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

JAZZ PHARMACEUTICALS, INC. and GENTIUM S.R.L., Plaintiffs, v. ALMAJECT, INC., ALVOGEN, INC., and ALVOGEN PB RESEARCH & DEVELOPMENT LLC, Defendants.	C.A. No. 25-cv-02785-SRC-LDW *Document Filed Electronically*

DEFENDANTS ALMAJECT, INC., ALVOGEN, INC., AND ALVOGEN PB RESEARCH & DEVELOPMENT LLC'S
ANSWER AND COUNTERCLAIMS

Defendants Almaject, Inc. ("Almaject"), Alvogen, Inc. ("Alvogen"), and Alvogen PB Research & Development LLC ("Alvogen PB") (collectively "Defendants") hereby respond to the corresponding paragraphs of the Complaint for Patent Infringement ("the Complaint") of Plaintiffs Jazz Pharmaceuticals, Inc. ("Jazz") and Gentium S.R.L. ("Gentium") (collectively "Plaintiffs") as follows:

NATURE OF THE ACTION

1. Paragraph 1 of the Complaint contains conclusions of law to which no response is required. To the extent an answer is required, Defendants admit that the Complaint purports to allege a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, that Plaintiffs allege is related to U.S. Patent Nos. 11,085,043 (the "'043 Patent"), 11,236,328 (the "'328 Patent"), and 11,746,348 (the "'348 Patent") (collectively the "Asserted Patents") and the pharmaceutical drug product Defitelio®. Defendants also admit that, through its regulatory agent Alvogen PB, Almaject submitted Abbreviated New Drug Application ("ANDA") No. 216293 to the United States Food and Drug Administration ("FDA"), seeking approval to market defibrotide sodium vials, 250 mg/2.5 mL, ("Almaject's ANDA Product") prior to the expiration of the Asserted Patents. Except as otherwise admitted, the allegations in Paragraph 1 of the Complaint are denied.

THE PARTIES

2. Defendants lack sufficient knowledge to admit or deny the allegations in Paragraph 2 of the Complaint, and therefore deny the same.

3. Defendants lack sufficient knowledge to admit or deny the allegations in Paragraph 3 of the Complaint, and therefore deny the same.

4. Admitted.

5. Admitted.

6. Defendants admit that Defendant Alvogen PB is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Bloomfield Ave., Building B, Pine Brook, NJ 07058. Defendants admit that a Notification Pursuant to Section 505(j)(B)(2)(iv), dated March 7, 2025 ("Notice Letter") identifies Alvogen PB as the Regulatory Agent for Almaject.

7. Defendants deny the allegations contained in Paragraph 7 of the Complaint.

THE PATENTS-IN-SUIT

8. Paragraph 8 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that Exhibit A to the Complaint purports to be a copy of the '043 Patent, has an issue date of August 10, 2021 on its face, and bears the title "Euglobulin-Based Method for Determining the Biological Activity of Defibrotide." Defendants admit that the face of the '043 Patent identifies Terenzio Ignoni, Vijay Kumar, and Khalid Islam as the inventors. Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 8 of the Complaint and therefore deny the same.

9. Paragraph 9 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that Exhibit A to the Complaint purports to be a copy of the '328 Patent, has an issue date of February 1, 2022 on its face, and bears the title "Euglobulin-Based Method for Determining the Biological Activity of Defibrotide." Defendants admit that the face of the '328 Patent identifies Terenzio Ignoni, Vijay Kumar, and Khalid Islam as the inventors. Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 9 of the Complaint and therefore deny the same.

10. Paragraph 10 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that Exhibit A to the Complaint purports to be a copy of the '348 Patent, has an issue date of September 5, 2023 on its face, and bears the title "Euglobulin-Based Method for Determining the Biological Activity of Defibrotide." Defendants admit that the face of the '348 Patent identifies Terenzio Ignoni, Vijay Kumar, and Khalid Islam as the inventors. Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 10 of the Complaint and therefore deny the same.

THE DEFITELIO® DRUG PRODUCT

11. Defendants admit that FDA's website lists Jazz as the applicant for New Drug Application ("NDA") No. 208114 for Defitelio®. Defendants admit that Defitelio® (defibrotide sodium) is currently indicated for the "treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT)." Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 11 of the Complaint and therefore deny the same.

12. Paragraph 12 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 12.

13. Defendants admit that the electronic version of the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") lists the '043, '328, and '348 Patents for NDA No. 208114. Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 13 of the Complaint and therefore deny the same.

14. Paragraph 14 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 14 of the Complaint.

15. Paragraph 15 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 15 of the Complaint.

JURISDICTION AND VENUE

16. Paragraph 16 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest that this Court has subject

matter jurisdiction over the claims asserted against Defendants for the limited purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 16.

17. Defendants deny the allegations contained in Paragraph 17 of the Complaint.

18. Paragraph 18 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest that this Court has personal jurisdiction over the claims asserted against Almaject for the limited purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 18 of the Complaint.

19. Defendants deny the allegations contained in Paragraph 19 of the Complaint.

20. Paragraph 20 contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest that this Court has personal jurisdiction over the claims asserted against Alvogen for the limited purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 20 of the Complaint.

21. Defendants deny the allegations contained in Paragraph 21 of the Complaint.

22. Paragraph 22 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest that this Court has personal jurisdiction over the claims asserted against Alvogen PB for the limited purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 22 of the Complaint.

23. Defendants admit that Alvogen PB is a regulatory agent for Almaject with respect to ANDA No. 216293. Defendants otherwise deny the allegations of Paragraph 23 of the Complaint.

24. Paragraph 24 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 24 of the Complaint.

25. Paragraph 25 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants state that Alvogen and Alvogen PB did not "submit" Almaject's ANDA No. 216293 as required by 35 U.S.C. § 271(e)(2). Defendants deny the remaining allegations of Paragraph 25 of the Complaint.

26. Paragraph 26 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 26 of the Complaint.

27. Paragraph 27 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 27 of the Complaint.

28. Paragraph 28 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 28 of the Complaint.

29. Paragraph 29 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 29 of the Complaint.

30. Paragraph 30 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 30 of the Complaint.

31. Paragraph 31 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 31 of the Complaint.

32. Paragraph 32 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 32 of the Complaint.

33. Paragraph 33 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that Alvogen PB and Alvogen did not contest that the United States District Court for the District of New Jersey had personal jurisdiction over them for the limited purposes of the civil action captioned by *Salix Pharmaceuticals, Inc. et al. v. Norwich Pharmaceuticals, Inc. et al.,* Civ. Action No. 1:24-cv-07140 (ESK)(AMD) (D.N.J.) and that Alvogen did not contest that the United States District Court for the District of New Jersey had personal jurisdiction over it for the limited purposes of the civil action captioned by *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Alvogen, Inc.*, Civ. Action No. 2:23-cv-03911 (MEF)(JRA) (D.N.J.).

34. Paragraph 34 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest venue for the limited purposes of this action only.

ACTS GIVING RISE TO THIS SUIT

35. Paragraph 35 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that the Notice Letter states that, through its regulatory agent, Almaject submitted ANDA No. 216293 to FDA seeking approval to

commercially manufacture and sell Almaject's ANDA Product in the United States prior to expiration of the Asserted Patents.

36. Admitted.

37. Admitted.

38. Admitted.

COUNT I: AS TO ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,085,043

39. Defendants restate and incorporate by reference their responses to the allegations of Paragraphs 1–38 of the Complaint as though fully set forth herein.

40. Paragraph 40 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 40 of the Complaint.

41. Defendants deny the allegations of Paragraph 41 of the Complaint.

42. Admitted.

43. Paragraph 43 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 43 of the Complaint.

44. Paragraph 44 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 44 of the Complaint.

45. Paragraph 45 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 45 of the Complaint.

46. Paragraph 46 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 46 of the Complaint.

47. Paragraph 47 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 47 of the Complaint.

48. Paragraph 48 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 48 of the Complaint.

COUNT II: AS TO ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,236,328

49. Defendants repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

50. Paragraph 50 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 50 of the Complaint.

51. Defendants deny the allegations of Paragraph 51 of the Complaint.

52. Admitted.

53. Paragraph 53 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 53 of the Complaint.

54. Paragraph 54 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 54 of the Complaint.

55. Paragraph 55 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 55 of the Complaint.

56. Paragraph 56 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 56 of the Complaint.

57. Paragraph 57 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 57 of the Complaint.

58. Paragraph 58 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 58 of the Complaint.

COUNT III: AS TO ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,746,348

59. Defendants repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

60. Paragraph 60 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 60 of the Complaint.

61. Defendants deny the allegations of Paragraph 61 of the Complaint.

62. Admitted.

63. Paragraph 63 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 63 of the Complaint.

64. Paragraph 64 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 64 of the Complaint.

65. Paragraph 65 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 65 of the Complaint.

66. Paragraph 66 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 66 of the Complaint.

67. Paragraph 67 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 67 of the Complaint.

68. Paragraph 68 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 68 of the Complaint.

PRAYER FOR RELIEF

WHEREFORE, Defendants deny that Plaintiffs are entitled to any of the relief requested in the "Prayer for Relief" or otherwise stated in the Complaint.

SEPARATE DEFENSES

Without prejudice to the denials set forth in their Answer or to their ability to seek and allege any defenses not presently known or that are revealed during the course of discovery, Defendants assert the following defenses in response to the Complaint:

First Separate Defense

Each claim of the Asserted Patents that Plaintiffs assert against Defendants is invalid for failing to comply with one or more provision of Title 35 of the United States Code, including §§ 101, 102, 103, 112, any of the equitable defenses, and/or the judicial doctrine barring double-patenting.

Second Separate Defense

Defendants have not infringed and are not infringing any valid and enforceable claim of the Asserted Patents under 35 U.S.C. § 271(e) by the submission of ANDA No. 216293.

Third Separate Defense

Defendants have not infringed, are not infringing, and will not infringe, either directly or by contribution or inducement, literally or by doctrine of equivalents, any valid and enforceable claim of the Asserted Patents under 35 U.S.C. § 271(a), (b), (c), or (g).

Fourth Separate Defense

The Complaint fails to state a claim upon which relief may be granted under 35 U.S.C. § 271(a), (b), (c), or (g).

Fifth Separate Defense

The Complaint fails to state a claim upon which relief may be granted under 35 U.S.C. § 271(a), (b), (c), (e), or (g). For example, Alvogen and Alvogen PB did not "submit" Almaject's ANDA No. 216293 as required by 35 U.S.C. § 271(e)(2). *See Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, C.A. No. 18-cv-73-LPS, 2019 WL 581618 (D. Del. Feb. 13, 2019). Alvogen PB is the authorized regulatory agent for Almaject's ANDA No. 216293. Alvogen is not named in the Notice Letter, nor is it the regulatory agent for Almaject's ANDA No. 216293 or the ANDA holder

for ANDA No. 216293. Alvogen PB will not engage in the commercial manufacture, use, or sale of Almaject's ANDA Product after FDA approves ANDA No. 216293.

COUNTERCLAIMS

For its counterclaims against Plaintiffs Jazz Pharmaceuticals, Inc. ("Jazz") and Gentium S.R.L. ("Gentium") (collectively "Plaintiffs"), Defendant Almaject, Inc. ("Almaject" or "Defendant") alleges upon knowledge with respect to its own acts, and upon information and belief as to other matters, as follows:

THE PARTIES

1. Almaject is a corporation organized and existing under the laws of the State of Delaware having its corporate offices and principal place of business at 44 Whippany Road, Suite 300, Morristown, New Jersey 07960.

2. On information and belief, Jazz is a corporation organized and existing under the laws of Delaware, having a principal place of business in Palo Alto, California.

3. On information and belief, Gentium is a corporation organized and existing under the laws of Italy, having a principal place of business in Villa Guardia CO, Italy.

JURISDICTION AND VENUE

4. Defendant realleges Paragraphs 1–3 of the Counterclaims as though fully set forth herein.

5. These are counterclaims for declaratory judgment of non-infringement and/or invalidity of one or more claims of United States Patent Nos. 11,085,043 ("the '043 Patent"), 11,236,328 ("the '328 Patent"), and 11,746,348 ("the '348 Patent") (collectively the "Asserted Patents") pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Patent Laws

of the United States, 35 U.S.C. § 1, et seq., 25 U.S.C. §271(e)(5), and 21 U.S.C. § 355(j) for the purpose of determining an actual and justiciable controversy between the parties.

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over the Plaintiffs because Plaintiffs have submitted to the personal jurisdiction of this Court.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400 because Plaintiffs have submitted to the jurisdiction of this Court.

ACTS GIVING RISE TO THE ACTION

9. Defendant realleges Paragraphs 1–8 of the Counterclaims as though fully set forth herein.

10. In the Complaint, Plaintiffs allege that Jazz is the owner of the Asserted Patents.

11. In the Complaint, Plaintiffs allege that Jazz holds approved NDA No. 208114 for Defitelio® (defibrotide sodium).

12. On its face, the ’043 Patent, attached as Exhibit A to the Complaint, contains the title “Euglobulin-Based Method for Determining the Biological Activity of Defibrotide” and states that the ’043 Patent issued on August 10, 2021.

13. On its face, the ’328 Patent, attached as Exhibit B to the Complaint, contains the title “Euglobulin-Based Method for Determining the Biological Activity of Defibrotide” and states that the ’328 Patent issued on February 1, 2022.

14. On its face, the ’348 Patent, attached as Exhibit C to the Complaint, contains the title “Euglobulin-Based Method for Determining the Biological Activity of Defibrotide” and states that the ’348 Patent issued on September 5, 2023.

15. On information and belief, Jazz caused the Asserted Patents to be listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Defitelio®.

16. On behalf of Almaject, Alvogen PB submitted ANDA No. 216293 in order to obtain approval to engage in the commercial manufacture, use, or sale of defibrotide sodium vials, 250mg/2.5 mL ("Almaject's ANDA Product") in the United States.

17. On March 5, 2025, Almaject sent, by and through Alvogen PB, a Notice Letter to Plaintiffs Jazz and Gentium notifying Plaintiffs that Almaject submitted ANDA No. 216293 to include a patent certification ("Paragraph IV certification") that the Asserted Patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject's ANDA Product. The Notice Letter included a detailed statement of the factual and legal bases for the Paragraph IV certification and an Offer of Confidential Access to Almaject's ANDA No. 216293.

CASE OR CONTROVERSY

18. Defendant realleges Paragraphs 1–17 of the Counterclaims as though fully set forth herein.

19. By maintaining the listing of the Asserted Patents in the Orange Book, Plaintiffs represent that the Asserted Patents claim the approved drug Defitelio®, or a method of using that drug, and that a claim for patent infringement "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

20. On April 16, 2025, Plaintiffs filed a Complaint alleging, *inter alia*, the infringement of the Asserted Patents against Defendant.

21. The submission of ANDA No. 216293 to FDA creates the necessary case or controversy and subject matter jurisdiction for Plaintiffs to sue Defendant—and for Defendant to obtain a declaratory judgment against Plaintiffs—regarding infringement of the Asserted Patents.

22. An actual and justiciable controversy exists between Defendant and Plaintiffs relating to the Asserted Patents.

23. A declaration of rights between the parties is both appropriate and necessary to establish that Defendant will not infringe any valid and/or enforceable claim of the Asserted Patents.

COUNT I: DECLARATION OF NONINFRINGEMENT OF THE '043 PATENT

24. Defendant realleges Paragraphs 1–23 of the Counterclaims as though fully set forth herein.

25. The submission of ANDA No. 216293 to FDA does not directly infringe or infringe through inducement or contribution, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '043 Patent.

26. The commercial manufacture, use, sale, offer for sale, and/or importation of Almaject's ANDA Product does not and will not directly infringe or infringe through inducement or contribution, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '043 Patent.

27. An actual and justiciable controversy exists between Defendant and Plaintiffs regarding the noninfringement of the '043 Patent.

28. Defendant is entitled to a declaration that the submission of ANDA No. 216293 to FDA does not infringe any valid and enforceable claim of the '043 Patent.

29. Defendant is entitled to a declaration that the commercial manufacture, use, sale, offer for sale and/or importation of Almaject's ANDA Product does not and will not infringe any valid and enforceable claim of the '043 Patent.

COUNT II: DECLARATION OF NONINFRINGEMENT OF THE '328 PATENT

30. Defendant realleges Paragraphs 1–29 of the Counterclaims as though fully set forth herein.

31. The submission of ANDA No. 216293 to FDA does not directly infringe or infringe through inducement or contribution, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '328 Patent.

32. The commercial manufacture, use, sale, offer for sale, and/or importation of Almaject's ANDA Product does not and will not directly infringe or infringe through inducement or contribution, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '328 Patent.

33. An actual and justiciable controversy exists between Defendant and Plaintiffs regarding the noninfringement of the '328 Patent.

34. Defendant is entitled to a declaration that the submission of ANDA No. 216293 to FDA does not infringe any valid and enforceable claim of the '328 Patent.

35. Defendant is entitled to a declaration that the commercial manufacture, use, sale, offer for sale and/or importation of Almaject's ANDA Product does not and will not infringe any valid and enforceable claim of the '328 Patent.

COUNT III: DECLARATION OF NONINFRINGEMENT OF THE '348 PATENT

36. Defendant realleges Paragraphs 1-35 of the Counterclaims as though fully set forth herein.

37. The submission of ANDA No. 216293 to FDA does not directly infringe or infringe through inducement or contribution, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’348 Patent.

38. The commercial manufacture, use, sale, offer for sale, and/or importation of Almaject’s ANDA Product does not and will not directly infringe or infringe through inducement or contribution, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’348 Patent.

39. An actual and justiciable controversy exists between Defendants and Plaintiffs regarding the noninfringement of the ’348 Patent.

40. Defendant is entitled to a declaration that the submission of ANDA No. 216293 to FDA does not infringe any valid and enforceable claim of the ’348 Patent.

41. Defendant is entitled to a declaration that the commercial manufacture, use, sale, offer for sale and/or importation of Almaject’s ANDA Product does not and will not infringe any valid and enforceable claim of the ’348 Patent.

COUNT IV: DECLARATION OF INVALIDITY OF ’043 PATENT

42. Defendant realleges Paragraphs 1–41 of the Counterclaims as though fully set forth herein.

43. The claims of the ’043 Patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting.

44. For example, the prior art publications including but not limited to U.S. Patent No. 7,338,777 to Porta et al. (issued Mar. 4, 2008) (“the ’777 Patent”); Clinical Study 2005-01; Sergio Coccheri et al., *Defibrotide*, in Cardiovascular Drug Reviews (Vol. 9, Num. 2 1991) (“Coccheri

1991); R. Chakrabarti et al., *Methodological Study and a Recommended Technique for Determining the Euglobulin Lysis Time*, in the Journal of Clinical Pathology (Vol. 21 1968) ("Chakrabarti 1968"); J.D. Cash et al., *Technical Methods: Automatic Determination of Euglobulin Lysis Time*, in the Journal of Clinical Pathology (Vol. 18 1965) ("Cash 1965"); Nurperi Hizal et al., *Investigation of the Fibrinolytic Activity of Defibrotide Fractions*, in General Pharmacology (Vol. 25, Num. 8 1994) ("Hizal 1994"); and Thomas C. Abshire, *Laboratory Assessment of Fibrinolysis, in Transfusion Medicine and Hemostasis* (Chistopher D. Hillyer et al. eds., 2009) ("Abshire 2009") render anticipated and/or obvious, alone or in combination with one or more prior art publications and common knowledge, each of the claims of the '043 Patent.

45. In addition, claims of the '043 Patent fail to comply with the requirements of 35 U.S.C. § 112, including, for example, the written description and/or enablement requirements.

46. An actual and justiciable controversy exists between Defendant and Plaintiffs regarding the validity of the '043 Patent.

47. Defendant is entitled to a declaration that the claims of the '043 Patent are invalid.

COUNT V: DECLARATION OF INVALIDITY OF '328 PATENT

48. Defendant realleges Paragraphs 1–47 of the Counterclaims as though fully set forth herein.

49. The claims of the '328 Patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting.

50. For example, the prior art publications including but not limited to the '777 Patent, Clinical Study 2005-01, Coccheri 1991, Chakrabarti 1968, Cash 1965, Hizal 1994, and Abshire

2009 render anticipated and/or obvious, alone or in combination with one or more prior art publications and common knowledge, each of the claims of the ’328 Patent.

51. In addition, claims of the ’328 Patent fail to comply with the requirements of 35 U.S.C. § 112, including, for example, the written description and/or enablement requirements.

52. An actual and justiciable controversy exists between Defendant and Plaintiffs regarding the validity of the ’328 Patent.

53. Defendant is entitled to a declaration that the claims of the ’328 Patent are invalid.

COUNT VI: DECLARATION OF INVALIDITY OF ’348 PATENT

54. Defendant realleges Paragraphs 1–53 of the Counterclaims as though fully set forth herein.

55. The claims of the ’348 Patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting.

56. For example, the prior art publications including but not limited to the ’777 Patent, Clinical Study 2005-01, Coccheri 1991, Chakrabarti 1968, Cash 1965, Hizal 1994, and Abshire 2009 render anticipated and/or obvious, alone or in combination with one or more prior art publications and common knowledge, each of the claims of the ’348 Patent.

57. In addition, claims of the ’348 Patent fail to comply with the requirements of 35 U.S.C. § 112, including, for example, the written description and/or enablement requirements.

58. An actual and justiciable controversy exists between Defendant and Plaintiffs regarding the validity of the ’348 Patent.

59. Defendant is entitled to a declaration that the claims of the ’348 Patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant respectfully requests this Court to enter judgment for Defendant as follows:

A. That the Complaint be dismissed with prejudice, and that Plaintiffs take nothing by their Complaint;

B. That Defendant does not and will not infringe any valid and enforceable claim of the Asserted Patents;

C. Declaring that the manufacture, use, offer for sale, sale, and importation of Almaject's ANDA Product does not and will not infringe any valid and enforceable claim of the Asserted Patents;

D. Declaring that the Submission of ANDA No. 216293 does not infringe any valid and enforceable claim of the Asserted Patents;

E. Declaring that the claims of the Asserted Patents are invalid;

F. Declaring that this is an exceptional case under 35 U.S.C. § 285;

G. Awarding Defendant its costs, expenses, and attorneys' fees pursuant to 35 U.S.C. § 285, other applicable statutes or rules, or the general power of the Court;

H. Preliminarily and permanently enjoining the Plaintiffs, their officers, agents, servants, employees, attorneys, successors, and any person who acts in concert or participation with Plaintiffs from using the Asserted Patents to block, hamper, hinder, or obstruct FDA approval of the products described in ANDA No. 216293; and

I. Awarding to Defendant such further relief as this Court may deem necessary, just, and proper.

/s/ *Arnold B. Calmann*
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Dated: May 23, 2025

CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy case is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: May 23, 2025

s/ Arnold B. Calmann
Arnold B. Calmann

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that Plaintiffs seek declaratory relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: May 23, 2025

s/ Arnold B. Calmann
Arnold B. Calmann