IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., FERRING INTERNATIONAL CENTER S.A., FERRING B.V., and POLYPEPTIDE LABORATORIES A/S,	)	
Plaintiffs,	)	C.A. No.
v.	)	
EUGIA PHARMA SPECIALTIES LTD., AUROBINDO PHARMA LTD., and AUROMEDICS PHARMA LLC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Ferring Pharmaceuticals Inc. ("Ferring Pharma"), Ferring International Center S.A. ("FICSA"), Ferring B.V. (collectively, "Ferring"), and Polypeptide Laboratories A/S ("PPL A/S") (together with Ferring, "Plaintiffs") bring this action against Defendants Eugia Pharma Specialties Ltd. ("Eugia"), Aurobindo Pharma Ltd. ("APL"), and AuroMedics Pharma LLC ("AuroMedics") (collectively "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Number 9,579,359 ("the '359 patent"), United States Patent Number 10,729,739 ("the '739 patent"), United States Patent Number 10,973,870 ("the '870 patent"), United States Patent Number 9,415,085 ("the '085 patent"), United States Patent Number 10,695,398 ("the '398 patent"), United States Patent Number 8,841,081 ("the '081 patent"), United States Patent Number 9,877,999 ("the '999 patent"), and United States Patent Number 8,828,938 ("the '938 patent") (collectively, the

"patents in suit") under the Patent Laws of the United States, Title 35 of the United States Code, § 100 *et seq.* and for a declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Eugia's submission of Abbreviated New Drug Application ("ANDA") No. 215800 ("Eugia's ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to commercially manufacture, use, or sell a generic version of Ferring's FIRMAGON® (degarelix for injection) ("Eugia's ANDA Product") prior to the expiration of the '359, '739, '870, '085, and '398 patents.

THE PARTIES

3. Plaintiff Ferring Pharma is a private Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

4. Plaintiff FICSA is a Swiss private limited liability company having its offices at Ch. de la Vergognausaz 50, 1162 Saint-Prex, Switzerland.

5. Plaintiff Ferring B.V. is a Dutch private limited liability company having its offices at Polaris Avenue 144, Hoofddorp, 2132 JX, Netherlands.

6. Plaintiff PPL A/S is a company organized and existing under the laws of Denmark, having its registered offices at Herredsvejen 2 Hillerod, 3400 Denmark.

7. Upon information and belief, Defendant Eugia is a company organized and existing under the laws of India with a place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India.

8. Upon information and belief, Defendant APL is a company organized and existing under the laws of India with a place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India.

9. Upon information and belief, Defendant AuroMedics is a limited liability company organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520.

10. Upon information and belief, Eugia is a wholly owned subsidiary of APL.

11. Upon information and belief, AuroMedics is a wholly-owned subsidiary of APL.

12. AuroMedics is Eugia's United States agent regarding Eugia's ANDA.

13. Upon information and belief, Eugia, APL, and AuroMedics acted in concert to prepare and file ANDA No. 215800.

14. Upon information and belief, Eugia and APL participated in, assisted, and cooperated with AuroMedics in the acts complained of herein.

15. Upon information and belief, following any FDA approval of Eugia's ANDA, Eugia, APL, and AuroMedics will act in concert to manufacture, distribute, and/or sell Eugia's ANDA Product throughout the United States, including in Delaware.

JURISDICTION

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

17. Upon information and belief, this Court has personal jurisdiction over Eugia because it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being sued in this State. Upon information and belief, Eugia, itself and through its agents, develops, manufactures, imports, offers to sell, markets, and/or sells generic drug products throughout the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims. Alternatively, to the extent this Court does not have personal jurisdiction over Eugia under Federal Rule of Civil Procedure 4(k)(1), upon information and belief, this Court has personal jurisdiction over Eugia under

Federal Rule of Civil Procedure 4(k)(2) because exercising jurisdiction over Eugia is consistent with the United States Constitution and laws.

18. Upon information and belief, Eugia (1) has substantial, continuous, and systematic contacts with Delaware; (2) intends to market, sell, and/or distribute Eugia's ANDA Product to the residents of Delaware; (3) has corporate affiliates that are organized under the laws of Delaware; (4) maintains a distribution network within Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in Delaware.

19. Upon information and belief, this Court has personal jurisdiction over APL because it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being sued in this State. Upon information and belief, APL, itself and through its subsidiaries, develops, manufactures, imports, offers to sell, markets, and/or sells generic drug products throughout the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims. Alternatively, to the extent this Court does not have personal jurisdiction over APL under Federal Rule of Civil Procedure 4(k)(1), upon information and belief, this Court has personal jurisdiction over APL under Federal Rule of Civil Procedure 4(k)(2) because exercising jurisdiction over APL is consistent with the United States Constitution and laws.

20. Upon information and belief, APL (1) has substantial, continuous, and systematic contacts with Delaware; (2) intends to market, sell, and/or distribute Eugia's ANDA Product to the residents of Delaware; (3) has corporate affiliates that are organized under the laws of Delaware; (4) maintains a distribution network within Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in Delaware.

21. Upon information and belief, this Court has personal jurisdiction over AuroMedics because it is organized under the laws of the State of Delaware and therefore has consented to general jurisdiction in this State. Upon information and belief, AuroMedics is registered to conduct business within the State of Delaware and maintains as a registered agent for service of process the Corporation Trust Company with an address at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Upon information and belief, AuroMedics develops, manufactures, imports, offers to sell, markets, and/or sells generic drug products throughout the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims.

22. Upon information and belief, Eugia and APL have purposefully availed themselves of this forum by making, using, importing, selling, or offering to sell pharmaceutical products within this State, including planning to distribute Eugia's ANDA Product in this State, and can therefore reasonably expect to be subject to jurisdiction in Delaware's courts.

23. Upon information and belief, Eugia and APL have substantial, continuous, and systematic contacts with Delaware including through its engagement in the direct marketing, distribution, and/or sales of generic pharmaceuticals within Delaware.

24. Upon information and belief, Eugia and APL, and/or their subsidiaries, affiliates, or agents, intend to place Eugia's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this District.

25. Upon information and belief, APL controls Eugia, and AuroMedics, and therefore Eugia and AuroMedics's activities in Delaware are attributable to APL under either an alter ego or agency theory.

26. Upon information and belief, this Court has personal jurisdiction over Defendants because upon approval of ANDA No. 215800, Defendants will distribute, market, offer for sale, sell, and/or import into the United States the generic drug products, including in Delaware, and will derive substantial revenue from their consumption in Delaware.

27. Defendants have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of Delaware, including by having asserted counterclaims in this jurisdiction in matters including, for example: *Covis Pharma GmBH et al v. Eugia Pharma Specialties Ltd. et al*, No. 21-00003-CFC, D.I. 43 (Aug 6, 2021): *Teva Pharmaceuticals International GmbH et al v. Aurobindo Pharma Ltd. et al.*, No. 20-632-CFC, D.I. 13 (D. Del. Jul 20, 2020); and *Pfizer Inc. et al v. Aurobindo Pharma, Ltd.*, No. 20-1528-CFC, D.I. 7 (D. Del. Dec 4, 2020).

VENUE

28. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

29. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b) with respect to Eugia and APL because both are foreign corporations that may be sued in any district in which they are subject to the court's personal jurisdiction, and upon information and belief, Eugia and APL are subject to this Court's personal jurisdiction.

30. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to AuroMedics because, upon information and belief, it resides in the State of Delaware.

THE PATENTS IN SUIT

The '359 Patent

31. On February 28, 2017, the United States Patent and Trademark Office ("PTO") duly and legally issued the '359 patent, which bears the title "Method of Treating Prostate Cancer with GnRH Antagonist" and names Tine Kold Olesen, Bo-Eric Persson, Per Cantor, Egbert A. van der Meulen, and Jens-Kristian Slott Jensen as inventors. A true and correct copy of the '359 patent is attached as Exhibit A.

32. Ferring B.V. is the owner by assignment of the '359 patent, and Ferring Pharma is an exclusive licensee of the '359 patent.

33. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '359 patent is listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering FIRMAGON®.

The '739 Patent

34. On August 4, 2020, the PTO duly and legally issued the '739 patent, which bears the title "Method of Treating Prostate Cancer with GnRH Antagonist" and names Tine Kold Olesen, Bo-Eric Persson, Per Cantor, Egbert A. van der Meulen, and Jens-Kristian Slott Jensen as inventors. A true and correct copy of the '739 patent is attached as Exhibit B.

35. Ferring B.V. is the owner by assignment of the '739 patent, and Ferring Pharma is an exclusive licensee of the '739 patent.

The '870 Patent

36. On April 13, 2021, the PTO duly and legally issued the '870 patent, which bears the title "Method of Treating Prostate Cancer with GnRH Antagonist" and names Tine Kold Olesen, Bo-Eric Persson, Per Cantor, Egbert A. van der Meulen, and Jens-Kristian Slott Jensen as inventors. A true and correct copy of the '870 patent is attached as Exhibit C.

37. Ferring B.V. is the owner by assignment of the ’870 patent, and Ferring Pharma is an exclusive licensee of the ’870 patent.

The ’085 Patent

38. On August 16, 2016, the PTO duly and legally issued the ’085 patent, which bears the title “Method of Treating Prostate Cancer with GnRH Antagonist” and names Egbert A. van der Meulen, and László Balázs Tankó as inventors. A true and correct copy of the ’085 patent is attached as Exhibit D.

39. Ferring B.V. is the owner by assignment of the ’085 patent, and Ferring Pharma is an exclusive licensee of the ’085 patent.

The ’398 Patent

40. On June 30, 2020, the PTO duly and legally issued the ’398 patent, which bears the title “Method of Treating Prostate Cancer with GnRH Antagonist” and names Egbert A. van der Meulen, and László Balázs Tankó as inventors. A true and correct copy of the ’398 patent is attached as Exhibit E.

41. Ferring B.V. is the owner by assignment of the ’398 patent, and Ferring Pharma is an exclusive licensee of the ’398 patent.

The ’081 Patent

42. On September 23, 2014, the PTO duly and legally issued the ’081 patent, which bears the title “Method of Treating Metastatic Stage Prostate Cancer” and names Bo-Eric Persson as the inventor. A true and correct copy of the ’081 patent is attached as Exhibit F.

43. FICSA is the owner by assignment of the ’081 patent, and Ferring Pharma is an exclusive licensee of the ’081 patent.

The ’999 Patent

44. On January 30, 2018, the PTO duly and legally issued the '999 patent, which bears the title "Method for Treating Metastatic Stage Prostate Cancer" and names Bo-Eric Persson as the inventor. A true and correct copy of the '999 patent is attached as Exhibit G.

45. FICSA is the owner by assignment of the '999 patent, and Ferring Pharma is an exclusive licensee of the '999 patent.

The '938 Patent

46. On September 9, 2014, the PTO duly and legally issued the '938 patent, which bears the title "Method for the Manufacture of Degarelix" and names Haixiang Zhang, Jens Fomsgaard, and Gunnar Staerkaer as inventors. A true and correct copy of the '938 patent is attached as Exhibit H.

47. PPL A/S is the owner by assignment of the '938 patent, and FICSA and its affiliates are an exclusive licensee of the '938 patent.

STATEMENT OF FACTS

48. Ferring Pharma is the holder of New Drug Application ("NDA") No. 022201 for FIRMAGON® (degarelix acetate) for injection, 80 mg and 120 mg.

49. On December 24, 2008, the United States Food and Drug Administration ("FDA") approved NDA No. 022201 for the manufacture, marketing, and sale of FIRMAGON® for treatment of patients with advanced prostate cancer.

50. Ferring Pharma has sold FIRMAGON® under NDA No. 022201 since its approval.

51. Upon information and belief, Eugia filed ANDA No. 215800 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Eugia's ANDA Product before the expiration of the '359, '739, '870, '085, and '398 patents.

52. Upon information and belief, Eugia, APL, and AuroMedics acted collaboratively and in concert in the preparation and submission of Eugia's ANDA and continue to act collaboratively in pursuing FDA approval of Eugia's ANDA and seeking to market Eugia's ANDA Product.

53. Upon information and belief, Eugia, in concert with APL and AuroMedics, submitted a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") of invalidity, unenforceability, and/or noninfringement of the '359, '739, '870, '085, and '398 patents.

54. On November 24, 2021 (Ferring Pharma) and November 25, 2021 (FICSA, and Ferring B.V.), respectively, received a letter from Defendants dated November 22, 2021, purporting to be a Notice of Certification for Eugia's ANDA ("Defendants' Notice Letter") under Section 505(j)(2)(B)(ii) of the Act and 21 C.F.R. § 314.95(c)(1). Defendants' Notice Letter enclosed a statement of alleged factual and legal bases that the '359, '739, '870, '085, and '398 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Eugia's ANDA Product (the "Detailed Statement").

55. Upon information and belief, Eugia, in concert with APL and AuroMedics, intends to seek permission from the FDA to market its ANDA Product prior to expiration of the '359, '739, '870, '085, and '398 patents.

56. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. *See* 21 C.F.R. § 201.56(a)(1)-(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

57. Consistent with FDA regulations, the package insert for FIRMAGON® includes prescribing information that recites the FDA-approved indication for FIRMAGON® and provides instructions for physicians and patients to safely and effectively administer FIRMAGON®.

58. Attached as Exhibit I is a true and correct copy of the February 2020 FIRMAGON® package insert, which is the current version of the FIRMAGON® package insert.

59. FIRMAGON® is indicated for the treatment of patients with advanced prostate cancer. (Ex. I at § 1.)

60. The recommended dosing information for FIRMAGON® is provided in Section 2.1 of the FIRMAGON® package insert as follows:

2.1 Dosing information

FIRMAGON is administered as a subcutaneous injection in the abdominal region only at the dosages in Table 1 below.

Table 1: FIRMAGON Recommended Dosages

Starting Dosage	Maintenance Dosage – Administered once every 28 days
• 240 mg given as two subcutaneous injections of 120 mg at a concentration of 40 mg/mL	• The first maintenance dose should be given 28 days after the starting dose. • 80 mg given as one subcutaneous injection at a concentration of 20 mg/mL

(Ex. I at § 2.1.)

61. Section 2.2 of the FIRMAGON® package insert provides that FIRMAGON® is to be administered by a healthcare professional only:

2.2 Reconstitution and Administration Instructions

FIRMAGON is to be administered by a healthcare professional only.

(Ex. I at § 2.2.)

62. The "Dosage Form and Strengths" section of the FIRMAGON® package insert provides:

3 DOSAGE FORMS AND STRENGTHS

For injection:

- FIRMAGON (240 mg): Two single-dose vials each delivering 120 mg of degarelix in a white to off-white lyophilized powder for reconstitution supplied with diluent in two prefilled syringes.
- FIRMAGON (80 mg): One single-dose vial delivering 80 mg of degarelix in a white to off-white lyophilized powder for reconstitution supplied with diluent in one prefilled syringe.

(Ex. I at § 3.)

63. The "Adverse Reactions" section of the FIRMAGON® package insert provides the following table:

Table 2: Adverse Reactions Reported in ≥ 5% of Patients

	FIRMAGON 240/80 mg (subcutaneous) N = 207	Leuprolide 7.5 mg (intramuscular) N = 201
Any adverse reaction	79%	78%
Body as a whole		
Injection site reactions[a]	35%	<1%
Weight increase	9%	12%
Chills	5%	0%
Cardiovascular system		
Hot flash	26%	21%
Hypertension	6%	4%
Digestive system		
Increases in Transaminases and GGT	10%	5%
Constipation	5%	5%
Musculoskeletal system		
Back pain	6%	8%
Arthralgia	5%	9%
Urogenital system		
Urinary tract infection	5%	9%

[a] Includes pain, erythema, swelling, induration, or nodule.

(Ex. I at § 6.1.)

64. The package insert for Eugia's ANDA Product will be substantially similar to the package insert for FIRMAGON® in all material respects.

65. Plaintiffs commenced this action within forty-five (45) days of receiving Defendants' Notice Letter.

66. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Defendants regarding whether Defendants will infringe the patents in suit.

COUNT I

Infringement of the '359 Patent

67. Plaintiffs reallege paragraphs 1 to 69 and incorporate them by reference.

68. Defendants' submission of ANDA No. 215800 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Eugia's ANDA Product before the expiration of the '359 patent constitutes infringement of one of more claims of the '359 patent under 35 U.S.C. § 271(e)(2)(A).

69. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA No. 215800, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '359 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

70. Upon information and belief, after the FDA has approved Defendants' ANDA No. 215800, Defendants intend to manufacture, market, sell, and offer to sell Eugia's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Eugia's ANDA Product.

71. Upon information and belief, Defendants will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Defendant knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '359 patent by marketing Eugia's ANDA Product with the FDA-approved product insert.

72. Upon information and belief, Defendants have knowledge of the '359 patent and knows that the use of Eugia's ANDA Product in accordance with the FDA-approved product

insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '359 patent.

73. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

74. Plaintiffs have no adequate remedy at law.

75. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II

Infringement of the '739 Patent

76. Plaintiffs reallege paragraphs 1 to 69 and incorporate them by reference.

77. Defendants' submission of ANDA No. 215800 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Eugia's ANDA Product before the expiration of the '739 patent constitutes infringement of one of more claims of the '739 patent under 35 U.S.C. § 271(e)(2)(A).

78. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA No. 215800, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '739 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

79. Upon information and belief, after the FDA has approved Defendants' ANDA No. 215800, Defendants intend to manufacture, market, sell, and offer to sell Eugia's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Eugia's ANDA Product.

80. Upon information and belief, Defendants will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Defendant knows will directly

infringe, either literally or under the doctrine of equivalents, one or more claims of the '739 patent by marketing Eugia's ANDA Product with the FDA-approved product insert.

81. Upon information and belief, Defendants have knowledge of the '739 patent and know that the use of Eugia's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '739 patent.

82. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

83. Plaintiffs have no adequate remedy at law.

84. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III

Infringement of the '870 Patent

85. Plaintiffs reallege paragraphs 1 to 69 and incorporate them by reference.

86. Defendants' submission of ANDA No. 215800 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Eugia's ANDA Product before the expiration of the '870 patent constitutes infringement of one of more claims of the '870 patent under 35 U.S.C. § 271(e)(2)(A).

87. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA No. 215800, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '870 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

88. Upon information and belief, after the FDA has approved Defendants' ANDA No. 215800, Defendants intend to manufacture, market, sell, and offer to sell Eugia's ANDA

Product with an FDA-approved product insert that will direct physicians and patients in the use of Eugia's ANDA Product.

89. Upon information and belief, Defendants will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Defendant knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '870 patent by marketing Eugia's ANDA Product with the FDA-approved product insert.

90. Upon information and belief, Defendants have knowledge of the '870 patent and know that the use of Eugia's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '870 patent.

91. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

92. Plaintiffs have no adequate remedy at law.

93. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV

Infringement of the '085 Patent

94. Plaintiffs reallege paragraphs 1 to 69 and incorporate them by reference.

95. Defendants' submission of ANDA No. 215800 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Eugia's ANDA Product before the expiration of the '085 patent constitutes infringement of one of more claims of the '085 patent under 35 U.S.C. § 271(e)(2)(A).

96. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA No. 215800, Defendants will infringe, either literally or under the doctrine of equivalents, one or

more claims of the '085 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

97. Upon information and belief, after the FDA has approved Defendants' ANDA No. 215800, Defendants intend to manufacture, market, sell, and offer to sell Eugia's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Eugia's ANDA Product.

98. Upon information and belief, Defendants will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Defendant knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '085 patent by marketing Eugia's ANDA Product with the FDA-approved product insert along with the knowledge of a person of ordinary skill in the art.

99. Upon information and belief, Defendants have knowledge of the '085 patent and know that the use of Eugia's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '085 patent.

100. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

101. Plaintiffs have no adequate remedy at law.

102. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT V

Infringement of the '398 Patent

103. Plaintiffs reallege paragraphs 1 to 69 and incorporate them by reference.

104. Defendants' submission of ANDA No. 215800 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Eugia's ANDA Product before the expiration of the '398 patent constitutes infringement of one of more claims of the '398 patent under 35 U.S.C. § 271(e)(2)(A).

105. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA No. 215800, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '398 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

106. Upon information and belief, after the FDA has approved Defendants' ANDA No. 215800, Defendants intend to manufacture, market, sell, and offer to sell Eugia's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Eugia's ANDA Product.

107. Upon information and belief, Defendants will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Defendant knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '085 patent by marketing Eugia's ANDA Product with the FDA-approved product insert along with the knowledge of a person of ordinary skill in the art.

108. Upon information and belief, Defendants have knowledge of the '085 patent and knows that the use of Eugia's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '398 patent.

109. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

110. Plaintiffs have no adequate remedy at law.

111. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VI

Infringement of the '081 Patent

112. Plaintiffs reallege paragraphs 1 to 69 and incorporate them by reference.

113. Defendants' submission of ANDA No. 215800 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Eugia's ANDA Product before the expiration of the '081 patent constitutes infringement of one of more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

114. 35 U.S.C. § 271(e)(2)(A) provides:

> It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

115. These claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

116. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

117. The claims of the '081 patent are directed to methods for treating metastatic stage prostate cancer in a subject using degarelix. The method includes, among other things, identifying or selecting a subject with metastatic stage prostate cancer, administering degarelix

under a specific dosing regimen, and reducing the subject's serum alkaline phosphatase ("S-ALP") level for a duration of treatment.

118. For example, independent claim 1 of the '081 patent states:

> A method of treating metastatic stage prostate cancer in a subject, the method comprising:
>
> identifying a subject with metastatic stage prostate cancer comprising measuring the subject's baseline serum alkaline phosphatase (S-ALP) level;
>
> and reducing the subject's S-ALP level with respect to the baseline level by administering an initial dose of degarelix ranging from about 160 to about 320 mg to the subject; and administering at least one maintenance dose of degarelix ranging from about 60 mg to about 160 mg to the subject, wherein the at least one maintenance dose is administered approximately 20 days to 36 days, after the previous dose of degarelix for a duration of treatment ranging from 20 days to 450 days;
>
> and further, wherein the S-ALP level is reduced for the duration of treatment relative to the initial S-ALP level measured at the start of treatment.

119. The package insert for Eugia's ANDA Product will be substantially similar to the package insert for FIRMAGON® in all material respects.

120. FIRMAGON® is indicated for the treatment of patients with advanced prostate cancer. (Ex. I at § 1.)

121. Section 14 of the FIRMAGON® package insert discloses the results of a clinical trial, CS21, evaluating the safety and efficacy of FIRMAGON® in patients with prostate cancer (20% metastatic, 29% locally advanced, 31% localized, and 20% classified as other). (Ex. I at § 14.)

122. Healthcare providers review and follow the package inserts for the drugs they use to treat their patients, and many are familiar with the package insert and the relevant medical literature about the drugs they use to treat their patients.

123. A healthcare provider administering Eugia's ANDA Product will read and follow the package insert for Eugia's ANDA Product.

124. A healthcare provider will use Eugia's ANDA Product in accordance with its FDA-approved indication, which is for the treatment of patients with advanced prostate cancer.

125. At least some healthcare providers will use Eugia's ANDA Product to treat patients with metastatic stage prostate cancer, which is a subset of advanced prostate cancer.

126. S-ALP is a known biomarker for metastatic prostate cancer, and many healthcare providers, especially medical oncologists, in their routine practice of diagnosing and treating patients with metastatic prostate cancer, will measure S-ALP.

127. At least some healthcare providers will identify a patient with metastatic prostate cancer by, inter alia, measuring the patient's baseline S-ALP level in addition to other diagnostic tools such as imaging.

128. A healthcare provider following Eugia's proposed package insert will administer an initial dose of 240 mg of Eugia's ANDA Product to the patient.

129. A healthcare provider following Eugia's proposed package insert will administer a maintenance dose of 80 mg of Eugia's ANDA Product once every approximately 28 days to the patient for the duration of treatment.

130. The S-ALP level of at least some metastatic prostate cancer patients who are administered Eugia's ANDA Product in accordance with the dosing instructions in Eugia's proposed package insert will be reduced with respect to the patient's baseline S-ALP level for a duration of treatment ranging from 20 days to 450 days.

131. Upon information and belief, a physician or other healthcare provider following the FDA-approved package insert for Eugia's ANDA Product will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '081 patent.

132. Defendants have made, and will continue to make, substantial preparation to manufacture, use, offer to sell, and/or sell within the United States, and/or to import into the United States, Eugia's ANDA Product prior to the expiration of the '081 patent.

133. Unless enjoined by this Court, upon FDA approval of ANDA No. 215800, Defendants will infringe, either literally or under the doctrine of equivalents, one or more of claims of the '081 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

134. Upon information and belief, after the FDA has approved ANDA No. 215800, Defendants intend to manufacture, market, sell, and offer to sell Eugia's ANDA Product with an FDA-approved product insert that will direct physicians in the use of Eugia's ANDA Product.

135. Upon information and belief, Defendants will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Defendants know will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '081 patent by marketing Eugia's ANDA Product with the FDA-approved product insert.

136. Upon information and belief, Defendants have knowledge of the '081 patent and know that the use of Eugia's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '081 patent.

137. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

138. Plaintiffs have no adequate remedy at law.

139. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VII

Infringement of the '999 Patent

140. Plaintiffs reallege paragraphs 1 to 69 and incorporate them by reference.

141. Defendants' submission of ANDA No. 215800 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Eugia's ANDA Product before the expiration of the '999 patent constitutes infringement of one of more claims of the '999 patent under 35 U.S.C. § 271(e)(2)(A).

142. 35 U.S.C. § 271(e)(2)(A) provides:

> It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

143. These claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

144. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

145. The claims of the '999 patent are directed to methods for treating metastatic stage prostate cancer in a subject using degarelix. The method includes, among other things, identifying or selecting a subject with metastatic stage prostate cancer, administering degarelix

under a specific dosing regimen, and reducing the subject's serum alkaline phosphatase ("S-ALP") level for a duration of treatment.

146. For example, independent claim 1 of the '999 patent states:

> A method for treating a subject with metastatic stage prostate cancer having a serum alkaline phosphatase (S-ALP) level above a normal range for S-ALP prior to treatment, the method comprising:
>
> identifying a subject with metastatic stage prostate cancer having a S-ALP level above the normal range for S-ALP;
>
> reducing the subject's S-ALP level by administering an initial dose of degarelix ranging from about 160 mg to about 320 mg to the subject; and administering at least one maintenance dose of degarelix ranging from about 60 mg to 160 mg to the subject,
>
> wherein the at least one maintenance dose is administered approximately 20 to 36 days after the previous dose of degarelix for a duration of treatment ranging from 20 days to 450 days.

147. The package insert for Eugia's ANDA Product will be substantially similar to the package insert for FIRMAGON® in all material respects.

148. FIRMAGON® is indicated for the treatment of patients with advanced prostate cancer. (Ex. I at § 1.)

149. Section 14 of the FIRMAGON® package insert discloses the results of a clinical trial, CS21, evaluating the safety and efficacy of FIRMAGON® in patients with prostate cancer (20% metastatic, 29% locally advanced, 31% localized, and 20% classified as other). (Ex. I at § 14.)

150. Healthcare providers review and follow the package inserts for the drugs they use to treat their patients, and many are familiar with the package insert and the relevant medical literature about the drugs they use to treat their patients.

151. A healthcare provider administering Eugia's ANDA Product will read and follow the package insert for Eugia's ANDA Product such as imaging

152. A healthcare provider will use Eugia's ANDA Product in accordance with its FDA-approved indication, which is for the treatment of patients with advanced prostate cancer.

153. At least some healthcare providers will use Eugia's ANDA Product to treat patients with metastatic prostate cancer, which is a subset of advanced prostate cancer.

154. S-ALP is a known biomarker for metastatic prostate cancer, and many healthcare providers, especially medical oncologists, in their routine practice of diagnosing and treating patients with metastatic prostate cancer, will measure S-ALP.

155. At least some healthcare providers will identify a patient with metastatic prostate cancer by, inter alia, measuring the patient's baseline S-ALP level in addition to other diagnostic tools.

156. A healthcare provider following Eugia's proposed package insert will administer an initial dose of 240 mg of Eugia's ANDA Product to the patient.

157. A healthcare provider following Eugia's proposed package insert will administer a maintenance dose of 80 mg of Eugia's ANDA Product once every approximately 28 days to the patient for the duration of treatment.

158. The S-ALP level of at least some metastatic prostate cancer patients who are administered Eugia's ANDA Product in accordance with the dosing instructions in Eugia's proposed package insert will be reduced with respect to the patient's baseline S-ALP level for a duration of treatment ranging from 20 days to 450 days.

159. Upon information and belief, a physician or other healthcare provider following the FDA-approved package insert for Eugia's ANDA Product will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '081 patent.

160. Defendants have made, and will continue to make, substantial preparation to manufacture, use, offer to sell, and/or sell within the United States, and/or to import into the United States, Eugia's ANDA Product prior to the expiration of the '081 patent.

161. Unless enjoined by this Court, upon FDA approval of ANDA No. 215800, Defendants will infringe, either literally or under the doctrine of equivalents, one or more of claims of the '999 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

162. Upon information and belief, after the FDA has approved ANDA No. 215800, Defendants intend to manufacture, market, sell, and offer to sell Eugia's ANDA Product with an FDA-approved product insert that will direct physicians in the use of Eugia's ANDA Product.

163. Upon information and belief, Defendants will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Defendants know will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '999 patent by marketing Eugia's ANDA Product with the FDA-approved product insert.

164. Upon information and belief, Defendants have knowledge of the '999 patent and know that the use of Eugia's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '081 patent.

165. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

166. Plaintiffs have no adequate remedy at law.

167. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VIII

Infringement of the '938 Patent

168. Plaintiffs reallege paragraphs 1 to 69 and incorporate them by reference.

169. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

170. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

171. Prior to the invention of the '938 patent, significant risks and drawbacks were associated with commercially viable methods to synthesize pharmaceutical grade degarelix. For example, the '938 patent recognizes that the synthesis of degarelix is disclosed in U.S. Patent No. 5,925,730A ("the '730 patent"), but that the synthesis described therein included risks to both humans and the environment. (Ex. H at 3:10-23.) The synthesis described in the '730 patent uses trifluoroacetic acid ("TFA"), and it is known that "[a] disadvantage with TFA is its high human toxicity, which puts manufacturing personnel at risk." (*Id.*) Additionally, "[a]nother disadvantage with TFA is its environmental toxicity, which either makes it disposure costly or, if disposed improperly, contaminates the environment." (*Id.*)

172. The '938 patent states it as an object of the invention to provide a method for synthesizing degarelix that does not put human health at risk, as opposed to the method disclosed in the '730 patent. (Ex. H at 3:27-30.) The '938 patent also states it is an object of the invention to provide a method for synthesizing degarelix that does not put the environment at risk, as opposed to the method disclosed in the '730 patent. (*Id.* at 3:31-35.)

173. In addition to decreasing the risks to human health and/or the environment, in order for degarelix synthesis to be of use in the manufacture of pharmaceutical products, it also must be capable of producing degarelix in a sufficiently pharmaceutically pure manner. To that end, the '938 patent notes:

> The inventors have surprisingly found that pharmaceutically pure degarelix can be manufactured by solid phase synthesis using Fmoc as α-amino protecting group. "Pharmaceutically pure" indicates the product does not contain more than 0.3% by weight of any single impurity. Unexpectedly the Aph(L-Hor) moiety does not undergo rearrangement during solid-phase synthesis in spite of being subjected to several cycles of Fmoc protection and deprotection under basic conditions.

(Ex. H at 3:46-54.)

174. Because of the risk to manufacturing personnel and the environment, upon information and belief, no pharmaceutical company would use the methods described in the '730 patent to synthesize degarelix when another commercially viable means, as described in the '938 patent, is available. Moreover, any alternative method of manufacturing would have to be capable of producing sufficiently pure degarelix for use in pharmaceutical applications and do so in a manner that was commercially viable so as to support the manufacture of a pharmaceutical product. Plaintiffs are not aware of any other commercially viable method of using solid-phase peptide synthesis to manufacture degarelix in sufficiently pure form that could be used to support Eugia's ANDA Product.

175. Similarly, upon information and belief, no pharmaceutical company would use exclusively liquid-phase peptide synthesis in place of the process described in the '938 patent to manufacture degarelix for a new pharmaceutical product, such as Eugia's ANDA Product, because of issues with respect to efficiency and manufacturing costs.

176. Upon information and belief, the degarelix in Defendants' ANDA is synthesized according to the methods of the '938 patent, and Defendants and/or its affiliates have made, and will continue to make, substantial preparations to manufacture, use, offer to sell, and/or sell within the United States, and/or to import into the United States, Eugia's ANDA Product prior to the expiration of the '938 patent.

177. Further, Plaintiffs are aware of the submission of a Drug Master File for degarelix that was submitted by Auro Peptides, Ltd., on August 7, 2020. Upon information and belief, Auro Peptides, Ltd., is a subsidiary of APL based in Hyderabad, Telangana, India.

178. Upon information and belief, Auro Peptides, Ltd., will manufacture the degarelix used in Eugia's ANDA Product, and even if Defendants do not make available information concerning the synthesis of the degarelix used in Eugia's ANDA Product, the lack of alternative commercially viable methods to synthesize sufficiently pure degarelix for use in pharmaceutical applications related to new pharmaceutical products, such as Eugia's ANDA Product, would implicate the presumption of 35 U.S.C. § 295.

179. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants' importation into the United States, and/or use, offer to sell, and/or sale within the United States, of Eugia's ANDA Product will constitute infringement, either literally or under the doctrine of equivalents, of one or more of claims of the '938 patent under 35 U.S.C. §§ 271(a) and/or (g).

180. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court.

181. Plaintiffs have no adequate remedy at law.

182. This case is an exceptional one, and Plaintiffs is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following judgment and relief:

a. A declaration that the claims of United States Patent Number 9,579,359 are valid and enforceable;

b. A declaration that Defendants' submission to the FDA of Defendants' ANDA No. 215800 to obtain approval for the commercial manufacture, use, offer for sale, sale within, or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 9,579,359 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

c. A declaration that Defendants' manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product prior to the expiration of United States Patent Number 9,579,359 will infringe one or more claims of United States Patent Number 9,579,359 under 35 U.S.C. § 271;

d. An order that the effective date of the approval of Defendants' ANDA No. 215800 be a date that is not earlier than the expiration of the term of United States Patent Number 9,579,359, including any extension(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

e. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 9,579,359 prior to the expiration date of United States Patent Number 9,579,359 and any additional dates of exclusivity;

f. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 215800 until the expiration date of United States Patent Number 9,579,359 and any additional dates of exclusivity;

g. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 9,579,359 and any additional dates of exclusivity;

h. A declaration that the claims of United States Patent Number 10,729,739 are valid and enforceable;

i. A declaration that Defendants' submission to the FDA of Defendant's ANDA No. 215800 to obtain approval for the commercial manufacture, use, offer for sale, sale within, or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 10,729,739 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

j. A declaration that Defendants' manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product prior to the expiration of United States Patent Number 10,729,739 will infringe one or more claims of United States Patent Number 10,729,739 under 35 U.S.C. § 271;

k. An order that the effective date of the approval of Defendants' ANDA No. 215800 be a date that is not earlier than the expiration of the term of United States Patent Number 10,729,739, including any extension(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

l. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 10,729,739 prior to the expiration date of United States Patent Number 10,729,739 and any additional dates of exclusivity;

m. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 215800 until the expiration date of United States Patent Number 10,729,739 and any additional dates of exclusivity;

n. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engage in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 10,729,739 and any additional dates of exclusivity;

o. A declaration that the claims of United States Patent Number 10,973,870 are valid and enforceable;

p. A declaration that Defendants' submission to the FDA of Defendant's ANDA No. 215800 to obtain approval for the commercial manufacture, use, offer for sale, sale within, or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 10,973,870 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

q. A declaration that Defendants' manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product prior to the expiration of United

States Patent Number 10,973,870 will infringe one or more claims of United States Patent Number 10,973,870 under 35 U.S.C. § 271;

r. An order that the effective date of the approval of Defendants' ANDA No. 215800 be a date that is not earlier than the expiration of the term of United States Patent Number 10,973,870, including any extension(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

s. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 10,973,870 prior to the expiration date of United States Patent Number 10,973,870 and any additional dates of exclusivity;

t. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 215800 until the expiration date of United States Patent Number 10,973,870 and any additional dates of exclusivity;

u. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 10,973,870 and any additional dates of exclusivity;

v. A declaration that the claims of United States Patent Number 9,415,085 are valid and enforceable;

w. A declaration that Defendants' submission to the FDA of Defendants' ANDA No. 215800 to obtain approval for the commercial use, offer for sale, sale within, or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 9,415,085 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

x. A declaration that Defendants' manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product prior to the expiration of United States Patent Number 9,415,085 will infringe one or more claims of United States Patent Number 9,415,085 under 35 U.S.C. § 271;

y. An order that the effective date of the approval of Defendants' ANDA No. 215800 be a date that is not earlier than the expiration of the term of United States Patent Number 9,415,085, including any extension(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

z. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 9,415,085 prior to the expiration date of United States Patent Number 9,415,085 and any additional dates of exclusivity;

aa. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 215800 until the expiration date of United States Patent Number 9,415,085 and any additional dates of exclusivity;

bb. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants

engage in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 9,415,085 and any additional dates of exclusivity;

cc. A declaration that the claims of United States Patent Number 10,695,398 are valid and enforceable;

dd. A declaration that Defendants' submission to the FDA of Defendant's ANDA No. 215800 to obtain approval for the commercial use, offer for sale, sale within, or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 10,695,398 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

ee. A declaration that Defendants' manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product prior to the expiration of United States Patent Number 10,695,398 will infringe one or more claims of United States Patent Number 10,695,398 under 35 U.S.C. § 271;

ff. An order that the effective date of the approval of Defendants' ANDA No. 215800 be a date that is not earlier than the expiration of the term of United States Patent Number 10,695,398, including any extension(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

gg. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 10,695,398 prior to the expiration date of United States Patent Number 10,695,398 and any additional dates of exclusivity;

hh. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 215800 until the expiration date of United States Patent Number 10,695,398 and any additional dates of exclusivity;

ii. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engage in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 10,695,398 and any additional dates of exclusivity;

jj. A declaration that the claims of United States Patent Number 8,841,081 are valid and enforceable;

kk. A declaration that Defendants' manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product prior to the expiration of United States Patent Number 8,841,081 will infringe one or more claims of United States Patent Number 8,841,081 under 35 U.S.C. § 271;

ll. A permanent injunction under 35 U.S.C. § 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 8,841,081 prior to the expiration date of United States Patent Number 8,841,081 and any additional dates of exclusivity;

mm. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from

seeking, obtaining, or maintaining approval of ANDA No. 215800 until the expiration date of United States Patent Number 8,841,081 and any additional dates of exclusivity;

nn. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engage in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 8,841,081 and any additional dates of exclusivity;

oo. A declaration that the claims of United States Patent Number 9,877,999 are valid and enforceable;

pp. A declaration that Defendants' manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product prior to the expiration of United States Patent Number 9,877,999 will infringe one or more claims of United States Patent Number 9,877,999 under 35 U.S.C. § 271;

qq. A permanent injunction under 35 U.S.C. § 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 9,877,999 prior to the expiration date of United States Patent Number 9,877,999 and any additional dates of exclusivity;

rr. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 215800 until the expiration date of United States Patent Number 9,877,999 and any additional dates of exclusivity;

ss. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product before the expiration of United States Patent Number 9,877,999 and any additional dates of exclusivity;

tt. A declaration that the claims of United States Patent Number 8,828,938 are valid and enforceable;

uu. A declaration that Defendants' manufacture, use, offer to sell, sale within, and/or importation into, the United States of Eugia's ANDA Product prior to the expiration of United States Patent Number 8,828,938 will infringe one or more claims of United States Patent Number 8,828,938 under 35 U.S.C. § 271;

vv. A permanent injunction under 35 U.S.C. § 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 8,828,938 prior to the expiration date of United States Patent Number 8,828,938 and any additional dates of exclusivity;

ww. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 215800 until the expiration date of United States Patent Number 8,828,938 and any additional dates of exclusivity;

xx. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engage in the manufacture, use, offer to sell, sale within, and/or importation into, the United

States of Eugia's ANDA Product before the expiration of United States Patent Number 8,828,938 and any additional dates of exclusivity;

yy. A judgment and order that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs their reasonable attorneys' fees, costs, and expenses; and

zz. Any and all other and further relief as this Court deems just and proper.

Dated: January 4, 2022

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