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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A.,	:	Honorable Zahid N. Quraishi, U.S.D.J.
	:	Civil Action No. 22 CV 4635 (ZNQ)(LHG)
Plaintiff,	:	
v.	:	**GLAND'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT**
GLAND PHARMA LIMITED,	:	
Defendant.	:	

Defendant Gland Pharma Ltd., ("Gland"), by and through its counsel, answers the Complaint of Helsinn Healthcare S.A. ("Helsinn" or "Plaintiff") as follows. All allegations not specifically admitted are denied.

THE PARTIES

1. Plaintiff Helsinn Healthcare S.A. is a Swiss corporation having its principal place of business at Via Pian Scairolo, 9, CH-6912 Lugano-Pazzallo, Switzerland.

ANSWER: Based upon Plaintiffs' allegations, and upon information and belief, admitted.

2. Helsinn manufactures, markets, distributes, and sells innovative pharmaceutical products for improving and extending the lives of patients suffering from cancer.

ANSWER: Gland is without knowledge or information sufficient to form a belief as to the truth of the allegations asserted in paragraph 2 and therefore denies them.

3. Upon information and belief, Defendant Gland is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal Medchal-Malkajgiri District, Hyderabad 500043, Telangana, India.

ANSWER: Admitted.

4. Upon information and belief, Defendant Gland develops, manufactures, markets, distributes, sells, and/or imports generic versions of branded pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: Denied.

NATURE OF THE ACTION

5. This is a civil action for patent infringement of U.S. Patent No. 8,426,450 ("the '450 patent"), U.S. Patent No. 8,895,586 ("the '586 patent"), U.S. Patent No. 9,186,357 ("the '357 patent"), U.S. Patent No. 9,403,772 ("the '772 patent"), U.S. Patent No. 9,908,907 ("the '907 patent"), U.S. Patent No. 10,208,073 ("the '073 patent"), U.S. Patent No. 10,624,911 ("the '911 patent"), U.S. Patent No. 10,717,721 ("the '721 patent"), U.S. Patent No. 10,828,297 ("the '297 patent"), and U.S. Patent No. 11,312,698 ("the '698 patent") (collectively, "the patents-in-suit")

ANSWER: Gland admits that Plaintiff's Complaint purports that this is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, involving U.S. Patent No. 8,426,450 ("the '450 patent"), U.S. Patent No. 8,895,586 ("the '586 patent"), U.S. Patent No. 9,186,357 ("the '357 patent"), U.S. Patent No. 9,403,772 ("the '772 patent"), U.S. Patent No. 9,908,907 ("the '907 patent"), U.S. Patent No. 10,208,073 ("the '073 patent"), U.S. Patent No. 10,624,911 ("the '911 patent"), U.S. Patent No. 10,717,721 ("the '721 patent"), U.S. Patent No. 10,828,297 ("the '297 patent"), and U.S. Patent No. 11,312,698 ("the '698 patent"), which appear to be attached to the Complaint as Exhibits A-G respectively, but denies that Plaintiff is entitled to any relief.

6. This action arises under the Patent Laws of the United States, 35. U.S.C. § 100, *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 6 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the Complaint purports to assert an action under the Patent Laws of the United States, 35. U.S.C. § 100, *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Gland denies any remaining allegations of paragraph 6.

JURISICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-02, and/or 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this action is an actual controversy within the Court's jurisdiction.

ANSWER: Paragraph 7 contains conclusions of law to which no response is required. To the extent that a response is required, Gland does not contest the Court's jurisdiction over the subject matter of this particular action.

8. This Court may exercise jurisdiction over Defendant Gland pursuant to Fed. R. Civ. P. 4(k)(2) because, inter alia: (1) Plaintiff Helsinn's claims arise under Federal Law; (2) Gland is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Gland has sufficient contacts with the United States as a whole, including, but not limited to, by submitting or causing to be submitted various Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA") and manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products throughout the United States, such that this Court's exercise of jurisdiction over Gland satisfies due process and is consistent with the U.S. Constitution and laws.

ANSWER: Paragraph 8 contains conclusions of law to which no response is required. To the extent that a response is required, Gland does not object to personal jurisdiction for this particular action. Gland denies all remaining allegations of paragraph 8.

9. Alternatively, this Court has personal jurisdiction over Defendant Gland because, inter alia: (1) upon information and belief, Gland has purposely availed itself of the privilege of doing business in New Jersey directly or indirectly through its subsidiary, agent, and/or alter ego; (2) upon information and belief, Gland maintains pervasive, continuous, and systematic contacts with New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical products in New Jersey; (3) upon information and belief, Gland derives substantial revenue from the sale of its generic pharmaceutical products in New Jersey; and (4) upon information and belief, Gland intends to, directly or indirectly, market, sell, or distribute Gland's ANDA Product (as defined in paragraph 25) in New Jersey.

ANSWER: Paragraph 9 contains conclusions of law to which no response is required. To the extent that a response is required, Gland does not object to personal jurisdiction in this Court with respect to this particular action. Gland denies all remaining allegations of paragraph 9.

10. Additionally, Defendant Gland has frequently submitted to this Court's jurisdiction and availed itself of the protections afforded by this Court. *See, e.g.*, *La Jolla Pharma. Co., et al. v. Gland Pharma Ltd., et al.*, No. 22-1754 (JXN) (JBC); *Aerie Pharm. Inc., et al. v. Gland Pharma Ltd.*, No. 22-1359 (GC) (LHG); *Fresenius Kabi USA, LLC, et al. v. Gland Pharma Ltd.*, No. 20-12347 (FLW) (TJB); *Merck Sharp & Dohme B.V., et al. v. Gland Pharma Ltd.*, No. 20-2750 (CCC) (MF); *Medicure Int'l, Inc. v. Gland Pharma Ltd.*, No. 18-16246 (KM) (MAH); *Chiesi USA Inc., et al. v. Gland Pharma Ltd.*, No. 19-21204 (MCA) (MAH); *Chiesi USA Inc., Gland Pharma Ltd.*, No. 19-18565 (MCA) (MAH).

ANSWER: Denied.

11. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(c)(3) and/or 1400(b) because Gland is a foreign corporation and may be sued in any judicial district in the United States in which Gland is subject to the court's personal jurisdiction. Gland has frequently consented to or not contested venue in this Judicial District, including in the cases identified above in paragraph 10.

ANSWER: Paragraph 11 contains conclusions of law to which no response is required. To the extent that a response is required, Gland does not object to venue in this Court for this particular action. Gland denies all remaining allegations of paragraph 11.

THE PATENTS-IN-SUIT

12. Helsinn holds New Drug Application ("NDA") No. 210493, which was first approved by the FDA on April 19, 2018. Helsinn markets and sells the innovative fosnetupitant chloride hydrochloride / palonosetron hydrochloride pharmaceutical product that is the subject of NDA No. 210493 in the United States under the brand name Akynzeo®. Akynzeo® is available for intravenous infusion supplied as a single dose 20 mL vial containing 235 mg of fosnetupitant (equivalent to 260 mg fosnetupitant chloride hydrochloride) and 0.25 mg of palonosetron (equivalent to 0.28 mg of palonosetron hydrochloride).

ANSWER: Upon information and belief, Gland avers that Helsinn is listed as holder of NDA No. 210493, which was approved by the U.S. Food and Drug (FDA) for the manufacture and sale of fosnetupitant chloride hydrochloride / palonosetron hydrochloride pharmaceutical products that are the subject of NDA No. 210493 in the United States under the brand name

Akynzeo®. The allegation that "Akynzeo® is available for intravenous infusion supplied as a single dose 20 mL vial containing 235 mg of fosnetupitant (equivalent to 260 mg fosnetupitant chloride hydrochloride) and 0.25 mg of palonosetron (equivalent to 0.28 mg of palonosetron hydrochloride)" is insufficiently specific for Gland to admit or deny, and as such Gland denies it. Gland denies any remaining allegations of paragraph 12.

13. Akynzeo® is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy.

ANSWER: Upon information and belief, admitted.

14. The '450 patent, titled "Substituted 4-Phenyl Pyridines Having Anti-Emetic Effect," was duly and legally issued by the U.S. Patent and Trademark Office ("USPTO") on April 23, 2013. Plaintiff Helsinn is the assignee of the '450 patent. A copy of the '450 patent is attached as Exhibit A.

ANSWER: Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '405 patent is titled "Substituted 4-Phenyl Pyridines Having Anti-Emetic Effect," and that the face of the '450 patent states the issue date as April 23, 2013. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff Helsinn is the assignee of the '450 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 14.

15. The '586 patent, titled "Methods of Treating Emesis," was duly and legally issued by the USPTO on November 25, 2014. Plaintiff Helsinn is the assignee of the '586 patent. A copy of the '586 patent is attached as Exhibit B.

ANSWER: Paragraph 15 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '586 patent is titled "Methods of Treating Emesis," and that the face of the '586 patent states the issue date as November 25, 2014. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff

Helsinn is the assignee of the '586 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 15.

16. The '357 patent, titled "Compositions and Methods for Treating Centrally Mediated Nausea and Vomiting," was duly and legally issued by the USPTO on November 17, 2015. Plaintiff Helsinn is the assignee of the '357 patent. A copy of the '357 patent is attached as Exhibit C.

ANSWER: Paragraph 16 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '357 patent is titled "Compositions and Methods for Treating Centrally Mediated Nausea and Vomiting," and that the face of the '357 patent states the issue date as November 17, 2015. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff Helsinn is the assignee of the '357 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 16.

17. The '772 patent, titled "4-(5-(2-(3,5-Bis(Trifluoromethyl)Phenyl)-N,2-Dimethylpropanamido)-4-(O-Tolyl)Pyridin-2-yl)-1-Methyl-1-((Phosphonooxy)Methyl)Piperazin-1-ium as a Neurokinin Receptor Modulator," was duly and legally issued by the USPTO on August 2, 2016. Plaintiff Helsinn is the assignee of the '772 patent. A copy of the '772 patent is attached as Exhibit D.

ANSWER: Paragraph 17 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '772 patent is titled "4-(5-(2-(3,5-Bis(Trifluoromethyl)Phenyl)-N,2-Dimethylpropanamido)-4-(O-Tolyl)Pyridin-2-yl)-1-Methyl-1-((Phosphonooxy)Methyl)Piperazin-1-ium as a Neurokinin Receptor Modulator," and that the face of the '772 patent states the issue date as August 2, 2016. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff Helsinn is the assignee of the '772 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 17.

18. The '907 patent, titled "Substituted Piperaziniums for the Treatment of Emesis," was duly and legally issued by the USPTO on March 6, 2018. Plaintiff Helsinn is the assignee of the '907 patent. A copy of the '907 patent is attached as Exhibit E.

ANSWER: Paragraph 18 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '907 patent is titled "Substituted Piperaziniums for the Treatment of Emesis," and that the face of the '907 patent states the issue date as March 6, 2018. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff Helsinn is the assignee of the '907 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 18.

19. The '073 patent, titled "Solution Comprising the Chloride Hydrochloride Salt of 4-(5-(2-(3,5-Bis(Trifluoromethyl)Phenyl)-N,2-Dimethylpropanamido)-4-(O-Tolyl)Pyridin-2-yl)-1-Methyl-1-((Phosphonooxy)Methyl)Piperazin-1-ium (Fosnetupitant) and Palonosetron Hydrochloride in Combination with Dexamethasone as a Neurokinin Receptor Modulator," was duly and legally issued by the USPTO on February 19, 2019. Plaintiff Helsinn is the assignee of the '073 patent. A copy of the '073 patent is attached as Exhibit F.

ANSWER: Paragraph 19 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '073 patent is titled "Substituted Piperaziniums for the Treatment of Emesis," and that the face of the '073 patent states the issue date as February 19, 2019. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff Helsinn is the assignee of the '073 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 19.

20. The '911 patent, titled "Physiologically Balanced Injectable Formulations of Fosnetupitant," was duly and legally issued by the USPTO on April 21, 2020. Plaintiff Helsinn is the assignee of the '911 patent. A copy of the '911 patent is attached as Exhibit G.

ANSWER: Paragraph 20 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '911 patent is titled "Physiologically Balanced Injectable Formulations of Fosnetupitant," and that the face of the '911 patent states the issue date as April 21, 2020. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff Helsinn is the assignee of the '911 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 20.

21. The '721 patent, titled "Substituted Piperaziniums for the Treatment of Emesis," was duly and legally issued by the USPTO on July 21, 2020. Plaintiff Helsinn is the assignee of the '721 patent. A copy of the '721 patent is attached as Exhibit H.

ANSWER: Paragraph 21 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '721 patent is titled "Substituted Piperaziniums for the Treatment of Emesis," and that the face of the '721 patent states the issue date as July 21, 2020. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff Helsinn is the assignee of the '721 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 21.

22. The '297 patent, titled "Compositions and Methods for Treating Centrally Mediated Nausea and Vomiting," was duly and legally issued by the USPTO on July 21, 2020. Plaintiff Helsinn is the assignee of the '297 patent. A copy of the '297 patent is attached as Exhibit I.

ANSWER: Paragraph 22 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '297 patent is titled "Compositions and Methods for Treating Centrally Mediated Nausea and Vomiting," and that the face of the '297 patent states the issue date as November 10, 2020. Gland is without sufficient knowledge or information sufficient to form a belief as to whether Plaintiff Helsinn is the assignee of the '297 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 22.

23. The '698 patent, titled "Fosnetupitant Chloride Hydrochloride Having Improved Stability," was duly and legally issued by the USPTO on April 26, 2022. Plaintiff Helsinn is the assignee of the '698 patent. A copy of the '698 patent is attached as Exhibit J.

ANSWER: Paragraph 23 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that the '698 patent is titled "Fosnetupitant Chloride Hydrochloride Having Improved Stability," and that the face of the '698 patent states the issue date as April 26, 2022. Gland is without sufficient knowledge or information sufficient to form a

belief as to whether Plaintiff Helsinn is the assignee of the '698 patent, and thus denies that allegation. Gland denies the remaining allegations of paragraph 23.

24. Pursuant to § 505(b)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA," 21 U.S.C. § 355(b)(1)), the patents-in-suit are listed in the FDA publication titled "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (commonly known as the "Orange Book") as covering Akynzeo® and/or its use.

ANSWER: Upon information and belief, Gland admits that the electronic version of the Orange Book currently lists the '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents in connection with NDA No. 210493 for Akynzeo®. Gland denies the remaining allegations of paragraph 24.

ACTS GIVING RISE TO THIS ACTION

25. Upon information and belief, Gland filed or caused to be filed ANDA No. 217374 with the FDA under § 505(j) of the FDCA (21 U.S.C. § 355(j)) seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of EQ 11.75 mg/mL fosnetupitant chloride hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235 mg /0.25 mg per 20 mL single-dose vials for intravenous administration ("Gland's ANDA Product") before the expiration of the patents-in-suit.

ANSWER: Paragraph 25 states a legal conclusion to which no response is required. To the extent a response is required, Gland admits that it filed ANDA No. 217374 with the FDA to obtain approval to engage in the manufacture, use, or sale of EQ 11.75 mg/mL fosnetupitant chloride hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235 mg /0.25 mg per 20 mL single-dose vials in the United States. Gland denies all remaining allegations of paragraph 25.

26. Upon information and belief, Gland sent a letter via Federal Express dated June 2, 2022 ("Gland's June 2 Notice Letter") providing notice of Gland's certification pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) ("Paragraph IV certification") with respect to the '450 patent, the '586 patent, the '357 patent, the '772 patent, the '907 patent, the '073 patent, the '911 patent, the '721 patent, and the '297 patent. Gland subsequently sent a second letter via Federal Express dated July 11, 2022 ("Gland's July 11 Notice Letter" and, together with Gland's June 2 Notice Letter, "Gland's Notice Letters") providing notice of Gland's Paragraph IV certification with respect to the '698 patent.

ANSWER: Admitted.

27. Gland's June 2 Notice Letter was received by Helsinn no earlier than June 7, 2022. Gland's July 11 Notice Letter was received by Helsinn no earlier than July 15, 2022. In Gland's Notice Letters, Gland represented that it had filed ANDA No. 217374 with accompanying Paragraph IV certifications to obtain approval to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States Gland's ANDA Product before the expiration of the patents-in-suit.

ANSWER: Gland admits that its Notice Letters state that Gland had submitted its ANDA to the FDA containing a Paragraph IV certification to obtain approval to engage in the manufacture, use, or sale of an intravenous solution of EQ 11.75 mg/mL fosnetupitant hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235 mg/0.25 mg per 20 mL single-dose vials, regarding the '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents. Gland denies the remaining allegations of paragraph 27.

28. In Gland's June 2 Notice Letter, Gland alleges that each claim of the '450 patent, the '586 patent, the '357 patent, the '772 patent, the '907 patent, the '073 patent, the '911 patent, the '721 patent, and the '297 patent is invalid, unenforceable, and/or will not be infringed by Gland's ANDA Product. In Gland's July 11 Notice Letter, Gland alleges that each claim of the '698 patent is invalid, unenforceable, and/or will not be infringed by Gland's ANDA Product.

ANSWER: Gland avers that Gland's June 2 Notice Letter enclosed a detailed statement of the factual and legal bases for Gland's ANDA certification that each claim of the '450 patent, the '586 patent, the '357 patent, the '772 patent, the '907 patent, the '073 patent, the '911 patent, the '721 patent, and the '297 patent is invalid, unenforceable, and/or will not be infringed by Gland's ANDA Product. Gland further avers that Gland's July 11 Notice Letter enclosed a detailed statement of the factual and legal bases for Gland's ANDA certification that each claim of the '698 patent is invalid, unenforceable, and/or will not be infringed by Gland's ANDA Product. Gland denies any remaining allegations of paragraph 28.

29. Plaintiff Helsinn has filed this action within 45 days of Helsinn's receipt of Gland's June 2 Notice Letter.

ANSWER: Upon information and belief, admitted.

COUNT I – INFRINGEMENT OF THE '450 PATENT

30. Plaintiff Helsinn re-alleges paragraphs 1-29 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-29. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

31. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '450 patent, Gland has infringed one or more claims of the '450 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 31 states a legal conclusion to which no response is required. To the extent a response is required, denied.

32. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '450 patent, would infringe and/or induce and/or contribute to the infringement of one or more claims of the '450 patent.

ANSWER: Paragraph 32 states a legal conclusion to which no response is required. To the extent a response is required, denied.

33. Upon information and belief, Gland was aware of the existence of the '450 patent and that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '450 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '450 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 33.

34. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA product before the expiration of the '450 patent would constitute an act of infringement of one or more claims of the '450 patent.

ANSWER: Denied.

35. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-3 of the '450 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclosed detailed factual legal bases for Gland's assertion that each claim of the '450 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed contentions regarding invalidity of claims 1-3 of the '450 patent, and further avers that such contentions provide basis for why claims 1-3 of the '450 patent will not be infringed. Gland denies any remaining allegations of paragraph 35.

36. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe the '450 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 36 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 36.

37. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '450 patent, including any later expiration of exclusivity for the '450 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 37 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 37.

38. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT II – INFRINGEMENT OF THE '586 PATENT

39. Plaintiff Helsinn re-alleges paragraphs 1-38 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-38. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

40. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '586 patent, Gland has infringed one or more claims of the '586 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 40 states a legal conclusion to which no response is required. To the extent a response is required, denied.

41. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '586 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '586 patent.

ANSWER: Paragraph 41 states a legal conclusion to which no response is required. To the extent a response is required, denied.

42. Upon information and belief, Gland was aware of the existence of the '586 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '586 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '586 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 42.

43. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '586 patent would constitute an act of infringement of one or more claims of the '586 patent.

ANSWER: Denied.

44. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-21 of the '586 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclosed detailed factual legal bases for Gland's assertion that each claim of the '586 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed contentions regarding invalidity of claims 1-21 of the '586 patent, and further avers that such contentions provide basis for why claims 1-21 of the '586 patent will not be infringed. Gland denies any remaining allegations of paragraph 44.

45. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '586 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 45 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 45.

46. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '586 patent, including any later expiration of exclusivity for the '586 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 46 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 46.

47. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT III – INFRINGEMENT OF THE '357 PATENT

48. Plaintiff Helsinn re-alleges paragraphs 1-47 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-47. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

49. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '357 patent, Gland has infringed one or more claims of the '357 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 49 states a legal conclusion to which no response is required. To the extent a response is required, denied.

50. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '357 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '357 patent.

ANSWER: Paragraph 50 states a legal conclusion to which no response is required. To the extent a response is required, denied.

51. Upon information and belief, Gland was aware of the existence of the '357 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '357 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '357 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 51.

52. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '357 patent would constitute an act of infringement of one or more claims of the '357 patent.

ANSWER: Denied.

53. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112 and a blanket denial of a specific intent to provide therapeutically effective blood levels of palonosetron and netupitant, Gland's Notice Letters do not identify any factual

bases for, or any position regarding, noninfringement of claims 4, 14-16, and 52-62 of the '357 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclosed detailed factual legal bases for Gland's assertion that each claim of the '357 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's Paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed contentions regarding invalidity of claims 4, 14-16, and 52-62 of the '357 patent, and further avers that such contentions provide basis for why claims 4, 14-16, and 52-62 of the '357 patent will not be infringed. Gland denies any remaining allegations of paragraph 53.

54. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe the '357 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 54 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 54.

55. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '357 patent, including any later expiration of exclusivity for the '357 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 55 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 55.

56. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT IV – INFRINGEMENT OF THE '772 PATENT

57. Plaintiff Helsinn re-alleges paragraphs 1-56 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-56. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

58. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '772 patent, Gland has infringed one or more claims of the '772 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 58 states a legal conclusion to which no response is required. To the extent a response is required, denied.

59. Upon information and belief, the manufacture, use, offer for sale, sale, or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '772 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '772 patent.

ANSWER: Paragraph 59 states a legal conclusion to which no response is required. To the extent a response is required, denied.

60. Upon information and belief, Gland was aware of the existence of the '772 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '772 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '772 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 60.

61. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA product before the expiration of the '772 patent would constitute an act of infringement of one or more claims of the '772 patent.

ANSWER: Denied.

62. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-14 of the '772 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclosed detailed factual legal bases for Gland's assertion that each claim of the '772 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's Paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed contentions regarding invalidity of claims 1-14 of the '772 patent, and further avers that such contentions provide basis for why claims 1-14 of the '772 patent will not be infringed. Gland denies any remaining allegations of paragraph 62.

63. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '772 patent pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

ANSWER: Paragraph 63 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 63.

64. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '772 patent, including any later expiration of exclusivity for the '772 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 64 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 64.

65. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT V – INFRINGEMENT OF THE '907 PATENT

66. Plaintiff Helsinn re-alleges paragraphs 1-65 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-65. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

67. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '907 patent, Gland has infringed one or more claims of the '907 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 67 states a legal conclusion to which no response is required. To the extent a response is required, denied.

68. Upon information and belief, the manufacture, use, offer for sale, sale, or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '907 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '907 patent.

ANSWER: Paragraph 68 states a legal conclusion to which no response is required. To the extent a response is required, denied.

69. Upon information and belief, Gland was aware of the existence of the '907 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '907 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '907 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 69.

70. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '907 patent would constitute an act of infringement of one or more claims of the '907 patent.

ANSWER: Denied.

71. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-6 of the '907 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclosed detailed factual legal bases for Gland's assertion that each claim of the '907 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's Paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed contentions regarding invalidity of claims 1-6 of the '907 patent, and further avers that such contentions provide basis for why claims 1-6 of the '907 patent will not be infringed. Gland denies any remaining allegations of paragraph 71.

72. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '907 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 72 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 72.

73. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '907 patent, including any later expiration of exclusivity for the '907 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 73 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 73.

74. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT VI – INFRINGEMENT OF THE '073 PATENT

75. Plaintiff Helsinn re-alleges paragraphs 1-74 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-74. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

76. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '073 patent, Gland has infringed one or more claims of the '073 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 76 states a legal conclusion to which no response is required. To the extent a response is required, denied.

77. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '073 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '073 patent.

ANSWER: Paragraph 77 states a legal conclusion to which no response is required. To the extent a response is required, denied.

78. Upon information and belief, Gland was aware of the existence of the '073 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '073 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '073 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 78.

79. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '073 patent would constitute an act of infringement of one or more claims of the '073 patent.

ANSWER: Denied.

80. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-13 of the '073 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclosed detailed factual legal bases for Gland's assertion that each claim of the '073 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's Paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed contentions regarding invalidity of claims 1-13 of the '073 patent, and further avers that such contentions provide basis for why claims 1-13 of the '073 patent will not be infringed. Gland denies any remaining allegations of paragraph 80.

81. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '073 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 36 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 81.

82. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '073 patent, including any later expiration of exclusivity for the '073 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 82 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 82.

83. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT VII – INFRINGEMENT OF THE '911 PATENT

84. Plaintiff Helsinn re-alleges paragraphs 1-83 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-83. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

85. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '911 patent, Gland has infringed one or more claims of the '911 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 85 states a legal conclusion to which no response is required. To the extent a response is required, denied.

86. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '911 patent, would infringe and/or induce and/or contribute to the infringement of one or more claims of the '911 patent.

ANSWER: Paragraph 86 states a legal conclusion to which no response is required. To the extent a response is required, denied.

87. Upon information and belief, Gland was aware of the existence of the '911 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '911 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '911 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 87.

88. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '911 patent would constitute an act of infringement of one or more claims of the '911 patent.

ANSWER: Denied.

89. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1, 3, 8-11, 14, and 19-21 of the '911 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclosed detailed factual legal bases for Gland's assertion that each claim of the '911 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's Paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed contentions regarding invalidity of claims 1, 3, 8-11, 14, and 19-21 of the '911 patent, and further avers that such contentions provide basis for why claims 1, 3, 8-11, 14, and 19-21 of the '911 patent will not be infringed. Gland denies any remaining allegations of paragraph 89.

90. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '911 patent pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

ANSWER: Paragraph 90 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 90.

91. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '911 patent, including any later expiration of exclusivity for the '911 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 91 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 91.

92. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT VIII – INFRINGEMENT OF THE '721 PATENT

93. Plaintiff Helsinn re-alleges paragraphs 1-92 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-92. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

94. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '721 patent, Gland has infringed one or more claims of the '721 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 94 states a legal conclusion to which no response is required. To the extent a response is required, denied.

95. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '721 patent, would infringe and/or induce and/or contribute to the infringement of one or more claims of the '721 patent.

ANSWER: Paragraph 95 states a legal conclusion to which no response is required. To the extent a response is required, denied.

96. Upon information and belief, Gland was aware of the existence of the '721 patent and was aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '721 patent.

ANSWER: Denied.

97. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '721 patent would constitute an act of infringement of one or more claims of the '721 patent.

ANSWER: Denied.

98. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claim 1 of the '721 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclosed detailed factual legal bases for Gland's assertion that each claim of the '721 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional

defenses because the objective of the detailed statement was to provide sufficient basis for Gland's Paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed contentions regarding invalidity of claim 1 of the '721 patent, and further avers that such contentions provide basis for why claim 1 of the '721 patent will not be infringed. Gland denies any remaining allegations of paragraph 98.

99. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '721 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 99 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 99.

100. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '721 patent, including any later expiration of exclusivity for the '721 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 100 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 100.

101. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT IX – INFRINGEMENT OF THE '297 PATENT

102. Plaintiff Helsinn re-alleges paragraphs 1-101 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-101. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

103. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '297 patent, Gland has infringed one or more claims of the '297 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 103 states a legal conclusion to which no response is required. To the extent a response is required, denied.

104. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '297 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of one or more claims of the '297 patent.

ANSWER: Paragraph 104 states a legal conclusion to which no response is required. To the extent a response is required, denied.

105. Upon information and belief, Gland was aware of the existence of the '297 patent and is aware that the submission of Gland's ANDA No. 217374 to the FDA constituted an act of infringement of one or more claims of the '297 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '297 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 105.

106. Upon information and belief, Gland is aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '297 patent would constitute an act of infringement of one or more claims of the '297 patent.

ANSWER: Denied.

107. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112 and a blanket denial of a specific intent to provide therapeutically effective blood levels of palonosetron and netupitant, Gland's Notice Letters do not identify any factual bases for, or position regarding, noninfringement of claims 1-23 of the '297 patent.

ANSWER: Gland avers that Gland's First Notice Letter enclose detailed factual legal bases for Gland's assertion that each claim of the '297 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's Paragraph IV certification. Gland avers that Gland's First Notice Letter disclosed detailed

contentions regarding invalidity of claims 1-23 of the '297 patent, and further avers that such contentions provide basis for why claims 1-23 of the '297 patent will not be infringed. Gland denies any remaining allegations of paragraph 107.

108. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '297 patent pursuant to 35 U.S.C. §§ 271(a), (b), (c).

ANSWER: Paragraph 108 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 108.

109. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '297 patent, including any later expiration of exclusivity for the '297 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 109 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 109.

110. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

COUNT X – INFRINGEMENT OF THE '698 PATENT

111. Plaintiff Helsinn re-alleges paragraphs 1-110 as if fully set forth herein.

ANSWER: No further response is required to the re-allegation of Plaintiffs' statements in paragraphs 1-110. To the extent a response is required, Gland incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

112. By seeking approval of ANDA No. 217374 to engage in the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '698 patent, Gland has infringed one or more claims of the '698 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 112 states a legal conclusion to which no response is required. To the extent a response is required, denied.

113. Upon information and belief, the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product, if approved by the FDA before the expiration of the '698 patent, would infringe and/or induce and/or contribute to the infringement of the '698 patent.

ANSWER: Paragraph 113 states a legal conclusion to which no response is required. To the extent a response is required, denied.

114. Upon information and belief, Gland is aware of the existence of the '698 patent and is aware that the submission of Gland's ANDA No. 217374 to the FDA constitutes an act of infringement of one or more claims of the '698 patent.

ANSWER: The allegation that "Gland was aware of the existence of the '698 patent" is insufficiently definite as to when Plaintiffs allege that Gland was aware of the patent for Gland to admit or deny, and as such Gland denies it. Gland denies the remaining allegations of paragraph 114.

115. Upon information and belief, Gland was aware that the manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the '698 patent would constitute an act of infringement of one or more claims of the '698 patent.

ANSWER: Denied.

116. Separate and apart from certain contentions regarding invalidity pursuant to 35 U.S.C. §§ 103 and 112, Gland's Notice Letters do not identify any factual bases for, or any position regarding, noninfringement of claims 1-6 of the '698 patent.

ANSWER: Gland avers that Gland's Second Notice Letters enclose detailed factual legal bases for Gland's assertion that each claim of the '698 patent will be deemed invalid, unenforceable, or not infringed, and that Gland specifically reserved the right to raise additional defenses because the objective of the detailed statement was to provide sufficient basis for Gland's Paragraph IV certification. Gland avers that Gland's Second Notice Letter disclosed detailed contentions regarding invalidity of claims 1-6 of the '698 patent, and further avers that such contentions provide basis for why claims 1-6 of the '698 patent will not be infringed. Gland denies any remaining allegations of paragraph 116.

117. Helsinn is entitled to a declaration that, if Gland manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, Gland's ANDA Product, and/or induces and/or contributes to any such conduct, it would further infringe one or more claims of the '698 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 117 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 117.

118. Helsinn is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 217374 be a date that is not earlier than the expiration of the '698 patent, including any later expiration of exclusivity for the '698 patent to which Helsinn is or becomes entitled.

ANSWER: Paragraph 118 states a legal conclusion to which no response is required. To the extent a response is required, Gland denies the allegations of paragraph 118.

119. Helsinn will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Helsinn does not have an adequate remedy at law.

ANSWER: Denied.

PRAYER FOR RELIEF

Gland denies all allegations of infringement and that Plaintiff is entitled to any relief. Gland respectfully requests that the Court dismiss Plaintiff's Complaint with prejudice, enter judgment in favor of Gland, award Gland its reasonable attorneys' fees and costs incurred in defending this suit, and award Gland such other relief as the Court deems just and proper.

GLAND'S AFFIRMATIVE DEFENSES

First Affirmative Defense

The claims of the '450 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Second Affirmative Defense

The claims of the '586 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Third Affirmative Defense

The claims of the '357 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Fourth Affirmative Defense

The claims of the '772 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Fifth Affirmative Defense

The claims of the '907 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Sixth Affirmative Defense

The claims of the '073 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Seventh Affirmative Defense

The claims of the '911 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Eighth Affirmative Defense

The claims of the '721 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Ninth Affirmative Defense

The claims of the '297 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Tenth Affirmative Defense

The claims of the '698 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Eleventh Affirmative Defense

The manufacture, use, or sale of the drug product described in ANDA No. 217374 has not infringed, and will not, if marketed, infringe, directly or indirectly, any valid and enforceable claim of the '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents, either literally or by the doctrine of equivalents.

Twelfth Affirmative Defense

Plaintiff is not entitled to relief because they have not appropriately shown nor proven adequate standing for the relief sought.

Thirteenth Affirmative Defense

The Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

Fourteenth Affirmative Defense

Plaintiff's cause of action is barred, in whole or in part, by the doctrine of prosecution history estoppel and other doctrines that limit the application of the claims to the accused products. Plaintiff is estopped from arguing and have waived arguments that its claims cover Gland's ANDA product based on the amendments, positions, and arguments made to the USPTO when obtaining the asserted patent.

Fifteenth Affirmative Defense

Plaintiff is not entitled to equitable relief because of the doctrine of unclean hands.

Reservation of Additional Defenses

Gland reserves the right to assert additional separate defenses that may be developed through discovery, or otherwise, in this action, such as claims of inequitable conduct during the prosecution of one or more of the patents-in-suit.

WHEREFORE, Gland prays that the Court enter judgment in its favor and against Plaintiff as follows:

a) Adjudging that no patent claim asserted by Plaintiff is valid or infringed;

b) Enjoining Plaintiff and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Gland or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Gland, or charging them either orally or in writing with infringement of any patent asserted herein against Gland;

c) Granting Gland judgment in its favor on Plaintiff's Complaint;

d) Denying Plaintiff's request for injunctive relief;

e) Dismissing Plaintiff's Complaint with prejudice;

f) Declaring that the claims of '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents are invalid;

g) Requiring that all costs be taxed against Plaintiff;

h) Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Gland its costs and reasonable attorneys' fees; and

i) Awarding any other such relief as is just and proper.

GLAND'S COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Gland Pharma Ltd, ("Gland"), by and through its counsel, brings the following Counterclaims against Plaintiff/Counterclaim-Defendant Helsinn Healthcare S.A. ("Helsinn" or "Counterclaim-Defendant") for a declaratory judgment that U.S. Patent No. 8,426,450 ("the '450 patent"), U.S. Patent No. 8,895,586 ("the '586 patent"), U.S.

Patent No. 9,186,357 ("the '357 patent"), U.S. Patent No. 9,403,772 ("the '772 patent"), U.S. Patent No. 9,908,907 ("the '907 patent"), U.S. Patent No. 10,208,073 ("the '073 patent"), U.S. Patent No. 10,624,911 ("the '911 patent"), U.S. Patent No. 10,717,721 ("the '721 patent"), U.S. Patent No. 10,828,297 ("the '297 patent"), and U.S. Patent No. 11,312,698 ("the '698 patent"), (collectively, the "Asserted Patents") are invalid and/or not infringed by the fosnetupitant 235 mg/palonosetron 0.25 mg, per 20 mL vial for injection that is the subject of Abbreviated New Drug Application ("ANDA") No. 217374 ("Gland's Proposed ANDA Product").

THE PARTIES

1. Gland is a corporation organized and existing under the laws of India, having a principal place of business at Survey. No. 143-148, 150 & 151, Near Gandimaisamma 'X' Roads, D.P. Pally, Dundigal, Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District, Hyderabad 500043, Telangana, India.

2. Upon information and belief and based upon allegations in the Complaint, Helsinn is a Swiss corporation having its principal place of business at Via Pian Scairolo, 9, CH-6912 Lugano-Pazzallo, Switzerland.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), based on an actual, substantial, continuing and justiciable controversy between Gland and Helsinn arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*.

4. This Court has personal jurisdiction over Helsinn because Helsinn has voluntarily subjected itself to the Court's jurisdiction by filing the Complaint, and has purposefully availed themselves of the benefits of jurisdiction in this State.

5. Helsinn is also subject to personal jurisdiction in this judicial district because, upon information and belief, Helsinn sells products here, including the Akynzeo® product that is the subject of this case, and regularly practices business here.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), and (c), and 1400(b) and because of Helsinn's choice of forum in which to bring suit against Gland.

BACKGROUND

7. Upon information and belief and based on paragraph 12 of the Complaint, Helsinn is the current sole owner of New Drug Application (NDA) No. 210493, which was approved by the U.S. Food and Drug Administration (FDA) for the manufacture and sale of Akynzeo® (fosnetupitant chloride hydrochloride/palonosetron hydrochloride) for intravenous infusion.

8. Upon information and belief and based on paragraph 14 to 23 of the Complaint, Helsinn is the current assignee of the Asserted Patents.

9. Gland filed ANDA No. 217374 ("Gland's ANDA") with the FDA seeking approval to market Fosnetupitant 235 mg/Palonosetron 0.25 mg, per 20 mL vial for injection.

10. As of the time Gland's ANDA was filed, the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") listed each of the Asserted Patents in connection with Akynzeo® and NDA No. 210493.

11. Upon information and belief, Helsinn caused the Asserted Patents to be listed in the Orange Book in connection with NDA No. 210493.

12. As part of its ANDA, Gland submitted to the FDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("a Paragraph IV certification") that each of the Asserted Patents is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Gland's Proposed ANDA Product.

13. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B), on or about June 2, 2022, Gland sent by Federal Express a first letter concerning its paragraph IV certification (the "First Notice Letter") to Helsinn.

14. The First Notice Letter enclosed a detailed statement of the factual and legal bases for Gland's ANDA certification that the '450, '586, '357, '772, '907, '073, '911, '721, and '297 patents are invalid, unenforceable, and/or not infringed by Gland's Proposed ANDA Product.

15. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B), on or about July 11, 2022, Gland sent by Federal Express a second letter concerning its paragraph IV certification (the "Second Notice Letter") to Helsinn.

16. The Second Notice Letter enclosed a detailed statement of the factual and legal bases for Gland's ANDA certification that the '698 patent is invalid, unenforceable, and/or not infringed by Gland's Proposed ANDA Product.

17. Helsinn has actual knowledge of the contents of the First and Second Notice Letters.

18. On July 18, 2022, Helsinn filed a Complaint in Case No. 2:22-cv-04635 against Gland , alleging that Gland's Proposed ANDA Product will infringe the '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents.

FIRST COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '450 PATENT)

19. Gland incorporates by reference the allegations set forth in paragraphs 1–18 of the Counterclaims as if fully set forth herein.

20. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly

infringe any valid or enforceable claim of the ’450 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland’s ANDA Certification enclosed in the First Notice Letter.

21. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the ’450 patent, and will not be liable for such infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

22. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the ’450 patent, either literally or under the doctrine of equivalents.

23. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the ’450 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

24. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

25. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the ’450 patent.

SECOND COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE ’450 PATENT)

26. Gland incorporates by reference the allegations set forth in paragraphs 1–25 of the Counterclaims as if fully set forth herein.

27. All claims of the ’450 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. §

282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

28. As a sufficient example, as described in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter, all claims of the '450 patent are at least invalid as obvious under § 103 in light of at least the following prior art: U.S. Pat. No. 6,479,483 ("Bös"); PCT Application International Publication Number WO 99/33846 ("WO '846"); DeGoey, D.A. et al., Water-Soluble Prodrugs of the Human Immunodeficiency Virus Protease Inhibitors Lopinavir and Ritonavir, J. Med. Chem., Vol. 52 2964-2970 (April 2009) ("DeGoey"); U.S. Pat. No. 7,211,579 ("Funk"); Krise, J.P. et al., Novel Prodrug Approach for Tertiary Amines: Synthesis and Preliminary Evaluation of N-Phosphonooxymethyl Prodrugs, J. Med. Chem., 42, pp. 3094-3100 (1999) ("Krise I"); and Oslob, J.D. et al., Water-soluble prodrugs of an Aurora kinase inhibitor, Bioorg. Med. Chem. Lett. 19, pp. 1409-1412 (2009) ("Oslob"). Additionally, the claims are invalid as indefinite and not enabled with respect to the pharmaceutically acceptable salt limitations.

29. Gland is entitled to a judicial declaration that the claims of the '450 patent are invalid.

THIRD COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '586 PATENT)

30. Gland incorporates by reference the allegations set forth in paragraphs 1–29 of the Counterclaims as if fully set forth herein.

31. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly

infringe any valid or enforceable claim of the '586 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

32. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '586 patent, and will not be liable for such infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

33. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '586 patent, either literally or under the doctrine of equivalents.

34. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '586 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

35. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

36. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '586 patent.

FOURTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '586 PATENT)

37. Gland incorporates by reference the allegations set forth in paragraphs 1–36 of the Counterclaims as if fully set forth herein.

38. All claims of the '586 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. §

282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

39. As a sufficient example, as described in the First Notice Letter, all claims of the '586 patent are at least invalid as obvious under § 103 in light of at least the following prior art: Bös; WO '846; DeGoey; Funk; Krise I; Oslob; ALOXI (palonosetron HCl) Injection for Intravenous Use Label ("ALOXI Label"); and EMEND (fosaprepitant dimeglumine) for injection Label ("EMEND Label"). Additionally, the claims are invalid as indefinite and not enabled with respect to the pharmaceutically acceptable salt limitations.

40. Gland is entitled to a judicial declaration that the claims of the '586 patent are invalid.

FIFTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '357 PATENT)

41. Gland incorporates by reference the allegations set forth in paragraphs 1–40 of the Counterclaims as if fully set forth herein.

42. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly infringe any valid or enforceable claim of the '357 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

43. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '357 patent, and will not be liable for such

infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

44. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '357 patent, either literally or under the doctrine of equivalents.

45. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '357 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

46. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

47. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '357 patent.

SIXTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '357 PATENT)

48. Gland incorporates by reference the allegations set forth in paragraphs 1–47 of the Counterclaims as if fully set forth herein.

49. All claims of the '357 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

50. As a sufficient example, as described in the First Notice Letter, all claims of the '357 patent are at least invalid as obvious under § 103 in light of at least the following prior art:

the ALOXI Label; Bös; Dewan, P. et al., Management of Chemotherapy-Induced Nausea and Vomiting, Indian Pediatrics Vol. 47 pp. 149-155 (Feb. 2010) ("Dewan"); and the EMEND Label. Additionally, the claims are invalid as indefinite and not enabled with respect to the "treating" limitations.

51. Gland is entitled to a judicial declaration that the claims of the '357 patent are invalid.

SEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '772 PATENT)

52. Gland incorporates by reference the allegations set forth in paragraphs 1–51 of the Counterclaims as if fully set forth herein.

53. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly infringe any valid or enforceable claim of the '772 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

54. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '772 patent, and will not be liable for such infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

55. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '772 patent, either literally or under the doctrine of equivalents.

56. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '772 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

57. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

58. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '772 patent.

EIGHTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '772 PATENT)

59. Gland incorporates by reference the allegations set forth in paragraphs 1–58 of the Counterclaims as if fully set forth herein.

60. All claims of the '772 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

61. As a sufficient example, as described in the First Notice Letter, all claims of the '772 patent are at least invalid as obvious under § 103 in light of at least the following prior art: Bös, WO '846; DeGoey; Funk; Krise I; and Oslob; the EMEND label; and/or the ALOXI label. Additionally, the claims are invalid as indefinite and not enabled at least with respect to the pharmaceutically acceptable salt limitations

62. Gland is entitled to a judicial declaration that the claims of the '772 patent are invalid.

NINTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '907 PATENT)

63. Gland incorporates by reference the allegations set forth in paragraphs 1–62 of the Counterclaims as if fully set forth herein.

64. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly infringe any valid or enforceable claim of the '907 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

65. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '907 patent, and will not be liable for such infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

66. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '907 patent, either literally or under the doctrine of equivalents.

67. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '907 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

68. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

69. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '907 patent.

TENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '907 PATENT)

70. Gland incorporates by reference the allegations set forth in paragraphs 1–69 of the Counterclaims as if fully set forth herein.

71. All claims of the '907 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

72. As a sufficient example, as described in the First Notice Letter, all claims of the '907 patent are at least invalid as obvious under § 103 in light of at least the following prior art: WO '846; DeGoey; Funk; Krise I; Oslob; the EMEND label; and/or the ALOXI label. Additionally, the claims are invalid as indefinite and not enabled with at least with respect to the pharmaceutically acceptable salt limitations.

73. Gland is entitled to a judicial declaration that the claims of the '907 patent are invalid.

ELEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '073 PATENT)

74. Gland incorporates by reference the allegations set forth in paragraphs 1–73 of the Counterclaims as if fully set forth herein.

75. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly

infringe any valid or enforceable claim of the '073 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

76. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '073 patent, and will not be liable for such infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

77. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '073 patent, either literally or under the doctrine of equivalents.

78. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '073 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

79. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

80. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '073 patent.

TWELFTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '073 PATENT)

81. Gland incorporates by reference the allegations set forth in paragraphs 1–80 of the Counterclaims as if fully set forth herein.

82. All claims of the '073 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. §

282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

83. As a sufficient example, as described in the First Notice Letter, all claims of the '073 patent are at least invalid as obvious under § 103 in light of at least the following prior art: WO '846; DeGoey; Funk; Krise I; Oslob; Bös; Dewan; and/or EMEND Label. Additionally, the claims are invalid as indefinite, lack written description, and lack enablement with respect to the "acute and delayed nausea" and "therapeutically effective amount" limitations.

84. Gland is entitled to a judicial declaration that the claims of the '073 patent are invalid.

THIRTEENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '911 PATENT)

85. Gland incorporates by reference the allegations set forth in paragraphs 1–84 of the Counterclaims as if fully set forth herein.

86. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly infringe any valid or enforceable claim of the '911 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

87. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '911 patent, and will not be liable for such infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

88. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '911 patent, either literally or under the doctrine of equivalents.

89. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '911 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

90. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

91. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '911 patent.

FOURTEENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '911 PATENT)

92. Gland incorporates by reference the allegations set forth in paragraphs 1–91 of the Counterclaims as if fully set forth herein.

93. All claims of the '911 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

94. As a sufficient example, as described in the First Notice Letter, all claims of the '911 patent are at least invalid as obvious under § 103 in light of at least the following prior art: CN103156813 ("CN '813"); CN101028267 ("CN '267"); WO 2013/082102 ("Fadini"); US Patent Application Pub. No. 2010/0048607 ("Kocherlakota"); Krise, J.P. et al., A Novel Approach for

Tertiary Amines. 2. Physicochemical and in Vitro Enzymatic Evaluation of Selected N-Phosphonooxymethyl Prodrugs, J. Pharm. Sci., Vol. 88 pp. 922-927 (1999) ("Krise II"); Eisai Press Release, June 2010 (available at http://www.eisai.com/news/news201027.html) ("Eisai Press Release"); U.S. Patent No. 5,985,856 ("Stella"); and Ruzza et al., In vitro and in vivo pharmacological characterization of Pronetupitant, a prodrug of the neurokinin 1 receptor antagonist Netupitant, Peptides (69) (2015), 26-32 ("Ruzza"). Additionally, the claims are invalid as indefinite and not enabled at least with respect to the claims claiming wide ranges of concentrations and formulations that are not described in the specification, and the claims having a "pharmaceutically stable formulation" limitation.

95. Gland is entitled to a judicial declaration that the claims of the '911 patent are invalid.

FIFTEENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '721 PATENT)

96. Gland incorporates by reference the allegations set forth in paragraphs 1–95 of the Counterclaims as if fully set forth herein.

97. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly infringe any valid or enforceable claim of the '721 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

98. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '721 patent, and will not be liable for such

infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

99. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '721 patent, either literally or under the doctrine of equivalents.

100. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '721 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

101. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

102. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '721 patent.

SIXTEENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '721 PATENT)

103. Gland incorporates by reference the allegations set forth in paragraphs 1–102 of the Counterclaims as if fully set forth herein.

104. All claims of the '721 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

105. As a sufficient example, as described in the First Notice Letter, all claims of the '721 patent are at least invalid as obvious under § 103 in light of at least the following prior art:

Bös; WO '846; DeGoey; Funk; Krise I; and Oslob. Additionally, the claims are invalid as indefinite and not enabled with respect to the pharmaceutically acceptable salt limitations.

106. Gland is entitled to a judicial declaration that the claims of the '721 patent are invalid.

SEVENTEENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '297 PATENT)

107. Gland incorporates by reference the allegations set forth in paragraphs 1–106 of the Counterclaims as if fully set forth herein.

108. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly infringe any valid or enforceable claim of the '297 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

109. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '297 patent, and will not be liable for such infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the First Notice Letter.

110. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '297 patent, either literally or under the doctrine of equivalents.

111. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '297 patent in the

complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

112. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

113. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '297 patent.

EIGHTEENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '297 PATENT)

114. Gland incorporates by reference the allegations set forth in paragraphs 1–113 of the Counterclaims as if fully set forth herein.

115. All claims of the '297 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the First Notice Letter.

116. As a sufficient example, as described in the First Notice Letter, all claims of the '297 patent are at least invalid as obvious under § 103 in light of at least the following prior art: the ALOXI Label; Bös; Dewan; and EMEND Label. Additionally, the claims are invalid as indefinite and not enabled at least with respect to the limitations requiring preventing "acute and delayed" CINV.

117. Gland is entitled to a judicial declaration that the claims of the '297 patent are invalid.

NINETEENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '698 PATENT)

118. Gland incorporates by reference the allegations set forth in paragraphs 1–117 of the Counterclaims as if fully set forth herein.

119. The commercial manufacture, use, offer for sale, sale, or importation of Gland's Proposed ANDA Product has not infringed, does not infringe, and will not directly or indirectly infringe any valid or enforceable claim of the '698 patent, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the Second Notice Letter.

120. Further, Gland will not infringe, contribute to the infringement of, or induce the infringement of any valid or enforceable claim of the '698 patent, and will not be liable for such infringement, either literally or under the doctrine of equivalents, for at least the reasons Gland presented in the Second Notice Letter.

121. Helsinn is barred by the doctrine of prosecution history estoppel from asserting that Gland has infringed, infringes, will infringe, or indirectly infringes, any valid claim of the '698 patent, either literally or under the doctrine of equivalents.

122. A definite, concrete, real, substantial, and justiciable controversy exists between Gland and Helsinn concerning the acts that Helsinn alleges are infringing of the '698 patent in the complaint, which controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

123. Helsinn bears the burden of proving infringement and will not be able to meet that burden.

124. Gland is entitled to a judicial declaration that it does not infringe, directly or indirectly, any valid or enforceable claim of the '698 patent.

TWENTIETH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '698 PATENT)

125. Gland incorporates by reference the allegations set forth in paragraphs 1–124 of the Counterclaims as if fully set forth herein.

126. All claims of the '698 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, or other judicially-created bases for invalidation, at least for the reasons stated in the detailed statement of the factual and legal bases for Gland's ANDA Certification enclosed in the Second Notice Letter.

127. As a sufficient example, as described in the Second Notice Letter, all claims of the '698 patent are at least invalid as obvious under § 103 in light of at least the following prior art: WO '846; Bös; Funk; DeGoey; Krise I; and Oslob. Additionally, the claims are invalid as indefinite and not enabled at least with respect to the limitations on "less than 0.7% degradants," pharmaceutically acceptable excipients, and fosnetupitant chloride hydrochloride in the form of an anhydrate.

128. Gland is entitled to a judicial declaration that the claims of the '698 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Gland prays that the Court enter judgment in its favor and against Helsinn as follows:

A. A declaration that the claims of the '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents are invalid;

B. A declaration that Gland's submission of ANDA No. 217374 seeking FDA approval to market Fosnetupitant 235 mg/Palonosetron 0.25 mg, per 20 mL vial, for injection has not infringed, and will not infringe, any valid claim of the '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents;

C. A declaration that Gland's commercial manufacture, use, offer for sale, sale, or importation of the Fosnetupitant 235 mg/Palonosetron 0.25 mg, per 20 mL vial, for injection that is the subject of ANDA No. 217374 will not infringe, induce infringement, or contribute to infringement of any valid claim of the '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents;

D. A declaration that Helsinn is entitled to no damages, interest, costs, or other relief from or against Gland;

E. A declaration that this is an exceptional case under 35 U.S.C. § 285 and awarding Gland its attorneys' fees, costs and expenses;

F. A declaration that Helsinn is not entitled to injunctive relief;

G. A declaration preliminarily and permanently enjoining Helsinn, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Helsinn, from taking any action to unlawfully prevent the FDA approval of Gland's ANDA No. 217374 and the product described therein;

H. A declaration preliminarily and permanently enjoining Helsinn, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Helsinn, from asserting or otherwise seeking to enforce the '450, '586, '357, '772, '907, '073, '911, '721, '297, and '698 patents against Gland or anyone in privity with Gland; and

I. Such other and further relief as the Court may deem proper.

MIDLIGE RICHTER LLC
Attorneys for Defendant, Gland Pharma Limited

By: s/ James S. Richter
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Dated: September 16, 2022

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding.

s/ James S. Richter
James S. Richter

Dated: September 16, 2022

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ James S. Richter
James S. Richter

Dated: September 16, 2022

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Gland's Answer, Affirmative Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on September 16, 2022.

s/ James S. Richter
James S. Richter

Dated: September 16, 2022