UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

ATHENEX PHARMA SOLUTIONS, LLC and
ATHENEX PHARMACUETICAL DIVISION, LLC,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC.,
PAR STERILE PRODUCTS, LLC, and
ENDO PAR INNOVATION COMPANY, LLC,

Defendants.

COMPLAINT

Case No.

JURY TRIAL DEMANDED

Athenex Pharma Solutions, LLC ("Athenex Pharma") and Athenex Pharmaceutical Division, LLC ("APD") (collectively "Athenex") file this complaint for declaratory judgment against Par Pharmaceutical, Inc. ("Par Pharmaceutical"), Par Sterile Products, LLC ("Par Sterile"), and Endo Par Innovation Company ("Endo") (collectively "Par") and allege as follows:

NATURE OF THE ACTION

1. This is a declaratory judgment action arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, Title 35 of the United States Code. Athenex seeks a declaration of noninfringement and invalidity of U.S. Patent Nos. 9,375,478 ("the '478 patent"); 9,687,526 ("the '526 patent"); 9,744,209 ("the '209 patent"); 9,744,239 ("the '239 patent"); 9,750,785 ("the '785 patent"); and 9,937,223 ("the '223 Patent") (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff Athenex Pharma is a limited liability company organized under the laws of Delaware with its principal place of business at 11342 Main Street, Clarence, New York 14031 and an office at 1001 Main Street, Suite 600, Buffalo, New York 14203.

3. Plaintiff APD is a limited liability company organized under the laws of Delaware with its principal place of business at 10 N. Martingale Road, Suite 230, Schaumburg, Illinois 60173 and an office at 1001 Main Street, Suite 600, Buffalo, New York 14203.

4. On information and belief, defendant Par Pharmaceutical is a New York corporation with its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

5. On information and belief, defendant Par Sterile is a limited liability company organized under the laws of Delaware with its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

6. On information and belief, defendant Endo is a limited liability company organized under the laws of Delaware with its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, Title 35 of the United States Code, with specific remedies sought based upon the laws authorizing actions for declaratory judgment in the courts of the United States, 28 U.S.C. §§ 2201 and 2202. Athenex seeks a declaration of non-infringement and invalidity of the patents-in-suit.

8. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 and 35 U.S.C. § 1 *et seq.*, because this action involves an

actual controversy between Athenex, on the one hand, and Par, on the other hand, for declaratory judgment of non-infringement and invalidity of the patents-in-suit.

9. This Court has personal jurisdiction over Par Pharmaceutical by virtue of, *inter alia*, Par Pharmaceutical being a New York corporation. Further, on information and belief, Par Pharmaceutical conducts substantial business in, and has regular systematic contact with, this District. On information and belief, Par Pharmaceutical is in the business of, among other things, researching, developing, manufacturing, marketing, and/or selling pharmaceutical products throughout the United States and New York. On information and belief, Par Pharmaceutical, directly or indirectly, researches, develops, manufactures, markets, and/or sells pharmaceutical products, including Vasostrict®, throughout the United States and in New York, including this District.

10. This Court has personal jurisdiction over Par Sterile by virtue of, *inter alia*, Par Sterile having its principal place of business in New York. Further, on information and belief, Par Sterile conducts substantial business in, and has regular systematic contact with, this District. On information and belief, Par Sterile is in the business of, among other things, researching, developing, manufacturing, marketing, and/or selling pharmaceutical products throughout the United States and New York. On information and belief, Par Sterile, directly or indirectly, researches, develops, manufactures, markets, and/or sells pharmaceutical products, including Vasostrict®, throughout the United States and in New York, including this District.

11. This Court has personal jurisdiction over Endo by virtue of, *inter alia*, Endo having its principal place of business in New York. Further, on information and belief, Endo conducts substantial business in, and has regular systematic contact with, this District. On information and belief, Endo is in the business of, among other things, researching, developing,

manufacturing, marketing, and/or selling pharmaceutical products throughout the United States and New York. On information and belief, Endo, directly or indirectly, researches, develops, manufactures, markets, and/or sells pharmaceutical products, including Vasostrict®, throughout the United States and in New York, including this District.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because, *inter alia*, the alleged infringing activities occurred or will occur in this District and the alleged infringing products are situated in this District, and because, on information and belief, Par is subject to personal jurisdiction in this District, and thus resides in this District.

PAR'S PATENTS-IN-SUIT

13. On information and belief, Par Sterile is the manufacturer of Vasostrict® and is the holder of the New Drug Application ("NDA") No. 204485, including all supplements, for Vasostrict®. The active ingredient in Vasostrict® is vasopressin.

14. On information and belief, the patents-in-suit are listed in the U.S. Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) with respect to Vasostrict®.

15. On information and belief, Par Pharmaceutical is the owner of the patents-in-suit and Endo is the exclusive licensee of the patents-in-suit.

16. The '478 patent issued on June 28, 2016 entitled "Vasopressin Formulations for Use in Treatment of Hypotension." A true and correct copy of the '478 patent is attached to this Complaint at Exhibit A.

17. The '526 patent issued on June 27, 2017 entitled "Vasopressin Formulations for Use in Treatment of Hypotension." A true and correct copy of the '526 patent is attached to this Complaint at Exhibit B.

18. The ’209 patent issued on August 29, 2017 entitled “Vasopressin Formulations for Use in Treatment of Hypotension.” A true and correct copy of the ’209 patent is attached to this Complaint at Exhibit C.

19. The ’239 patent issued on August 29, 2017 entitled “Vasopressin Formulations for Use in Treatment of Hypotension.” A true and correct copy of the ’239 patent is attached to this Complaint at Exhibit D.

20. The ’785 patent issued on September 5, 2017 entitled “Vasopressin Formulations for Use in Treatment of Hypotension.” A true and correct copy of the ’785 patent is attached to this Complaint at Exhibit E.

21. The ’223 patent issued on April 10, 2018 entitled “Vasopressin Formulations for Use in Treatment of Hypotension.” A true and correct copy of the ’223 patent is attached to this Complaint at Exhibit F.

ATHENEX’S COMPOUNDED VASOPRESSIN PRODUCTS

22. Athenex Pharma is an outsourcing facility registered with the FDA pursuant to Section 503B of the Federal Food, Drug, and Cosmetic Act (“FFDCA”). Athenex Pharma focuses its 503B operations on producing high-quality sterile compounded human drug products for hospitals and other health care providers. APD is a biopharmaceutical company that develops and delivers drug products in various disciplines.

23. Section 503B of the FFDCA allows an outsourcing facility to compound sterile drug products from bulk active pharmaceutical ingredients if the facility is registered with the FDA and complies with all of the requirements of Section 503B. A registered 503B outsourcing facility must also comply with current good manufacturing practice (cGMP) requirements.

24. Vasopressin is an active pharmaceutical ingredient that can be compounded into a drug product for use as an injection to raise arterial blood pressure in patients to ensure adequate delivery of blood to the patients' vital organs. Vasopressin is on the FDA's 503B Category 1 list of Bulk Substances Nominated for Use in Compounding pursuant to FDA's *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

25. Athenex Pharma is manufacturing compounded vasopressin drug products and will be supplying them to hospitals and other health care providers in August 2018. APD is marketing the compounded vasopressin drug products manufactured by Athenex Pharma.

26. Drug products compounded by outsourcing facilities in accordance with the conditions of Section 503B are exempt from certain FDA drug approval requirements including those under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments. Under the Hatch-Waxman Amendments, a company can seek FDA approval to market a generic drug before the expiration of patents related to the brand-name drug. To seek this approval, a generic applicant must provide in its Abbreviated New Drug Application ("ANDA") a "certification" that a patent submitted to the FDA by the brand-name drug's sponsor and listed in the list regularly published by FDA's Office of Generic Drugs titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book) is, in the generic applicant's opinion and to the best of its knowledge, invalid, unenforceable, or will not be infringed by the generic product. This certification is called a "Paragraph IV certification."

27. If the brand product sponsor or patent holder files an infringement suit against the generic applicant within 45 days of receipt of the Paragraph IV certification, FDA approval to

market the generic drug is generally postponed for 30 months unless the patent expires or is judged to be invalid or not infringed before that time. This 30-month postponement, commonly referred to as the "30-month stay," gives the brand product sponsor and patent holder a prescribed amount of time to assert patent rights in court before a generic competitor is approved and can market the drug.

28. Athenex's compounded vasopressin products are exempted from certain FDA drug approval requirements including the scheme established by the Hatch-Waxman Amendments for resolving patent disputes. Thus, Athenex does not need to provide a Paragraph IV certification to Par prior to marketing its compounded vasopressin products and Par would not be able to bring a patent infringement suit under the Hatch-Waxman Amendments and be entitled to an automatic 30-month stay to keep Athenex's compounded vasopressin products off the market.

29. Athenex's compounded vasopressin products are neither generic versions nor copies of Vasostrict®. Unlike Par's Vasostrict®, which is sold in a vial and needs to be mixed by the health care professional before being administered to the patient, Athenex's compounded vasopressin products will be administered to patients in a ready-to-use form.

30. Most FDA-approved products that are available, and intended, for intravenous administration require a hospital pharmacist, or other authorized health care practitioner, to use and manipulate multiple containers, and at times, do so under uncontrolled, non-sterile conditions, such as in "immediate use" situations (e.g., nurses mixing drugs on the floors in unclassified areas) in order to prepare the final infusion solution required by the prescriber for any given patient. Ready-to-use forms (i.e., immediately administrable form) created in a 503B registered outsourcing facility eliminate multiple risk-prone compounding steps. In addition,

ready-to-use containers minimize the number of manipulations required to create a form that is ready to be administered in a hospital or clinic environment.

31. Thus, use of Athenex's compounded vasopressin products eliminates the need for health practitioners to dilute the drug product prior to administering it to the patient and thereby avoids the number of manipulations that are required by health practitioners before administering Par's Vasostrict® to patients. Hence, Athenex's compounded vasopressin products fulfill a specific need that is not addressed by Vasostrict®.

THERE IS AN IMMEDIATE AND REAL CONTROVERSY BETWEEN ATHENEX AND PAR REGARDING THE PATENTS-IN-SUIT

32. On information and belief, recognizing that its Vasostrict® product would suffer from competitive disadvantages in the market against compounded vasopressin products manufactured by registered 503B outsourcing facilities, Par has launched a campaign to keep compounded vasopressin products from being on the market.

33. Par Sterile and Endo sued the FDA on October 26, 2017 in the United States District Court for the District of Columbia seeking, *inter alia*, to enjoin the FDA from continuing its policy of allowing bulk compounding of vasopressin and to remove vasopressin from FDA's Category 1 nominations list. *See Par Sterile Products, LLC v. Hargan, Acting Secretary of Health and Human Services*, 1:17-cv-02221 (D.D.C.). In its complaint, Par Sterile and Endo allege that the FDA has authorized bulk compounding of vasopressin that will be "administered to patients in the form that is essentially a copy of Vasostrict®." (1:17-cv-02221, D.I. 1, ¶ 11).

34. Par Sterile and Endo further allege that "[a]nd because certain uses of vasopressin are covered by Par's five unexpired patents listed in FDA's Orange Book, *see* U.S. Patent Nos. 9,375,478; 9,687,526; 9,744,209; 9,744,239; 9,750,785, anyone seeking FDA's approval to market such a follow-on version of Vasostrict® must comply with the patent-protection

provisions of the FDCA applicable to follow-on products introduced by the Hatch-Waxman amendments. For example, under those amendments, a follow-on drug applicant must provide a certification regarding the patents listed in the Orange Book and provide notice to Par, 21 U.S.C. § 355(b)(2)(A), (b)(3)(C), (j)(2)(A), (j)(2)(B)(iii), Par is entitled to confidential access to the follow-on drug application, id. § 355(c)(3)(D)(i)(I)(cc), (j)(5)(C)(i)(I)(cc), and, most importantly, approval of the drug application would be automatically stayed for up to 30 months in the event Par initiates patent litigation, *id*., § 355(c)(3)(C), (j)(5)(B)(iii)." (*Id*. ¶ 12).

35. In other words, as laid out in the complaint against the FDA, Par's position is that compounded vasopressin products are essentially copies of Vasostrict® and are designed to circumvent the Hatch-Waxman Amendments, under which Par would be able to bring suit alleging infringement of the patents-in-suit against any applicant seeking FDA approval to market a generic version of Vasostrict® and thereby obtain an automatic 30-month stay.

36. On information and belief, in May 2018 Endo stated publicly that "Endo opposes the unapproved, bulk compounding of vasopressin, and will vigorously defend and protect its substantial investment in its proprietary products."

37. Par Pharmaceutical and Par Sterile have sued QuVa Pharma, Inc. ("QuVa") in the United States District Court for the District of New Jersey in August 2017 for, *inter alia*, misappropriation of trade secrets. *See Par Pharmaceutical, Inc. v. QuVa Pharma, Inc.*, 3:17-cv-06115 (D.N.J.). QuVa, on information and belief, plans to launch a compounded vasopressin product. In that lawsuit, QuVa filed declaratory judgment counterclaims of non-infringement of five of the six patents-in-suit, namely the '478 patent, the '526 patent, the '209 patent, the '239 patent, and the '785 patent, which were the Par patents that were listed in the Orange Book as being applicable to Vasostrict®. (3:17-cv-06115, D.I. 48, ¶¶ 46-60.) At the time QuVa filed its

counterclaims, the ’223 patent had not yet issued. On information and belief, when answering QuVa’s counterclaims, Par will assert that QuVa’s compounded vasopressin product infringes Par’s Orange Book-listed patents, i.e., the patents-in-suit.

38. Par’s parent company Endo International PLC in its May 8, 2018 Form 8-K filed with the United States Securities and Exchange Commission made statements describing Par’s lawsuits against the FDA and QuVa. In referring to these Vasostrict® related matters, Endo states that “[w]e will continue to vigorously defend or prosecute the foregoing matters as appropriate, to protect our intellectual property rights, to pursue all available legal and regulatory avenues and to explore other options as appropriate in our best interests.”

39. On information and belief, Par’s position is that because compounded vasopressin products are essentially copies of Vasostrict®, they will infringe the patents-in-suit, which are listed in the Orange Book as being applicable to Vasostrict®; and if there are compounded vasopressin products on the market, Par will bring patent infringement suits against the manufacturers and/or marketers of the compounded vasopressin products being marketed.

40. Par has also brought suit against Eagle Pharmaceuticals, Inc. (“Eagle”) in the United States District Court for the District of Delaware in May 2018 alleging infringement of the patents-in-suit based on Eagle’s filing of an ANDA seeking FDA approval to market a generic version Vasostrict®. *See Par Pharmaceutical, Inc. v. Eagle Pharmaceuticals, Inc.*, 1:18-cv-00823 (D. Del.). In the complaint against Eagle, Par alleges that it “requested confidential access to Eagle’s ANDA pursuant to the terms of Eagle’s Offer of Confidential Access, but Eagle produced heavily redacted copies of portions of the Eagle ANDA.” (1:18-cv-00823, D.I. 1, ¶ 31). Par states that it “objected to Eagle’s improper and incomplete production, advising

Eagle that Par could not conduct a full and complete infringement analysis based on the incomplete and heavily redacted portions of the ANDA that Eagle had produced." (*Id*. ¶ 32).

41. On information and belief, Eagle did not supplement its production. But despite Par's concession that it "could not conduct a full and complete infringement analysis," Par still brought its action against Eagle alleging infringement of the patents-in-suit.

42. Par's pattern of actions creates a reasonable apprehension and substantial likelihood that Par will sue Athenex for the alleged infringement of the patents-in-suit, in an attempt to disrupt Athenex's plans to market its compounded vasopressin drug products.

COUNT I
DECLARATION OF NONINFRINGEMENT OF THE '478 PATENT

43. Athenex realleges and incorporates by reference the allegations of paragraphs 1-42 of this Complaint as if fully set forth herein.

44. The manufacture, use, offer to sell, or sale of Athenex's compounded vasopressin products does not, and would not, if marketed, infringe any claim of the '478 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

45. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-11 of the '478 patent are not infringed.

46. This is an exceptional case entitling Athenex to an award of its reasonable attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT II
DECLARATION OF INVALIDITY OF THE '478 PATENT

47. Athenex realleges and incorporates by reference the allegations of paragraphs 1-46 of this Complaint as if fully set forth herein.

48. Claims 1-11 of the '478 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 1, *et seq*., including §§ 101, 102, 103, and 112. For example, claims 1-11 of the '478 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least in view of Arginine Vasopressin (AVP), WHO International Standard, Instructions for Use, Version 6.0, April 4, 2013 ("AVP WHO Standard"), T. Treschan, "The Vasopressin System, Physiology and Clinical Studies," Anesthesiology, V. 105, No. 3, pp. 599-612 Sep. 2006 ("Treschan"), Birmingham Children's Hospital Injectable Medicine Guide, Vasopressin, February 2013 ("BCH Vasopressin Medicine Guide"), Pharmaceutical Partners of Canada, Vasopressin Injection, USP, June 2009 ("PPC Vasopressin"), Fresenius NovaPlus®, Pitressin®, and Cardinal Health Vasopressin Labels, (collectively, "Prior Vasopressin Labels"). Additionally, claims 1-11 of the '478 patent are invalid under 35 U.S.C. § 112 because they lack, for example, an adequate written description and are not enabled.

49. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-11 of the '478 patent are invalid.

50. This is an exceptional case entitling Athenex to an award of its reasonable attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT III
DECLARATION OF NONINFRINGEMENT OF THE ’526 PATENT

51. Athenex realleges and incorporates by reference the allegations of paragraphs 1-50 of this Complaint as if fully set forth herein.

52. The manufacture, use, offer to sell, or sale of Athenex’s compounded vasopressin products does not, and would not, if marketed, infringe any claim of the ’526 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

53. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-20 of the ’526 patent are not infringed.

54. This is an exceptional case entitling Athenex to an award of its reasonable attorneys’ fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT IV
DECLARATION OF INVALIDITY OF THE ’526 PATENT

55. Athenex realleges and incorporates by reference the allegations of paragraphs 1-54 of this Complaint as if fully set forth herein.

56. Claims 1-20 of the ’526 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 1, *et seq*., including §§ 101, 102, 103, and 112. For example, claims 1-20 of the ’526 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least in view of AVP WHO Standard, Treschan, BCH Vasopressin Medicine Guide, PPC Vasopressin, and Prior Vasopressin Labels. Additionally, claims 1-20 of the ’526 patent are invalid under 35 U.S.C. § 112 because they lack, for example, an adequate written description and are not enabled.

57. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-20 of the ’526 patent are invalid.

58. This is an exceptional case entitling Athenex to an award of its reasonable attorneys’ fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT V
DECLARATION OF NONINFRINGEMENT OF THE ’209 PATENT

59. Athenex realleges and incorporates by reference the allegations of paragraphs 1-58 of this Complaint as if fully set forth herein.

60. The manufacture, use, offer to sell, or sale of Athenex’s compounded vasopressin products does not, and would not, if marketed, infringe any claim of the ’209 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

61. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-13 of the ’209 patent are not infringed.

62. This is an exceptional case entitling Athenex to an award of its reasonable attorneys’ fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT VI
DECLARATION OF INVALIDITY OF THE ’209 PATENT

63. Athenex realleges and incorporates by reference the allegations of paragraphs 1-62 of this Complaint as if fully set forth herein.

64. Claims 1-13 of the ’209 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 1, *et seq*., including §§ 101, 102, 103, and 112. For example, claims 1-13 of the ’209 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least in view of AVP WHO Standard, Treschan, BCH Vasopressin Medicine Guide, PPC Vasopressin, and Prior Vasopressin Labels. Additionally, claims 1-13 of the ’209 patent are invalid under 35 U.S.C. § 112 because they lack, for example, an adequate written description and are not enabled.

65. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-13 of the ’209 patent are invalid.

66. This is an exceptional case entitling Athenex to an award of its reasonable attorneys’ fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT VII
DECLARATION OF NONINFRINGEMENT OF THE ’239 PATENT

67. Athenex realleges and incorporates by reference the allegations of paragraphs 1-66 of this Complaint as if fully set forth herein.

68. The manufacture, use, offer to sell, or sale of Athenex’s compounded vasopressin products does not, and would not, if marketed, infringe any claim of the ’239 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

69. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-19 of the ’239 patent are not infringed.

70. This is an exceptional case entitling Athenex to an award of its reasonable attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT VIII
DECLARATION OF INVALIDITY OF THE '239 PATENT

71. Athenex realleges and incorporates by reference the allegations of paragraphs 1-70 of this Complaint as if fully set forth herein.

72. Claims 1-19 of the '239 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 1, *et seq*., including §§ 101, 102, 103, and 112. For example, claims 1-19 of the '239 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least in view of AVP WHO Standard, Treschan, BCH Vasopressin Medicine Guide, PPC Vasopressin, and Prior Vasopressin Labels. Additionally, claims 1-19 of the '239 patent are invalid under 35 U.S.C. § 112 because they lack, for example, an adequate written description and are not enabled.

73. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-19 of the '239 patent are invalid.

74. This is an exceptional case entitling Athenex to an award of its reasonable attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT IX
DECLARATION OF NONINFRINGEMENT OF THE '785 PATENT

75. Athenex realleges and incorporates by reference the allegations of paragraphs 1-74 of this Complaint as if fully set forth herein.

76. The manufacture, use, offer to sell, or sale of Athenex's compounded vasopressin products does not, and would not, if marketed, infringe any claim of the '785 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

77. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-11 of the '785 patent are not infringed.

78. This is an exceptional case entitling Athenex to an award of its reasonable attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT X
DECLARATION OF INVALIDITY OF THE '785 PATENT

79. Athenex realleges and incorporates by reference the allegations of paragraphs 1-78 of this Complaint as if fully set forth herein.

80. Claims 1-11 of the '785 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 1, *et seq*., including §§ 101, 102, 103, and 112. For example, claims 1-11 of the '785 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least in view of AVP WHO Standard, Treschan, BCH Vasopressin Medicine Guide, PPC Vasopressin, and Prior Vasopressin Labels. Additionally, claims 1-11 of the '785 patent are invalid under 35 U.S.C. § 112 because they lack, for example, an adequate written description and are not enabled.

81. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-11 of the '785 patent are invalid.

82. This is an exceptional case entitling Athenex to an award of its reasonable attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XI
DECLARATION OF NONINFRINGEMENT OF THE '223 PATENT

83. Athenex realleges and incorporates by reference the allegations of paragraphs 1-82 of this Complaint as if fully set forth herein.

84. The manufacture, use, offer to sell, or sale of Athenex's compounded vasopressin products does not, and would not if marketed, infringe any claim of the '223 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

85. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-18 of the '223 patent are not infringed.

86. This is an exceptional case entitling Athenex to an award of its reasonable attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XII
DECLARATION OF INVALIDITY OF THE '223 PATENT

87. Athenex realleges and incorporates by reference the allegations of paragraphs 1-86 of this Complaint as if fully set forth herein.

88. Claims 1-18 of the '223 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 1, *et seq*., including §§ 101, 102, 103, and 112. For example, claims 1-18 of the '223 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least in view of AVP WHO Standard, Treschan, BCH Vasopressin Medicine Guide, PPC Vasopressin, and Prior Vasopressin Labels. Additionally, claims 1-18 of the '223 patent are

invalid under 35 U.S.C. § 112 because they lack, for example, an adequate written description and are not enabled.

89. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., to warrant the issuance of a declaratory judgment that claims 1-18 of the ’223 patent are invalid.

90. This is an exceptional case entitling Athenex to an award of its reasonable attorneys’ fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Athenex respectfully requests that this Court:

(1) Issue a declaratory judgment on Count I that claims 1-11 of the ’478 patent are not infringed.

(2) Issue a declaratory judgment on Count II that claims 1-11 of the ’478 patent are invalid.

(3) Issue a declaratory judgment on Count III that claims 1-20 of the ’526 patent are not infringed.

(4) Issue a declaratory judgment on Count IV that claims 1-20 of the ’526 patent are invalid.

(5) Issue a declaratory judgment on Count V that claims 1-13 of the ’209 patent are not infringed.

(6) Issue a declaratory judgment on Count VI that Claims 1-13 of the ’209 patent are invalid.

(7) Issue a declaratory judgment on Count VII that claims 1-19 of the ’239 patent are not infringed.

(8) Issue a declaratory judgment on Count VIII that claims 1-19 of the ’239 patent are invalid.

(9) Issue a declaratory judgment on Count IX that claims 1-11 of the ’785 patent are not infringed.

(10) Issue a declaratory judgment on Count X that claims 1-11 of the ’785 patent are invalid.

(11) Issue a declaratory judgment on Count XI that claims 1-18 of the ’223 patent are not infringed.

(12) Issue a declaratory judgment on Count XII that claims 1-18 of the ’223 patent are invalid.

(13) Award Athenex costs, expenses and attorneys’ fees incurred in connection with Counts I - XII.

(14) Enter such other relief as the Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Athenex hereby requests a trial by jury on all issues so triable.

Dated: August 13, 2018

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