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, v. JIANGSU HANSOH PHARMACEUTICAL GROUP CO., LTD., Defendant.	C.A. No.

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 Defendant Jiangsu Hansoh Pharmaceutical Group Co., Ltd. ("Defendant") 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"), 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 Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 217496 ("Defendant'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) ("Defendant'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 is a corporation organized and existing under the laws of China, having a place of business at 9 Dongjin Road, Economic and Technical Development Zone, Lianyungang City, Jiangsu, 222069, China.

8. Upon information and belief, Defendant prepared and filed ANDA No. 217496.

9. Upon information and belief, following any FDA approval of Defendant's ANDA, Defendant will manufacture, distribute, and/or sell Defendant's ANDA Product throughout the United States, including in Delaware.

JURISDICTION

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

11. Upon information and belief, this Court has personal jurisdiction over Defendant 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, Defendant, 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. This Court also has personal jurisdiction over Defendant under Federal Rule of Civil Procedure 4(k)(2) because exercising jurisdiction over Defendant is consistent with the United States Constitution and laws.

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

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

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

15. Upon information and belief, Defendant, and/or its subsidiaries, affiliates, or agents, intend to place Defendant'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.

16. Upon information and belief, this Court has personal jurisdiction over Defendant because, upon approval of ANDA No. 217496, Defendant 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.

VENUE

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

18. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b) because Defendant is a foreign corporation that may be sued in any district in which it is subject to the court's personal jurisdiction, and upon information and belief, Defendant is subject to this Court's personal jurisdiction.

THE PATENTS IN SUIT

The '359 Patent

19. 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.

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

21. 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

22. 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.

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

24. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '739 patent is listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering FIRMAGON®.

The '870 Patent

25. 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.

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

27. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '870 patent is listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering FIRMAGON®.

The '085 Patent

28. 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.

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

30. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '085 patent is listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering FIRMAGON®.

The '398 Patent

31. 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.

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

33. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '398 patent is listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering FIRMAGON®.

The '938 Patent

34. 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 F.

35. 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

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

37. 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.

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

39. Upon information and belief, Defendant filed ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Defendant's ANDA Product before the expiration of the '359, '739, '870, '085, and '398 patents.

40. Upon information and belief, Defendant prepared and submitted Defendant's ANDA and continues to pursue FDA approval of Defendant's ANDA and seeks to market Defendant's ANDA Product.

41. Upon information and belief, Defendant 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.

42. On September 27, 2022, Ferring Pharma received a letter from Defendant purporting to be a Notice of Certification for Defendant's ANDA ("Defendant's Notice Letter") under Section 505(j)(2)(B)(i)-(iv) of the Act. Defendant's 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 Defendant's ANDA Product (the "Detailed Statement").

43. Upon information and belief, Defendant intends to seek permission from the FDA to market its ANDA Product prior to expiration of the '359, '739, '870, '085, and '398 patents.

44. 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).

45. 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®.

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

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

48. 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. G at § 2.1.)

49. 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. G at § 2.2.)

50. 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. G at § 3.)

51. 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. G at § 6.1.)

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

53. Plaintiffs commenced this action within forty-five (45) days of receiving Defendant's Notice Letter.

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

COUNT I

Infringement of the '359 Patent

55. Plaintiffs reallege paragraphs 1 to 54 and incorporate them by reference.

56. Defendant's submission of ANDA No. 217496 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Defendant'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).

57. Unless enjoined by this Court, upon FDA approval of Defendant's ANDA No. 217496, Defendant 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).

58. Upon information and belief, after the FDA has approved Defendant's ANDA No. 217496, Defendant intends to manufacture, market, sell, and offer to sell Defendant's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Defendant's ANDA Product.

59. Upon information and belief, Defendant 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 Defendant's ANDA Product with the FDA-approved product insert.

60. Upon information and belief, Defendant has knowledge of the '359 patent and knows that the use of Defendant'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.

61. Plaintiffs will be irreparably harmed by Defendant’s infringing activities unless those activities are enjoined by this Court.

62. Plaintiffs have no adequate remedy at law.

63. 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

64. Plaintiffs reallege paragraphs 1 to 54 and incorporate them by reference.

65. Defendant’s submission of ANDA No. 217496 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Defendant’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).

66. Unless enjoined by this Court, upon FDA approval of Defendant’s ANDA No. 217496, Defendant 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).

67. Upon information and belief, after the FDA has approved Defendant’s ANDA No. 217496, Defendant intends to manufacture, market, sell, and offer to sell Defendant’s ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Defendant’s ANDA Product.

68. Upon information and belief, Defendant 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 Defendant's ANDA Product with the FDA-approved product insert.

69. Upon information and belief, Defendant has knowledge of the '739 patent and knows that the use of Defendant'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.

70. Plaintiffs will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court.

71. Plaintiffs have no adequate remedy at law.

72. 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

73. Plaintiffs reallege paragraphs 1 to 54 and incorporate them by reference.

74. Defendant's submission of ANDA No. 217496 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Defendant'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).

75. Unless enjoined by this Court, upon FDA approval of Defendant's ANDA No. 217496, Defendant 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).

76. Upon information and belief, after the FDA has approved Defendant's ANDA No. 217496, Defendant intends to manufacture, market, sell, and offer to sell Defendant's

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

77. Upon information and belief, Defendant 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 Defendant's ANDA Product with the FDA-approved product insert.

78. Upon information and belief, Defendant has knowledge of the '870 patent and knows that the use of Defendant'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.

79. Plaintiffs will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court.

80. Plaintiffs have no adequate remedy at law.

81. 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

82. Plaintiffs reallege paragraphs 1 to 54 and incorporate them by reference.

83. Defendant's submission of ANDA No. 217496 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Defendant'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).

84. Unless enjoined by this Court, upon FDA approval of Defendant's ANDA No. 217496, Defendant 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).

85. Upon information and belief, after the FDA has approved Defendant's ANDA No. 217496, Defendant intends to manufacture, market, sell, and offer to sell Defendant's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Defendant's ANDA Product.

86. Upon information and belief, Defendant 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 Defendant's ANDA Product with the FDA-approved product insert along with the knowledge of a person of ordinary skill in the art.

87. Upon information and belief, Defendant has knowledge of the '085 patent and knows that the use of Defendant'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.

88. Plaintiffs will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court.

89. Plaintiffs have no adequate remedy at law.

90. 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

91. Plaintiffs reallege paragraphs 1 to 54 and incorporate them by reference.

92. Defendant's submission of ANDA No. 217496 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Defendant'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).

93. Unless enjoined by this Court, upon FDA approval of Defendant's ANDA No. 217496, Defendant 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).

94. Upon information and belief, after the FDA has approved Defendant's ANDA No. 217496, Defendant intends to manufacture, market, sell, and offer to sell Defendant's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Defendant's ANDA Product.

95. Upon information and belief, Defendant 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 Defendant's ANDA Product with the FDA-approved product insert along with the knowledge of a person of ordinary skill in the art.

96. Upon information and belief, Defendant has knowledge of the '085 patent and knows that the use of Defendant'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.

97. Plaintiffs will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court.

98. Plaintiffs have no adequate remedy at law.

99. 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 '938 Patent

100. Plaintiffs reallege paragraphs 1 to 54 and incorporate them by reference.

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

102. 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.

103. 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. F 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.*)

104. 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. F 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.)

105. 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. F at 3:46-54.)

106. 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 Defendant’s ANDA Product.

107. 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 Defendant's ANDA Product, because of issues with respect to efficiency and manufacturing costs.

108. Upon information and belief, the degarelix in Defendant's ANDA is synthesized according to the methods of the '938 patent, and Defendant 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, Defendant's ANDA Product prior to the expiration of the '938 patent.

109. Upon information and belief, Defendant will manufacture the degarelix used in Defendant's ANDA Product, and even if Defendant does not make available information concerning the synthesis of the degarelix used in Defendant'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 Defendant's ANDA Product, would implicate the presumption of 35 U.S.C. § 295.

110. Unless enjoined by this Court, upon FDA approval of Defendant's ANDA, Defendant's importation into the United States, and/or use, offer to sell, and/or sale within the United States, of Defendant'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).

111. Plaintiffs will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court.

112. Plaintiffs have no adequate remedy at law.

113. This case is an exceptional one, and Plaintiffs are 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 Defendant's submission to the FDA of Defendant's ANDA No. 217496 to obtain approval for the commercial manufacture, use, offer for sale, sale within, or importation into, the United States of Defendant'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 Defendant's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 Defendant's ANDA No. 217496 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 become entitled;

e. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendant 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 Defendant 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. 217496 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 Defendant engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 Defendant's submission to the FDA of Defendant's ANDA No. 217496 to obtain approval for the commercial manufacture, use, offer for sale, sale within, or importation into, the United States of Defendant'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 Defendant's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 Defendant's ANDA No. 217496 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 become entitled;

l. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendant 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 Defendant 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. 217496 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 Defendant engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 Defendant's submission to the FDA of Defendant's ANDA No. 217496 to obtain approval for the commercial manufacture, use, offer for sale, sale within, or importation into, the United States of Defendant'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 Defendant's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 Defendant's ANDA No. 217496 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 become entitled;

s. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendant 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 Defendant 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. 217496 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 Defendant engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United

States of Defendant'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 Defendant's submission to the FDA of Defendant's ANDA No. 217496 to obtain approval for the commercial use, offer for sale, sale within, or importation into, the United States of Defendant'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 Defendant's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 Defendant's ANDA No. 217496 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 become entitled;

z. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendant 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 Defendant 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. 217496 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 Defendant engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 Defendant's submission to the FDA of Defendant's ANDA No. 217496 to obtain approval for the commercial use, offer for sale, sale within, or importation into, the United States of Defendant'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 Defendant's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 Defendant's ANDA No. 217496 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 become entitled;

gg. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendant 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 Defendant 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. 217496 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 Defendant engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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 8,828,938 are valid and enforceable;

kk. A declaration that Defendant's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant'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;

ll. A permanent injunction under 35 U.S.C. § 283, enjoining Defendant 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;

mm. A permanent injunction enjoining Defendant 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. 217496 until the expiration date of United States Patent Number 8,828,938 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 Defendant engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Defendant's ANDA Product before the expiration of United States Patent Number 8,828,938 and any additional dates of exclusivity;

oo. 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

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

Dated: November 9, 2022

/s/ Mary W. Bourke
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