251 Patent at least because the '251 Patent is listed in the Orange Book for BYFAVO® (remimazolam) drug product. Notwithstanding this knowledge, Galenicum continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of Galenicum's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 219794 and any amendments thereto.

58. Upon information and belief, Galenicum plans and intends to, and will, actively induce infringement of the '251 Patent when ANDA No. 219794 and any amendments thereto are approved by selling its Proposed ANDA Product with a label that provides instructions to administer remimazolam besylate to sedate patients in a manner that infringes claims of the '251 Patent, and will do so with specific intent to induce infringement of the '251 Patent. Further, upon information and belief, Galenicum plans and intends to, and will, do so immediately and imminently upon approval.

59. Upon information and belief, Galenicum knows that its Proposed ANDA Product is especially made or adapted for use in infringing the '251 Patent, and that Galenicum's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use. Upon information and belief, Galenicum plans and intends to, and will, contribute to infringement of the '251 Patent immediately and imminently upon approval of ANDA No. 219794 and any amendments thereto.

60. The foregoing actions by Galenicum constitute and/or will constitute infringement of the '251 Patent, active inducement of infringement of the '251 Patent, and contribution to the

infringement of the ’251 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and (c).

61. Unless Galenicum is enjoined from infringing the ’251 Patent and actively inducing and contributing to infringement of the ’251 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Galenicum’s submission of ANDA No. 219794 to the FDA was an act of infringement of one or more claims of the Asserted Patents;

(b) A judgment that Galenicum’s making, using, offering to sell, selling, marketing, distributing, or importing into the United States Galenicum’s Proposed ANDA Product prior to the expiration of the Asserted Patents will infringe, will actively induce infringement, and/or will contribute to infringement of one or more claims of the Asserted Patents;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Galenicum to make, use, offer for sale, sell, market, distribute, or import Galenicum’s Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining Galenicum, Galenicum’s affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Galenicum, from making, using, selling, offering to sell, marketing, distributing, or importing Galenicum’s Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, or the inducement of any of the foregoing, prior to the

expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

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

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

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

Date: January 3, 2025

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