

**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. 22-1474-MN

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**JIANGSU HANSOH PHARMACEUTICAL GROUP CO., LTD.’S**  
**ANSWER AND ADDITIONAL DEFENSES**

Defendant Jiangsu Hansoh Pharmaceutical Group Co., Ltd. (“Hansoh” or “Defendant”), by its undersigned attorneys, hereby respond to the Complaint filed by Plaintiffs Ferring Pharmaceuticals Inc., Ferring International Center S.A., Ferring B.V., and Polypeptide Laboratories A/S (collectively, “Ferring” or “Plaintiffs”). Hansoh denies all allegations in Plaintiffs’ Complaint, except those expressly admitted below.

**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.

**ANSWER**

Hansoh admits that Plaintiffs' Complaint purports to state an action for infringement of the patents in suit under the Patent Laws of the United States. Hansoh denies all remaining allegations in Paragraph 1.

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<sup>®</sup> (degarelix for injection) ("Defendant's ANDA Product") prior to the expiration of the '359, '739, '870, '085, and '398 patents.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale in the United States of degarelix acetate for injection, equivalent to 120 mg base/vial and 80 mg base/vial, that is the subject of ANDA No. 217496 ("Hansoh's ANDA Product"), as a generic version of FIRMAGON (degarelix for injection) prior to the expiration of the '359, '739, '870, '085, and '398 patents. Hansoh denies any remaining allegations in Paragraph 2.

**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.

**ANSWER**

Hansoh is without knowledge or information sufficient to admit or deny the allegations of Paragraph 3 of the Complaint, and therefore denies them.

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

**ANSWER**

Hansoh is without knowledge or information sufficient to admit or deny the allegations of Paragraph 4 of the Complaint, and therefore denies them.

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

**ANSWER**

Hansoh is without knowledge or information sufficient to admit or deny the allegations of Paragraph 5 of the Complaint, and therefore denies them.

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.

**ANSWER**

Hansoh is without knowledge or information sufficient to admit or deny the allegations of Paragraph 6 of the Complaint, and therefore denies them.

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.

**ANSWER**

Admitted.

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

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 to FDA seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product. Hansoh denies all remaining allegations of Paragraph 8.

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.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 to FDA seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product. Hansoh denies all remaining allegations of Paragraph 9.

**JURISDICTION**

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

**ANSWER**

Paragraph 10 states legal conclusions to which no response is required. To the extent any response is required, Hansoh does not contest that the Court has jurisdiction over the subject matter of this action for the limited purpose of this action only. Hansoh denies all remaining allegations of Paragraph 10.

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.

**ANSWER**

Paragraph 11 states legal conclusions to which no response is required. To the extent any response is required, Hansoh does not contest personal jurisdiction in this District for the limited purpose of this action only. Hansoh denies all remaining allegations in Paragraph 11.

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.

**ANSWER**

Paragraph 12 states legal conclusions to which no response is required. To the extent any response is required, Hansoh does not contest personal jurisdiction in this District for the limited purpose of this action only. Hansoh denies all remaining allegations in Paragraph 12.

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.

**ANSWER**

Paragraph 13 states legal conclusions to which no response is required. To the extent any response is required, Hansoh does not contest personal jurisdiction in this District for the limited purpose of this action only. Hansoh denies all remaining allegations in Paragraph 13.

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.

**ANSWER**

Paragraph 14 states legal conclusions to which no response is required. To the extent any response is required, Hansoh does not contest personal jurisdiction in this District for the limited purpose of this action only. Hansoh denies all remaining allegations in Paragraph 14.

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.

**ANSWER**

Paragraph 15 states legal conclusions to which no response is required. To the extent any response is required, Hansoh does not contest personal jurisdiction in this District for the limited purpose of this action only. Hansoh denies all remaining allegations in Paragraph 15.

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.

**ANSWER**

Paragraph 16 states legal conclusions to which no response is required. To the extent any response is required, Hansoh does not contest personal jurisdiction in this District for the limited purpose of this action only. Hansoh denies the remaining allegations in Paragraph 16.

**VENUE**

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

**ANSWER**

Hansoh incorporates by reference the answers of the preceding paragraphs as if set forth fully 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.

**ANSWER**

Paragraph 18 states legal conclusions to which no response is required. To the extent any response is required, Hansoh does not contest venue in this District for the limited purpose of this action only. Hansoh denies the remaining allegations in Paragraph 18.

**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.

**ANSWER**

Paragraph 19 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits, according to the cover page of the '359 patent, that the title of the '359 patent appears to be “Method of Treating Prostate Cancer with GnRH Antagonist,” that February 28, 2017 appears to be the listed issuance date of the '359 patent, and that Tine Kold Olesen, Bo-Eric Persson, Per Cantor, Egbert A. van der Meulen, and Jens-Kristian Slott Jensen appear to be listed as inventors of the '359 patent. Hansoh further admits that a purported copy of the '359 patent was attached to the Complaint as Exhibit A. Hansoh denies all remaining allegations in Paragraph 19.

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

**ANSWER**

Paragraph 20 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that Ferring B.V. appears to be listed as the assignee of the '359 patent according to the cover of the '359 patent. Hansoh is without knowledge or information sufficient to admit or deny all remaining allegations of Paragraph 20, and therefore denies them.

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®.

**ANSWER**

Paragraph 21 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that the ’359 patent is listed in FDA’s Orange Book. Hansoh denies all remaining allegations of Paragraph 21.

**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.

**ANSWER**

Paragraph 22 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits, according to the cover page of the ’739 patent, that the title of the ’739 patent appears to be “Method of Treating Prostate Cancer with GnRH Antagonist,” that August 4, 2020 appears to be the listed issuance date of the ’739 patent, and that Tine Kold Olesen, Bo-Eric Persson, Per Cantor, Egbert A. van der Meulen, and Jens-Kristian Slott Jensen appear to be listed as inventors of the ’739 patent. Hansoh further admits that a purported copy of the ’739 patent was attached to the Complaint as Exhibit B. Hansoh denies all remaining allegations in Paragraph 22.

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

**ANSWER**

Paragraph 23 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that Ferring B.V. appears to be listed as the assignee of the ’739 patent according to the cover of the ’739 patent. Hansoh is without knowledge or

information sufficient to admit or deny all remaining allegations of Paragraph 23, and therefore denies them.

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®.

**ANSWER**

Paragraph 24 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that the '739 patent is listed in FDA's Orange Book. Hansoh denies all remaining allegations of Paragraph 24.

**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.

**ANSWER**

Paragraph 25 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits, according to the cover page of the '870 patent, that the title of the '870 patent appears to be "Method of Treating Prostate Cancer with GnRH Antagonist," that April 13, 2021 appears to be the listed issuance date of the '870 patent, and that Tine Kold Olesen, Bo-Eric Persson, Per Cantor, Egbert A. van der Meulen, and Jens-Kristian Slott Jensen appear to be listed as inventors of the '870 patent. Hansoh further admits that a purported copy of the '870 patent was attached to the Complaint as Exhibit C. Hansoh denies all remaining allegations in Paragraph 25.

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

**ANSWER**

Paragraph 26 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that Ferring B.V. appears to be listed as the assignee of the '870 patent according to the cover of the '870 patent. Hansoh is without knowledge or information sufficient to admit or deny all remaining allegations of Paragraph 26, and therefore denies them.

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®.

**ANSWER**

Paragraph 27 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that the '870 patent is listed in FDA's Orange Book. Hansoh denies all remaining allegations of Paragraph 27.

**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.

**ANSWER**

Paragraph 28 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits, according to the cover page of the '085 patent, that the title of the '085 patent appears to be "Method of Treating Prostate Cancer with GnRH Antagonist," that August 16, 2016 appears to be the listed issuance date of the '085 patent, and that Egbert A. van der Meulen and László Balázs Tankó appear to be listed as inventors of the '085 patent.

Hansoh further admits that a purported copy of the '085 patent was attached to the Complaint as Exhibit D. Hansoh denies all remaining allegations in Paragraph 28.

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

**ANSWER**

Paragraph 29 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that Ferring B.V. appears to be listed as the assignee of the '085 patent according to the cover of the '085 patent. Hansoh is without knowledge or information sufficient to admit or deny all remaining allegations of Paragraph 29, and therefore denies them.

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®.

**ANSWER**

Paragraph 30 states legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that the '085 patent is listed in FDA's Orange Book. Hansoh denies all remaining allegations of Paragraph 30.

**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.

**ANSWER**

Paragraph 31 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits, according to the cover page of the '398 patent, that the

title of the '398 patent appears to be “Method of Treating Prostate Cancer with GnRH Antagonist,” that June 30, 2020 appears to be the listed issuance date of the '398 patent, and that Egbert A. van der Meulen and László Balázs Tankó appear to be listed as inventors of the '398 patent. Hansoh further admits that a purported copy of the '398 patent was attached to the Complaint as Exhibit E. Hansoh denies all remaining allegations in Paragraph 31.

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

**ANSWER**

Paragraph 32 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that Ferring B.V. appears to be listed as the assignee of the '398 patent according to the cover of the '398 patent. Hansoh is without knowledge or information sufficient to admit or deny all remaining allegations of Paragraph 32, and therefore denies them.

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®.

**ANSWER**

Paragraph 33 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that the '398 patent is listed in FDA's Orange Book. Hansoh denies all remaining allegations of Paragraph 33.

**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.

**ANSWER**

Paragraph 34 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits, according to the cover page of the '938 patent, that the title of the '938 patent appears to be "Method for the Manufacture of Degarelix," that September 9, 2014 appears to be the listed issuance date of the '938 patent, and that Haixiang Zhang, Jens Fomsgaard, and Gunnar Staerkaer appear to be listed as inventors of the '938 patent. Hansoh further admits that a purported copy of the '938 patent was attached to the Complaint as Exhibit F. Hansoh denies all remaining allegations in Paragraph 34.

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.

**ANSWER**

Paragraph 35 contains legal conclusions to which no response is required. To the extent any response is required, Hansoh admits that PPL A/S appears to be listed as the assignee of the '938 patent according to the cover of the '938 patent. Hansoh is without knowledge or information sufficient to admit or deny all the remaining allegations of Paragraph 35, and therefore denies them.

**STATEMENT OF FACTS**

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

**ANSWER**

Hansoh admits that, according to the electronic version of FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book"), Ferring Pharma is the purported application holder for NDA 022201, which is listed in connection with FIRMAGON<sup>®</sup> (degarelix acetate), 80 mg base/vial and 120 mg base/vial.

Hansoh is without knowledge or information sufficient to admit or deny all remaining allegations of Paragraph 36, and therefore denies them.

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<sup>®</sup> for treatment of patients with advanced prostate cancer.

**ANSWER**

Hansoh admits that December 24, 2008 appears to be the listed approval date of NDA No. 022201 in FDA’s Orange Book and that the label for FIRMAGON states that it is indicated for treatment of patients with advanced prostate cancer. Hansoh denies all remaining allegations in Paragraph 37.

38. Ferring Pharma has sold FIRMAGON<sup>®</sup> under NDA No. 022201 since its approval.

**ANSWER**

Hansoh is without knowledge or information sufficient to admit or deny all the allegations of Paragraph 38, and therefore denies them.

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.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh’s ANDA Product before the expiration of the ’359, ’739, ’870, ’085, and ’398 patents. Hansoh denies all remaining allegations in Paragraph 39.

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.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product. Hansoh denies all remaining allegations in Paragraph 40.

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.

**ANSWER**

Hansoh admits that it submitted to FDA ANDA No. 217496 that contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the '359, '739, '870, '085, and '398 patents are invalid, unenforceable and/or will not be infringed by Hansoh's ANDA Product. Hansoh denies all remaining allegations in Paragraph 41.

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").

**ANSWER**

Hansoh admits that on or before September 27, 2022, Hansoh sent a letter pursuant to Section 505(j)(2)(B)(i)-(iv) of the Act and enclosed a statement of 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 Hansoh's ANDA Product. Hansoh further admits that it received notification that the letter and enclosures were received on September 27, 2022. Hansoh denies all remaining allegations in Paragraph 42.

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.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product prior to the expiration of the '359, '739, '870, '085, and '398 patents. Hansoh denies all remaining allegations in Paragraph 43.

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).

**ANSWER**

Paragraph 44 contains legal conclusions to which no answer is required. To the extent that an answer is required, Hansoh refers to 21 C.F.R. §§ 201.56(a)(1)-(3) and 201.57(a)-(c) for the contents thereof, the terms of which speak for themselves, except to state that the allegations inconsistent with the express terms of 21 C.F.R. §§ 201.56(a)(1)-(3) and 201.57(a)-(c) are denied. Hansoh denies all remaining allegations in Paragraph 44.

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

**ANSWER**

Hansoh admits that FIRMAGON<sup>®</sup> has a package insert. Hansoh refers to the package insert for the contents thereof, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of the package insert are denied. Hansoh denies all remaining allegations in Paragraph 45.

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

**ANSWER**

Hansoh admits that Exhibit G is the purported true and correct copy of the February 2020 FIRMAGON® package insert. Hansoh denies all remaining allegations in Paragraph 46.

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

**ANSWER**

Hansoh admits that Exhibit G at § 1 attached to the Complaint states “FIRMAGON® is indicated for treatment of patients with advanced prostate cancer.” Hansoh denies all remaining allegations in Paragraph 47.

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

<p><b>2.1 Dosing information</b>                  FIRMAGON is administered as a subcutaneous injection in the abdominal region only at the dosages in Table 1 below.</p>	
<p><b>Table 1: FIRMAGON Recommended Dosages</b></p>	
<p><b>Starting Dosage</b></p>	<p><b>Maintenance Dosage – Administered once every 28 days</b></p>
<ul style="list-style-type: none"> <li>• 240 mg given as two subcutaneous injections of 120 mg at a concentration of 40 mg/mL.</li> </ul>	<ul style="list-style-type: none"> <li>• The first maintenance dose should be given 28 days after the starting dose.</li> <li>• 80 mg given as one subcutaneous injection at a concentration of 20 mg/mL.</li> </ul>

(Ex. G at § 2.1.)

**ANSWER**

Hansoh refers to the FIRMAGON® package insert for the contents thereof, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of the package insert are denied. Hansoh denies all remaining allegations in Paragraph 48.

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.)

**ANSWER**

Hansoh refers to the FIRMAGON<sup>®</sup> package insert for the contents thereof, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of the package insert are denied. Hansoh denies all remaining allegations of Paragraph 49.

50. The “Dosage Form and Strengths” section of the FIRMAGON<sup>®</sup> 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.)

**ANSWER**

Hansoh refers to the FIRMAGON<sup>®</sup> package insert for the contents thereof, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of the package insert are denied. Hansoh denies all remaining allegations of Paragraph 50.

51. The “Adverse Reactions” section of the FIRMAGON<sup>®</sup> package insert provides the following table:

**Table 2: Adverse Reactions Reported in  $\geq$  5% of Patients**

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

<sup>a</sup> Includes pain, erythema, swelling, induration, or nodule.

(Ex. G at § 6.1.)

**ANSWER**

Hansoh refers to the FIRMAGON<sup>®</sup> package insert for the contents thereof, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of the package insert are denied. Hansoh denies all remaining allegations of Paragraph 51.

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

**ANSWER**

Paragraph 52 contains legal conclusions to which no response is required. To the extent an answer is required, Hansoh refers to the package insert in ANDA No. 217496 for the contents therein, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of the package insert in ANDA No. 217496 are denied. Hansoh denies all remaining allegations in Paragraph 52.

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

**ANSWER**

Admitted.

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

**ANSWER**

Admitted.

**COUNT I**

**Infringement of the '359 Patent**

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

**ANSWER**

Hansoh repeats and incorporates by reference the responses to each of paragraphs 1 to 54 of the Complaint as if fully set forth herein.

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).

**ANSWER**

Denied.

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).

**ANSWER**

Denied.

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.

**ANSWER:**

Hansoh admits that it submitted ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product. Hansoh denies all remaining allegations in Paragraph 58.

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.

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it has knowledge of the '359 patent. Hansoh denies all remaining allegations of Paragraph 60.

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

**ANSWER**

Denied.

62. Plaintiffs have no adequate remedy at law.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

**COUNT II**

**Infringement of the '739 Patent**

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

**ANSWER**

Hansoh repeats and incorporates by reference the responses to each of paragraphs 1-54 of the Complaint as if fully set forth herein.

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).

**ANSWER**

Denied.

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).

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product. Hansoh denies all remaining allegations in Paragraph 67.

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.

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it has knowledge of the '739 patent. Hansoh denies all remaining allegations of Paragraph 69.

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

**ANSWER**

Denied.

71. Plaintiffs have no adequate remedy at law.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

**COUNT III**

**Infringement of the '870 Patent**

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

**ANSWER**

Hansoh repeats and incorporates by reference the responses to each of paragraphs 1 to 54 of the Complaint as if fully set forth herein.

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 or more claims of the '870 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER**

Denied.

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).

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product. Hansoh denies all remaining allegations in Paragraph 76.

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.

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it has knowledge of the '870 patent. Hansoh denies all remaining allegations of Paragraph 78.

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

**ANSWER**

Denied.

80. Plaintiffs have no adequate remedy at law.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

**COUNT IV**

**Infringement of the '085 Patent**

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

**ANSWER**

Hansoh repeats and incorporates by reference the responses to each of paragraphs 1 to 54 of the Complaint as if fully set forth herein.

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).

**ANSWER**

Denied.

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).

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product. Hansoh denies all remaining allegations in Paragraph 85.

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.

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it has knowledge of the '085 patent. Hansoh denies all remaining allegations of Paragraph 87.

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

**ANSWER**

Denied.

89. Plaintiffs have no adequate remedy at law.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

**COUNT V**

**Infringement of the '398 Patent**

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

**ANSWER**

Hansoh repeats and incorporates by reference the responses to each of paragraphs 1 to 54 of the Complaint as if fully set forth herein.

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).

**ANSWER**

Denied.

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).

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it submitted ANDA No. 217496 seeking approval to engage in the commercial manufacture, use, or sale in the United States of Hansoh's ANDA Product. Hansoh denies all remaining allegations in Paragraph 94.

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.

**ANSWER**

Denied.

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.

**ANSWER**

Hansoh admits that it has knowledge of the '085 patent. Hansoh denied all remaining allegations of Paragraph 96.

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

**ANSWER**

Denied.

98. Plaintiffs have no adequate remedy at law.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

**COUNT VI**

**Infringement of the '938 Patent**

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

**ANSWER**

Hansoh repeats and incorporates by reference the responses to each of paragraphs 1 to 54 of the Complaint as if fully set forth herein.

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

**ANSWER**

Hansoh admits that these claims purportedly arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Hansoh denies all remaining allegations of Paragraph 101.

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.

**ANSWER**

Hansoh admits that an actual case or controversy exists between Plaintiffs and Hansoh for this Court to declare rights regarding the '938 patent.

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 dispose costly or, if disposed improperly, contaminates the environment.” (*Id.*)

**ANSWER**

Hansoh states that the contents of the '938 patent speak for themselves. By way of further response, Hansoh lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 103 and therefore denies the same.

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.)

**ANSWER**

Hansoh states that the contents of the '938 patent speak for themselves. By way of further response, Hansoh lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 104 and therefore denies the same.

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  $\alpha$ -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.)

**ANSWER**

Hansoh states that the contents of the '938 patent speak for themselves. By way of further response, Hansoh lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 105 and therefore denies the same.

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.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

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)

**ANSWER**

Denied.

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

**ANSWER**

Denied.

112. Plaintiffs have no adequate remedy at law.

**ANSWER**

Denied.

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.

**ANSWER**

Denied.

### **RESPONSE TO PRAYER FOR RELIEF**

Hansoh denies that Plaintiffs are entitled to any relief sought in Plaintiffs' Prayer for Relief in the Complaint or any relief whatsoever, including but not limited to Plaintiffs' Prayer for Relief a-pp.

### **ADDITIONAL DEFENSES**

Hansoh asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Hansoh does not assume the burden of proof with respect to those matters that, under the law, Plaintiffs bear the burden of proof.

#### **FIRST ADDITIONAL DEFENSE**

Plaintiffs fail to state a claim upon which relief can be granted.

#### **SECOND ADDITIONAL DEFENSE**

Each claim of the '359, '739, '870, '085, '398 and '938 patents is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability, including obviousness-type double patenting.

#### **THIRD ADDITIONAL DEFENSE**

Defendant has not infringed, induced infringement of, or contributed to the infringement of, and Defendant will not infringe, induce infringement of, or contribute to the infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '359, '739, '870, '085, '398 and '938 patents.

**FOURTH ADDITIONAL DEFENSE**

Plaintiffs are not entitled to injunctive relief against Defendant because the alleged harm would be neither immediate nor irreparable, and therefore Plaintiffs have an adequate remedy at law.

**FIFTH ADDITIONAL DEFENSE**

Any additional legal or equitable defenses or counterclaims that discovery may reveal, including but not limited to, defenses of unenforceability, as well as any defenses raised by another defendant in any action involving the '359, '739, '870, '085, '398 and/or '938 patents. Hansoh reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

**REQUEST FOR RELIEF**

**WHEREFORE**, Defendant respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs:

- (1) Dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;
- (2) Adjudging that the submission of Hansoh's ANDA No. 217496 has not infringed, does not infringe, and will not infringe any valid or enforceable claim of the '359, '739, '870, '085, '398 and '938 patents;
- (3) Adjudging that the manufacture, use, sale, offer for sale, or importation of Hansoh's ANDA Product does not and will not directly or indirectly infringe, induce the infringement of, or contribute to the infringement of any valid or enforceable claim of the '359, '739, '870, '085, '398 and '938 patents, either literally or under the doctrine of equivalents;

- (4) Adjudging that all claims of the '359, '739, '870, '085, '398 and '938 patents are invalid;
- (5) Adjudging that this is an exceptional case under 35 U.S.C. § 285 and/or other applicable laws and awarding Hansoh attorney fees, costs and expenses in this action;
- (6) Awarding Hansoh the costs and fees of this action; and
- (7) Awarding Hansoh any and all such other relief as this Court deems just and proper.

Dated: February 10, 2023

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