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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff/ Counterclaim Defendant,* v. GLAND PHARMA LIMITED, *Defendant/ Counterclaim Plaintiff.*	C.A. No. 24-07756-BRM-CLW (Filed Electronically)

DEFENDANT, GLAND PHARMA LIMITED'S
ANSWER TO AMENDED COMPLAINT FOR PATENT INFRINGEMENT,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant, Gland Pharma Limited ("Gland" or "Defendant"), by and through its undersigned attorneys, hereby respectfully responds to the Amended Complaint filed by Plaintiff, American Regent, Inc. ("ARI," or "Plaintiff"), as follows:

Responses to Allegations Pertaining to the Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Gland Pharma's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 219632 ("the ANDA") which contained a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation of generic versions of ARI's Tralement® (trace elements injection 4*, USP) in 1 mL single-dose vials and Multrys® (trace elements injection 4*, USP) in 1 mL single-dose vials drug products ("the ANDA Products") prior to the expiration of United States Patent Nos. 11,786,548 ("the '548 patent"), 11,975,022 ("the '022 patent"), 11,998,565 ("the '565 patent"), 12,150,956 ("the '956 patent"), and 12,150,957 ("the '957 patent") (collectively, the "Patents-in-Suit").

RESPONSE: Gland admits Plaintiff purports to bring this action for alleged patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq*. Gland admits filing ANDA number 219632 with Paragraph IV Certifications seeking approval of its product prior to the expiration of the '548, '022 and '565 patents and avers that it supplemented ANDA number 219632 with Paragraph IV Certifications addressing the '956 and '957 patents, which had not issued at the time Gland submitted its ANDA. Gland admits that it seeks approval of ANDA number 219632 prior to the expiration of the Patents-in-Suit. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

2. By email correspondence dated December 19, 2024, Gland consented to the filing of this Amended Complaint.

RESPONSE: Admitted.

Responses to Allegations Pertaining to the Parties

3. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

RESPONSE: Gland is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

4. On information and belief, Gland Pharma is a corporation organized and existing under the laws of India with its principal place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal MedchalMalkjgiri District, Hyderabad 500043, Telangana, India.

RESPONSE: Gland admits it is organized and existing under the laws of the Republic of India with a place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal MedchalMalkjgiri District, Hyderabad 500043, Telangana, India. Gland denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Pertaining to Jurisdiction and Venue

5. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE: Gland admits the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

6. On information and belief, this Court has personal jurisdiction over Gland Pharma under the New Jersey state long arm statute and consistent with due process of law because Gland Pharma has extensive contacts with the State of New Jersey and regularly does business in this judicial district. Further, Gland Pharma plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

RESPONSE: Solely for the purpose of this litigation, Gland does not contest the Court's exercise of personal jurisdiction over Gland. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

7. This Court has personal jurisdiction over Gland Pharma because Gland Pharma has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Gland Pharma regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Gland Pharma derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within

New Jersey. On information and belief, Gland Pharma derives substantial revenue from selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

RESPONSE: Solely for the purpose of this litigation, Gland does not contest the Court's exercise of personal jurisdiction over Gland. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

8. This Court has personal jurisdiction over Gland Pharma because, on information and belief, Gland Pharma derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

RESPONSE: Solely for the purpose of this litigation, Gland does not contest the Court's exercise of personal jurisdiction over Gland. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

9. Upon information and belief, Gland Pharma is in the business of, among other things, the development, manufacturing, importation, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district. Gland Pharma's website states that Gland Pharma has "a global footprint across 60 countries, including the United States," with a "focus on complex injectables including NCE-1s, First-to-File products and 505(b)(2) filings."

RESPONSE: Solely for the purpose of this litigation, Gland does not contest the Court's exercise of personal jurisdiction over Gland. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

10. This Court has personal jurisdiction over Gland Pharma because, *inter alia*, Gland Pharma has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to ARI in New Jersey. Further, on information and belief, following the FDA's approval of the ANDA, Gland Pharma will make, use, import, sell, and/or offer for sale the ANDA Products in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

RESPONSE: Solely for the purpose of this litigation, Gland does not contest the Court's exercise of personal jurisdiction over Gland. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

11. On information and belief, this Court also has personal jurisdiction over Gland Pharma because it has previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting jurisdiction in this judicial district, and pursuing counterclaims in this judicial district, including in at least *Merck Sharp & Dohme LLC v. Gland Pharma Limited*, No. 22-05461, ECF No. 12 (D.N.J. Mar. 6, 2023).

RESPONSE: Solely for the purpose of this litigation, Gland does not contest the Court's exercise of personal jurisdiction over Gland. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

12. In the alternative, this Court has personal jurisdiction over Gland Pharma because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) ARI's claims arise under federal law; (b) Gland Pharma is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Gland Pharma has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting the ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Gland Pharma satisfies due process.

RESPONSE: Solely for the purpose of this litigation, Gland does not contest the Court's exercise of personal jurisdiction over Gland. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

13. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

RESPONSE: Solely for the purpose of this litigation, Gland does not contest venue in this Court. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

14. On information and belief, venue is proper in this judicial district under 28 U.S.C. § 1391(c)(3) because Gland Pharma is a foreign company not residing in any United States judicial district and may be sued in any judicial district.

RESPONSE: Solely for the purpose of this litigation, Gland does not contest venue in this Court. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Pertaining to Background

15. ARI holds New Drug Application ("NDA") No. 209376 for Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), which were approved by the FDA on July 2, 2020 and which ARI manufactures and sells in this judicial district and throughout the United States.

RESPONSE: On information and belief, Gland admits Plaintiff ARI is the holder of NDA No. 209376 approved by the FDA. Gland is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

16. Tralement® is the first and only FDA-approved multi-trace element injection product for patients weighing at least 10 kg. The FDA has approved both 1 mL and 5 mL forms of Tralement®; ARI markets a 1 mL Tralement® product.

RESPONSE: Gland is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

17. Tralement® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

RESPONSE: Gland is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

18. Multrys® is the first and only FDA-approved multi-trace element injection product for neonatal and pediatric patients weighing less than 10 kg.

RESPONSE: Gland is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

19. Multrys® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in neonatal and pediatric patients weighing less than 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

RESPONSE: Gland is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

20. Tralement® and Multrys®, as well as the use of Tralement® and Multrys® in accordance with their labels, are covered by one or more claims of the Patents-in-Suit.

RESPONSE: Gland is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

21. ARI is the owner of the ’548 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on October 17, 2023. A copy of the ’548 patent is attached as Exhibit 1.

RESPONSE: Gland admits Exhibit 1 to the Complaint appears to be a copy of the ’548 patent, which Gland admits is titled “Trace element compositions, methods of making and use.” Gland admits the face of the ’548 patent states the ’548 patent issued October 17, 2023. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

22. The ’548 patent has been listed in connection with Tralement® and Multrys® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

RESPONSE: Gland admits the '548 patent is listed in the Orange Book in connection with NDA 209376. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

23. As indicated in the Orange Book, the patent expiration date for the '548 patent is July 1, 2041.

RESPONSE: Gland admits the Orange Book indicates the '548 patent expires on July 1, 2041. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

24. ARI is the owner of the '022 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on May 7, 2024. A copy of the '022 patent is attached as Exhibit 2.

RESPONSE: Gland admits Exhibit 2 to the Complaint appears to be a copy of the '022 patent, which Gland admits is titled "Trace element compositions, methods of making and use." Gland admits the face of the '022 patent states the '022 patent issued May 7, 2024. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

25. As indicated in the Orange Book, the patent expiration date for the '022 patent is July 1, 2041.

RESPONSE: Gland admits the Orange Book indicates the '022 patent expires on July 1, 2041. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

26. ARI is the owner of the '565 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on June 4, 2024. A copy of the '565 patent is attached as Exhibit 3.

RESPONSE: Gland admits Exhibit 3 to the Complaint appears to be a copy of the '565 patent, which Gland admits is titled "Trace element compositions, methods of making and use." Gland

admits the face of the '565 patent states the '565 patent issued June 4, 2024. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

27. As indicated in the Orange Book, the patent expiration date for the '565 patent is July 1, 2041.

RESPONSE: Gland admits the Orange Book indicates the '565 patent expires on July 1, 2041. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

28. By letter dated June 14, 2024 ("the Notice Letter"), Gland Pharma notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act that Gland Pharma had submitted to the FDA the ANDA with a Paragraph IV Certification to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the Patents-in-Suit.

RESPONSE: Gland admits that it properly notified ARI that it had submitted its ANDA with a Paragraph IV certification with respect to the '548, '022 and '565 patents by letter dated June 14, 2024, one of two notice letters Gland sent Plaintiff. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

29. On information and belief, Gland Pharma submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the Patents-in-Suit are invalid.

RESPONSE: Gland admits that Gland Pharma submitted ANDA No. 219632 to FDA with Paragraph IV Certifications regarding the '548, '022 and '565 patents. Gland avers that it supplemented its filed ANDA with Paragraph IV Certifications pertaining to the '956 and '957 patents. Gland admits that its Paragraph IV Certifications assert that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, or importation of Gland's ANDA products

and/or that the Patents-in-Suit are invalid and/or unenforceable. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

30. The Notice Letter asserted defenses of non-infringement for certain, but not all, claims of the Patents-in-Suit. The Notice Letter did not assert defenses of non-infringement for any claim of the '022 patent and did not assert defenses of non-infringement for claims 1–6, 9, and 12–58 of the '548 patent.

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Gland admits that Gland's Notice Letter contains non-infringement positions for certain claims. Gland otherwise denies the allegations of this paragraph.

31. Since ARI received the Notice Letter and filed its initial Complaint against Gland Pharma (ECF No. 1), the '956 and '957 patents has been listed in connection with Tralement® and Multrys® in the Orange Book.

RESPONSE: Upon information and belief, admitted.

32. ARI is the owner of the '956 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on November 26, 2024. A copy of the '956 patent is attached as Exhibit 4.

RESPONSE: Gland admits Exhibit 4 to the Complaint appears to be a copy of the '956 patent, which Gland admits is titled "Trace element compositions, methods of making and use." Gland admits the face of the '956 patent states the '956 patent issued November 26, 2024. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

33. As indicated in the Orange Book, the patent expiration date for the '956 patent is July 1, 2041.

RESPONSE: Gland admits the Orange Book indicates the '956 patent expires on July 1, 2041. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

34. ARI is the owner of the '957 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on November 26, 2024. A copy of the '957 patent is attached as Exhibit 5.

RESPONSE: Gland admits Exhibit 5 to the Complaint appears to be a copy of the '957 patent, which Gland admits is titled "Trace element compositions, methods of making and use." Gland admits the face of the '957 patent states the '957 patent issued November 26, 2024. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

35. As indicated in the Orange Book, the patent expiration date for the '957 patent is July 1, 2041.

RESPONSE: Gland admits the Orange Book indicates the '957 patent expires on July 1, 2041. Gland denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

36. On information and belief, the ANDA Products are generic versions of Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

RESPONSE: Gland admits only that the Gland ANDA Product is a generic version of Tralement® (1ml) and Multrys®. Otherwise, Paragraph 36 of the Complaint states legal conclusions and irrelevant facts – a comparison between the brand Tralement® and Multrys® product and the Gland ANDA product is irrelevant to infringement – to which no response is required. Gland objects to this paragraph as vague and ambiguous inasmuch as it is not reasonably clear what Plaintiff means by "same or equivalent," the latter of which Gland avers is a legal term of art, and, therefore, denies all allegations using the phrase "same or equivalent." To the extent a further response is required, Gland denies any allegation or implication that there is infringement.

37. In the Notice Letter, Gland Pharma disclosed that the ANDA Products are (1) a single-dose, 1 mL generic version of Tralement® containing 3 mg of zinc, 0.3 mg of copper, 55 mcg of manganese, and 60 mcg of selenium; and (2) a single-dose, 1 mL generic version of Multrys® containing 1000 mcg of zinc, 60 mcg of copper, 3 mcg of manganese, and 6 mcg of selenium.

RESPONSE: Gland admits that its Notice Letters indicated that one of its ANDA Products contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg and selenium 60 mcg and the other ANDA product contains zinc 1000 mcg, copper 60 mcg, manganese 3 mcg and selenium 6 mcg. Gland denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

38. On information and belief, the ANDA Products contain zinc, copper, manganese, and selenium in the same or equivalent amounts as Tralement® and Multrys®, respectively.

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Gland admits that, according to prescribing information of Tralement and Multrys, each mL of Tralement® provides zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg and Multrys® provides zinc 1000 mcg, copper 60 mcg, manganese 3 mcg and selenium 6 mcg. Gland objects to this paragraph as vague and ambiguous inasmuch as it is not reasonably clear what Plaintiff means by "same or equivalent," the latter of which Gland avers is a legal term of art, and, therefore, denies all allegations using the phrase "same or equivalent." Gland otherwise denies the allegations of this paragraph.

39. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as Tralement® and Multrys®.

RESPONSE: This paragraph contains legal conclusions to which no answer is required. Gland objects to this paragraph as vague and ambiguous inasmuch as it is not reasonably clear what Plaintiff means by "same or equivalent," the latter of which Gland avers is a legal term of art, and, therefore, denies all allegations using the phrase "same or equivalent." To the extent a further

response is required, Gland lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

Responses to Allegations Pertaining to Count I
Alleged Infringement of the '548 Patent

40. ARI realleges paragraphs 1–39 as if fully set forth herein.

RESPONSE: Gland incorporates its responses to paragraphs 1-39 as if fully set forth herein.

41. Gland Pharma's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '548 patent, constitutes direct and indirect infringement of the '548 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

RESPONSE: Denied.

42. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '548 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Gland Pharma's specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '548 patent.

RESPONSE: Denied.

43. On information and belief, Gland Pharma's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '548 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Products are especially made or adapted for use in infringing the '548 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

RESPONSE: Denied.

44. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '548 patent, or any later expiration of exclusivity for the '548 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

RESPONSE: Denied.

45. Gland Pharma has had knowledge of the '548 patent since at least the date Gland Pharma submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied. Allegations not expressly admitted are denied.

46. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Denied.

Responses to Allegations Pertaining to Count II
Alleged Infringement of the '022 Patent

47. ARI realleges paragraphs 1–46 as if fully set forth herein.

RESPONSE: Gland incorporates its responses to paragraphs 1- 46 as if fully set forth herein.

48. Gland Pharma's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '022 patent, constitutes infringement of the '022 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

RESPONSE: Denied.

49. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '022 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Gland Pharma's specific intent and encouragement, and will be conduct that Gland Pharma knows or

should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '022 patent.

RESPONSE: Denied.

50. On information and belief, Gland Pharma's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute induced infringement under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '022 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Products are especially made or adapted for use in infringing the '022 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

RESPONSE: Denied.

51. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '022 patent, or any later expiration of exclusivity for the '022 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

RESPONSE: Denied.

52. Gland Pharma has had knowledge of the '022 patent since at least the date Gland Pharma submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied. Allegations not expressly admitted are denied.

53. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Denied.

Responses to Allegations Pertaining to Count III
Alleged Infringement of the '565 Patent

54. ARI realleges paragraphs 1–54 [stet] as if fully set forth herein.

RESPONSE: Gland incorporates its responses to paragraphs 1- 53 as if fully set forth herein.

55. Gland Pharma's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '565 patent, constitutes direct and indirect infringement of the '565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

RESPONSE: Denied.

56. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Gland Pharma's specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '565 patent.

RESPONSE: Denied.

57. On information and belief, Gland Pharma's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '565 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Products are especially made or adapted for use in infringing the '565 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

RESPONSE: Denied.

58. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '565 patent, or any later expiration of exclusivity for the '565 patent

to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

RESPONSE: Denied.

59. Gland Pharma has had knowledge of the '565 patent since at least the date Gland Pharma submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

RESPONSE: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, denied. Allegations not expressly admitted are denied.

60. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Denied.

Responses to Allegations Pertaining to Count IV
Alleged Infringement of the '956 Patent

61. ARI realleges paragraphs 1–60 as if fully set forth herein.

RESPONSE: Gland incorporates its responses to paragraphs 1- 60 as if fully set forth herein.

62. Gland Pharma's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '956 patent, constitutes direct and indirect infringement of the '956 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

RESPONSE: Denied.

63. On information and belief, the ANDA Product, if the ANDA is approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '956 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Gland Pharma's specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '956 patent.

RESPONSE: Denied.

64. On information and belief, Gland Pharma's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '956 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Product is especially made or adapted for use in infringing the '956 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

RESPONSE: Denied.

65. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '956 patent, or any later expiration of exclusivity for the '956 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

RESPONSE: Denied.

66. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Denied.

Responses to Allegations Pertaining to Count V
Alleged Infringement of the '957

67. ARI realleges paragraphs 1–66 as if fully set forth herein.

RESPONSE: Gland incorporates its responses to paragraphs 1- 66 as if fully set forth herein.

68. Gland Pharma's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '957 patent, constitutes direct and indirect infringement of the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

RESPONSE: Denied.

69. On information and belief, the ANDA Product, if the ANDA is approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Gland Pharma or on its behalf, and will be administered by patients and/or medical

practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Gland Pharma's specific intent and encouragement, and will be conduct that Gland Pharma knows or should know will occur. On information and belief, Gland Pharma will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '957 patent.

RESPONSE: Denied.

70. On information and belief, Gland Pharma's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '957 patent, either literally or under the doctrine of equivalents. On information and belief, Gland Pharma intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Gland Pharma knows that the ANDA Product is especially made or adapted for use in infringing the '957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

RESPONSE: Denied.

71. ARI will be irreparably harmed if Gland Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

RESPONSE: Denied.

72. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFF'S REQUEST FOR RELIEF

All allegations in Plaintiff's Complaint not expressly admitted by Gland are hereby denied. Having answered Plaintiff's Complaint, Gland denies Plaintiff is entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Gland asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiff.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the product(s) that is the subject of Gland's ANDA has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the Patents-in-Suit.

SECOND SEPARATE DEFENSE

Each of claim of the Patents-in-Suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102 or 103, respectively, for example, for at least the reasons set forth in Gland's Notice Letters.

THIRD SEPARATE DEFENSE

Each claim of the Patents-in-Suit is invalid, pursuant to 35 U.S.C. § 112, as, for example, indefinite, not enabled and/or failing to provide adequate written description.

FOURTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the Patent-in-suit, and specifically prosecution history estoppel, Plaintiff is estopped from maintaining that any valid or enforceable claim of the Asserted Patents is infringed by the product that is the subject of Gland's ANDA.

FIFTH SEPARATE DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

SIXTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Gland hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the Patents-in-Suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

GLAND'S COUNTERCLAIM

1. Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Gland Pharma Limited ("Gland"), by and through its counsel, for its Counterclaim against Plaintiff, American Regent, Inc. (herein "ARI" or "Counterclaim-Defendant"), hereby states the following:

2. This is an action for a declaratory judgment of non-infringement and invalidity of the claims of U.S. Patent Nos. 11,786,548 ("'548 patent"), 11,975,022 ("'022 patent), 11,998,565 ("'565 patent), 12,150,956 ("'956 patent") and 12,150,957 ("'957" patent) (collectively, the '548, '022, '565, '956 and '957 patents are referred to herein as the "Counterclaim Patents-In-Suit") pursuant to the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment

Act, 28 U.S.C. §§ 2201, 2202, and provisions of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

3. Upon information and belief, true and complete copies of the '548, '022, '565, '956 and '957 patents are attached to the Defendant, Gland Pharma Limited's Answer to Complaint, Affirmative Defenses and Counterclaim as Exhibit A, B, C, D and E.

THE PARTIES

4. Counterclaim-Plaintiff, Gland Pharma Limited (herein, "Gland" or "Counterclaim Plaintiff") is a corporation organized and existing under the laws of India with a place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal MedchalMalkjgiri District, Hyderabad 500043, Telangana, India.

5. Upon information and belief, and based upon the Complaint filed in the above-referenced case, Counterclaim-Defendant, American Regent, Inc. (herein, "ARI" or "Counterclaim Defendant"), is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

JURISDICTION

6. This Court has subject matter jurisdiction over this Counterclaim for declaratory judgment pursuant to 28 US.C. §§ 1331, 1338(a), 2201and 2202, based on an actual controversy between Counterclaim-Plaintiff, on the one hand, and the Counterclaim-Defendant on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

7. This Court has personal jurisdiction over Counterclaim-Defendant based, *inter alia*, on the filing by Counterclaim-Defendant of the underlying action in this Court.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)(1) and 1400(b) because Counterclaim-Defendant initiated the underlying action in this District, and Gland did not challenge venue in this District.

ORANGE BOOK LISTING OF THE COUNTERCLAIM PATENT-IN-SUIT

9. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require New Drug Application ("NDA") holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

10. On information and belief, Counterclaim-Defendant holds NDA No. 209376 for Tralement® and Multrys® ("ARI NDA").

11. On information and belief, Counterclaim-Defendant owns and holds the exclusive right to enforce the Counterclaim Patents-In-Suit.

12. On information and belief, on October 17, 2023, the U.S. Patent and Trademark Office ("PTO") issued the '548 patent.

13. On information and belief, on May 7, 2024, the PTO issued the '022 patent.

14. On information and belief, on June 4, 2024, the PTO issued the '565 patent.

15. On information and belief, on November 26, 2024, the PTO issued the '956 patent.

16. On information and belief, on November 26, 2024, the PTO issued the '957 patent.

17. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(l), Counterclaim-Defendant caused the FDA to list the Counterclaim Patents-In-Suit in the Orange Book in connection with the ARI NDA.

18. By maintaining the listing of the Counterclaim Patent-In-Suit in the Orange Book, Counterclaim-Defendant represents to the world its intent to enforce the Counterclaim Patents-In-Suit against any person not licensed by ARI engaged in the manufacture, use, sale, or importation of Tralement® and Multrys® before the expiration of the Counterclaim Patents-in-Suit.

GLAND'S ABBREVIATED NEW DRUG APPLICATION

19. Gland filed ANDA No. 219632 (the "Gland ANDA") with the FDA. Gland's ANDA, as supplemented, includes a Paragraph IV Certification to the Counterclaim Patents-In-Suit, certifying that to the best of its knowledge that all of the claims of the Counterclaim Patents-In-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in the Gland ANDA.

20. On June 14, 2024, Gland properly notified ARI that Gland had submitted the Gland ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) as required in accordance with 21 U.S.C. § 355(j)(2)(B) ("Gland's June 14, 2024 Notice Letter"). Included with Gland's June 14, 2024 Notice Letter was an Offer of Confidential Access to Gland's ANDA in accordance with 21 U.S.C. § 355(j)(5)(C)(III).

21. On December 17, 2024, Gland properly notified ARI that Gland had submitted the Gland ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) as required in accordance with 21 U.S.C. § 355(j)(2)(B) ("Gland's December 17, 2024 Notice Letter"). Included with Gland's December 17, 2024 Notice Letter was an Offer of Confidential Access to Gland's ANDA in accordance with 21 U.S.C. § 355(j)(5)(C)(III).

THE PRESENCE OF A CASE OR CONTROVERSY

22. By maintaining the Orange Book listing of the Counterclaim Patents-In-Suit in connection with the ARI NDA, Counterclaim-Defendant indicates its intent to enforce the Counterclaim Patents-In-Suit.

23. By maintaining the Orange Book listing of the Counterclaim Patents-In-Suit in connection with the ARI NDA, Counterclaim-Defendant is preserving its ability to pursue Gland for a claim of infringement of the Counterclaim Patents-In-Suit at any time.

24. Resolving Gland's Counterclaim is necessary to eliminate all foreseeable potential risk that Plaintiff will later assert the Counterclaim Patents-In-Suit to try to frustrate Gland's ability to market its ANDA product.

25. There has been, and is now, an actual and justiciable controversy between Counterclaim-Plaintiff on the one hand, and Counterclaim-Defendant, on the other hand, as to whether the products disclosed in Gland's ANDA infringe the Counterclaim Patents-In-Suit, and whether any claim in the Counterclaim Patents-In-Suit is valid or enforceable.

26. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendant and Counterclaim-Plaintiff as to whether the claims of the Counterclaim Patents-In-Suit are invalid and/or not infringed by Counterclaim-Plaintiff.

27. This is an exceptional case entitling Gland to an award of its reasonable attorney's fees in connection with the underlying Action and this Counterclaim in accordance with 35 U.S.C. § 285.

COUNT I
(Declaratory Judgment of Non-Infringement of the '548 Patent)

28. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-27 of the Counterclaim, above, as if fully set forth herein.

29. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists

between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the Counterclaim Patent-In-Suit and the claims of the Counterclaim Patents-In-Suit.

30. Gland's ANDA and the product described therein do not and would not, following FDA approval, infringe any valid claims of the '548 patent either directly or indirectly.

31. Counterclaim-Plaintiff is entitled to a declaration that Gland's ANDA and the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA product does not infringe any valid claims of the '548 patent.

COUNT II
(Declaratory Judgment of Invalidity/Unenforceability of the '548 Patent)

32. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-31 of the Counterclaim, above, as if fully set forth herein.

33. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the Counterclaim-Plaintiff and Counterclaim-Defendant concerning the claims of the Counterclaim Patents-In-Suit.

34. The '548 patent is invalid at least on one or more of the grounds that the '548 patent claims and the inventions described therein are anticipated by one or more prior art reference as of the time of the alleged inventions, pursuant to 35 U.S.C. § 102, would have been obvious to persons of ordinary skill in the art as of the time of the invention, pursuant to 35 U.S.C. § 103, and/or fail to satisfy the definiteness, written description and/or enablement requirements set forth in 35 U.S.C. § 112.

35. Counterclaim-Plaintiff is entitled to a declaration that the claims of the '548 patent are invalid under one or more provisions of 35 U.S.C. §§ 102, 103, or 112, or other judicially-created bases for invalidation/unenforceability.

COUNT III
(Declaratory Judgment of Non-Infringement of the '022 Patent)

36. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-35 of the Counterclaim, above, as if fully set forth herein.

37. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the Counterclaim Patent-In-Suit and the claims of the Counterclaim Patents-In-Suit.

38. Gland's ANDA and the product described therein do not and would not, following FDA approval, infringe any valid claims of the '022 patent either directly or indirectly.

39. Counterclaim-Plaintiff is entitled to a declaration that Gland's ANDA and the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA product does not infringe any valid claims of the '022 patent.

COUNT IV
(Declaratory Judgment of Invalidity/Unenforceability of the '022 Patent)

40. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-39 of the Counterclaim, above, as if fully set forth herein.

41. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual,

substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the Counterclaim-Plaintiff and Counterclaim-Defendant concerning the claims of the Counterclaim Patents-In-Suit.

42. The ’022 patent is invalid at least on one or more of the grounds that the ’022 patent claims and the inventions described therein are anticipated by one or more prior art reference as of the time of the alleged inventions, pursuant to 35 U.S.C. § 102, would have been obvious to persons of ordinary skill in the art as of the time of the invention, pursuant to 35 U.S.C. § 103, and/or fail to satisfy the definiteness, written description and/or enablement requirements set forth in 35 U.S.C. § 112.

43. Counterclaim-Plaintiff is entitled to a declaration that the claims of the ’022 patent are invalid under one or more provisions of 35 U.S.C. §§ 102, 103, or 112, or other judicially-created bases for invalidation/unenforceability.

COUNT V
(Declaratory Judgment of Non-Infringement of the ’565 Patent)

44. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-43 of the Counterclaim, above, as if fully set forth herein.

45. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the Counterclaim Patent-In-Suit and the claims of the Counterclaim Patents-In-Suit.

46. Gland's ANDA and the product described therein do not and would not, following FDA approval, infringe any valid claims of the '565 patent either directly or indirectly.

47. Counterclaim-Plaintiff is entitled to a declaration that Gland's ANDA and the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA product does not infringe any valid claims of the '565 patent.

COUNT VI
(Declaratory Judgment of Invalidity/Unenforceability of the '565 Patent)

48. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-47 of the Counterclaim, above, as if fully set forth herein.

49. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the Counterclaim-Plaintiff and Counterclaim-Defendant concerning the claims of the Counterclaim Patents-In-Suit.

50. The '565 patent is invalid at least on one or more of the grounds that the '565 patent claims and the inventions described therein are anticipated by one or more prior art reference as of the time of the alleged inventions, pursuant to 35 U.S.C. § 102, would have been obvious to persons of ordinary skill in the art as of the time of the invention, pursuant to 35 U.S.C. § 103, and/or fail to satisfy the definiteness, written description and/or enablement requirements set forth in 35 U.S.C. § 112.

51. Counterclaim-Plaintiff is entitled to a declaration that the claims of the '565 patent are invalid under one or more provisions of 35 U.S.C. §§ 102, 103, or 112, or other judicially-created bases for invalidation/unenforceability.

COUNT VII
(Declaratory Judgment of Non-Infringement of the '956 Patent)

52. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-51 of the Counterclaim, above, as if fully set forth herein.

53. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the Counterclaim Patent-In-Suit and the claims of the Counterclaim Patents-In-Suit.

54. Gland's ANDA and the product described therein do not and would not, following FDA approval, infringe any valid claims of the '956 patent either directly or indirectly.

55. Counterclaim-Plaintiff is entitled to a declaration that Gland's ANDA and the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA product does not infringe any valid claims of the '956 patent.

COUNT VIII
(Declaratory Judgment of Invalidity/Unenforceability of the '956 Patent)

56. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-55 of the Counterclaim, above, as if fully set forth herein.

57. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists

between the Counterclaim-Plaintiff and Counterclaim-Defendant concerning the claims of the Counterclaim Patents-In-Suit.

58. The ’956 patent is invalid at least on one or more of the grounds that the ’956 patent claims and the inventions described therein are anticipated by one or more prior art reference as of the time of the alleged inventions, pursuant to 35 U.S.C. § 102, would have been obvious to persons of ordinary skill in the art as of the time of the invention, pursuant to 35 U.S.C. § 103, and/or fail to satisfy the definiteness, written description and/or enablement requirements set forth in 35 U.S.C. § 112.

59. Counterclaim-Plaintiff is entitled to a declaration that the claims of the ’956 patent are invalid under one or more provisions of 35 U.S.C. §§ 102, 103, or 112, or other judicially-created bases for invalidation/unenforceability.

COUNT IX
(Declaratory Judgment of Non-Infringement of the ’957 Patent)

60. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-59 of the Counterclaim, above, as if fully set forth herein.

61. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the Counterclaim Patent-In-Suit and the claims of the Counterclaim Patents-In-Suit.

62. Gland’s ANDA and the product described therein do not and would not, following FDA approval, infringe any valid claims of the ’957 patent either directly or indirectly.

63. Counterclaim-Plaintiff is entitled to a declaration that Gland's ANDA and the manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA product does not infringe any valid claims of the '957 patent.

COUNT X
(Declaratory Judgment of Invalidity/Unenforceability of the '957 Patent)

64. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-63 of the Counterclaim, above, as if fully set forth herein.

65. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the Counterclaim-Plaintiff and Counterclaim-Defendant concerning the claims of the Counterclaim Patents-In-Suit.

66. The '957 patent is invalid at least on one or more of the grounds that the '957 patent claims and the inventions described therein are anticipated by one or more prior art reference as of the time of the alleged inventions, pursuant to 35 U.S.C. § 102, would have been obvious to persons of ordinary skill in the art as of the time of the invention, pursuant to 35 U.S.C. § 103, and/or fail to satisfy the definiteness, written description and/or enablement requirements set forth in 35 U.S.C. § 112.

67. Counterclaim-Plaintiff is entitled to a declaration that the claims of the '957 patent are invalid under one or more provisions of 35 U.S.C. §§ 102, 103, or 112, or other judicially-created bases for invalidation/unenforceability.

PRAYER FOR RELIEF

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

a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiff/Counterclaim Defendant therein;

b) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Gland's ANDA Products has not infringed, does not infringe, and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any claims of the Patents-in-Suit;

c) Declaring that the claims of the Patents-in-Suit are invalid;

d) Granting Gland judgment in its favor on Counterclaim Defendant's claims;

e) Declaring that this is an exceptional case in favor of Gland pursuant to 35 U.S.C. § 285;

f) Declaring that Gland is the prevailing party and awarding costs, attorneys' fees, and expenses to Gland; and

g) Awarding Gland such other and further relief to which it may be entitled.

WHEREFORE, Gland hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the Patents-in-Suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: January 23, 2025

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