IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MELINTA THERAPEUTICS, LLC, MELINTA SUBSIDIARY CORP., and REMPEX PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. 25-cv-3676
v.	)	
GLAND PHARMA LIMITED,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Melinta Therapeutics, LLC, Melinta Subsidiary Corp., and Rempex Pharmaceuticals, Inc. (collectively, "Melinta" or "Plaintiffs"), for their Complaint against Defendant Gland Pharma Limited ("Gland" or "Defendant"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the Patent Laws of the United States. 35 U.S.C. § 100 et seq., involving U.S. Patent Nos. 9,278,105 (the "'105 patent"), attached as Exhibit A, 9,084,802 (the "'802 patent"), attached as Exhibit B, 11,944,634 (the "'634 patent"), attached as Exhibit C, and 12,161,656 (the "'656 patent"), attached as Exhibit D (collectively, the "patents-in-suit"). This action arises out of Defendant's submission of ANDA No. 220209 (the "Gland ANDA") seeking FDA approval to manufacture, use, and/or sell a generic version of Melinta's Minocin® (minocycline) for injection, also known as Minocin® IV ("Minocin®") product before the expiration of the patents-in-suit.

THE PARTIES

2. Plaintiff Melinta Therapeutics, LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 389 Interpace Parkway, Suite 450, Parsippany, New Jersey 07054. Melinta Therapeutics, LLC was formed in November 2020 from a conversion of Melinta Therapeutics, Inc., a Delaware corporation.

3. Plaintiff Melinta Subsidiary Corp. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 389 Interpace Parkway, Suite 450, Parsippany, New Jersey 07054. Melinta Subsidiary Corp. is a wholly owned subsidiary of Melinta Therapeutics, LLC.

4. Plaintiff Rempex Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 389 Interpace Parkway, Suite 450, Parsippany, New Jersey 07054. Rempex Pharmaceuticals, Inc. is a wholly owned subsidiary of Melinta Therapeutics, LLC.

5. Upon information and belief, Defendant is a corporation organized and existing under the laws of India, having its 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.

6. Upon information and belief, Defendant, by itself and/or through its affiliates and agents, is in the business of, among other things, the development, manufacture, marketing, importing, sale, and distribution of generic pharmaceutical products throughout the United States, including in Illinois.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

8. This Court has personal jurisdiction over Defendant at least because, upon information and belief: Defendant is the owner of the Gland ANDA and is seeking FDA approval to engage in the commercial use, sale, and/or distribution of 100 mg/vial generic minocycline hydrochloride for injection (the "Gland ANDA Product") throughout the United States, including in Illinois, before the expiration of the patents-in-suit; by submitting the Gland ANDA to FDA Defendant has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led and will lead to foreseeable harm and injury to Plaintiffs in Illinois and throughout the United States; if the Gland ANDA receives final approval, the Gland ANDA Product will be marketed, sold, offered for sale, distributed, and/or used by Defendant in Illinois; Defendant's activities with respect to the Gland ANDA product will be purposefully directed at Illinois (either directly or indirectly, *e.g.*, through wholesalers, distributors, etc.), and Defendant will derive revenue therefrom; the Gland ANDA Product will be prescribed by physicians practicing in Illinois and/or administered to patients in Illinois; Defendant, either directly or through its affiliates, regularly and continuously does and solicits business in Illinois, engages in other persistent courses of conduct in Illinois, and/or derives substantial revenue from services or things used or consumed in Illinois, including by selling its pharmaceutical products in Illinois, and therefore can reasonably expect to be subject to jurisdiction in the Illinois courts; Defendant conducts marketing and sales activities in Illinois, including but not limited to distribution, marketing, and sales of pharmaceutical products to Illinois residents that are continuous and systematic.

9. This Court further has personal jurisdiction over Defendant by virtue of the fact that Defendant has previously submitted to the jurisdiction and venue of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in a civil action for patent infringement, including *e.g.*, *Allergan, Inc. et al. v. Gland Pharma Limited*, C.A. 20-cv-4094 (N.D. Ill.) (D.I. 21).

10. Alternatively, this Court may exercise jurisdiction over Defendant pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (2) Defendant is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Defendant has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Defendant satisfies due process.

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

12. Venue is proper in this district for Defendant because, *inter alia*, Defendant is a foreign corporation not residing in any United States district and may be sued in any judicial district.

BACKGROUND

Plaintiffs' NDA and the Patents-in-Suit

13. Plaintiffs (via Rempex Pharmaceuticals, Inc.) are the owner of NDA No. 050444 concerning 100 mg/vial minocycline hydrochloride for injection, marketed under the trade name Minocin® (minocycline) for injection. Minocin® is indicated in the treatment of certain bacterial infections.

14. The '105 patent, titled "Tetracycline Compositions," issued on March 8, 2016. The '105 patent was assigned to Plaintiffs. The '105 patent describes and claims methods of treating bacterial infection comprising, *inter alia*, intravenous administration of compositions

comprising 7-dimethylamino-tetracyline antibiotic and a magnesium cation, with a certain molar ratio, pH, and osmolality.

15. The ’802 patent, titled “Tetracycline Compositions,” issued on July 21, 2015. The ’802 patent was assigned to Plaintiffs. The ’802 patent describes and claims methods of treating bacterial infection consisting of intravenous administration of compositions consisting of minocycline, a magnesium cation, and a base, with a certain molar ratio, pH, and other properties.

16. The ’634 patent, titled “Tetracycline Compositions,” issued on April 2, 2024. The ’634 patent was assigned to Plaintiffs. The ’634 patent describes and claims formulations comprising, *inter alia*, minocycline and a magnesium cation, with a certain molar ratio, pH, and other properties.

17. The ’656 patent, titled “Tetracycline Compositions,” issued on December 10, 2024. The ’656 patent was assigned to Plaintiffs. The ’656 patent describes and claims formulations consisting essentially of, *inter alia*, minocycline and a magnesium cation, with a certain molar ratio, pH, and other properties.

18. Plaintiffs own the patents-in-suit.

19. The patents-in-suit are listed in the FDA’s “Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations” in connection with NDA No. 050444 for Minocin®.

20. The ’105 and ’802 patents were at issue in *Melinta Therapeutics, LLC et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:21-cv-2636 and 1:21-cv-05995 (N.D. Ill.) (the “Nexus Litigation”). Following a four-day bench trial, on November 15, 2024, the District Court issued

findings of fact and conclusions of law that the asserted claims of the ’105 and ’802 patents are valid and infringed.

Defendant’s ANDA and Notice Letter

21. Upon information and belief, Defendant prepared and submitted the Gland ANDA to the FDA with a paragraph IV certification seeking approval to manufacture, use or sell the Gland ANDA Product before the expiration of the patents-in-suit.

22. Defendant’s February 21, 2025 Notice Letter purported to notify Plaintiffs that its ANDA contained a paragraph IV certification pursuant to 21 U.S.C. § 355(j) alleging that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the Gland ANDA Product, and purported to attach a “detailed statement of the legal and factual basis” for the paragraph IV certification.

23. Defendant’s February 21, 2025 Notice Letter identifies the following prior art references as allegedly rendering the claims of the ’105, ’802, ’634, and ’656 patents obvious: (a) the prior art minocycline intravenous (IV) formulation (product approved in 1972); (b) CN101301268A (CN’268); (c) Gibbs (EP0337733A2); (d) Weidenheimer et al. (US3335055); (e) Beutel et al. (US3674859); (f) Akazawa et al. (US3846548); (g) Noseworthy et al. (US3957980); (h) Guy Berthon et al.: Metal Ion-Tetracycline Interactions in Biological Fluids; and (i) GB1131007A (GB’007) (collectively, “Defendant’s References”).

24. All but one of Defendant’s References were raised and considered by the District Court in the Nexus Litigation. Defendant’s February 21, 2025 Notice Letter arguments that the ’105, ’802, ’634, and ’656 patents are obvious over Defendant’s References are nearly identical to the arguments considered and decided by the District Court in the Nexus Litigation. During the four-day bench trial, substantial evidence was presented about those references. The District Court’s November 15, 2024 findings of fact and conclusions of laws found the claims of

the ’105 and ’802 patents not invalid, including finding them not obvious over Defendant’s References. For purposes of obviousness, the claims of the ’634 and ’656 patents are not materially different from those of the ’105 and ’802 patents, all of which are in the same patent family. Although Defendant’s February 21, 2025 Notice Letter was sent more than three months after the findings of fact and conclusions of law published, Defendant neither mentioned the Nexus Litigation nor attempted to distinguish its obviousness arguments from the District Court’s findings of fact and conclusions.

25. This action was filed within 45 days of Plaintiffs’ receipt of Defendant’s February 21, 2025 Notice Letter. Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5).

COUNT I – INFRINGEMENT OF THE ’105 PATENT

26. Plaintiffs repeat and reallege each of the foregoing paragraphs 1-22, as if fully set forth herein.

27. Under 35 U.S.C. § 271(e)(2)(A), Defendant’s submission of ANDA No. 220209 with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, sale, and/or importation of the Gland ANDA Product before the expiration of the ’105 patent was an act of infringement of the ’105 patent.

28. Upon information and belief, Defendant had actual knowledge of the ’105 patent prior to its ANDA submission and was aware that the filing of the Gland ANDA would constitute an act of infringement of the ’105 patent.

29. If Defendant’s ANDA is approved, upon information and belief, Defendant’s manufacture, use, offer to sell, sale, and/or importation of the Gland ANDA Product before the expiration of the ’105 patent would infringe, either literally and/or under the doctrine of equivalents, one or more claims of the ’105 patent pursuant to 35 U.S.C. § 271(a); would induce

infringement of one or more claims of the '105 patent pursuant to 35 U.S.C. § 271(b); and/or would constitute contributory infringement of one or more claims of the '105 patent pursuant to 35 U.S.C. § 271(c). If the Gland ANDA is approved, upon information and belief, Defendant specifically intends to and will infringe, actively induce infringement of, and/or contribute to infringement of the '105 patent, and intends to and will do so immediately upon approval.

30. Upon information and belief, the Gland ANDA Product will contain the active ingredient minocycline, which is a 7-dimethylamino-tetracycline antibiotic. Upon information and belief, the Gland ANDA Product will have the same formulation and properties as Minocin®. Pursuant to 21 C.F.R. § 314.94(a)(9)(iii), an ANDA drug product intended for parenteral use "must contain the same inactive ingredients and in the same concentration as the reference listed drug . . . ."

31. Upon information and belief, the Gland ANDA product will be accompanied by a product label, prescribing information, and/or instructions for use that will substantially copy the Minocin® label. Upon information and belief, physicians will follow such instructions for use when administering the Gland ANDA Product. Upon information and belief, the label for the Gland ANDA product will induce physicians to treat bacterial infections in a manner within the scope of one or more claims of the '105 patent. Upon information and belief, Defendant knows that physicians who act according to the label for the Gland ANDA Product will infringe one or more claims of the '105 patent, and Defendant has specific intent to actively encourage physicians to infringe one or more claims of the '105 patent. If the Gland ANDA is approved, upon information and belief, physicians will in fact directly infringe one or more claims of the '105 patent.

32. Defendant's Notice Letter does not allege non-infringement of the '105 patent.

33. Defendant's Notice Letter does not include any allegation that a physician using the Gland ANDA Product following the accompanying label will not directly infringe the '105 patent.

34. By not identifying non-infringement defenses for the '105 patent, Defendant admits that the Gland ANDA Product meets all limitations of its claims.

35. Upon information and belief, Defendant does not have a reasonable basis for believing that the Gland ANDA Product would not infringe the '105 patent.

36. Upon information and belief, Defendant copied the claimed invention of the '105 patent.

37. Upon information and belief, there are no substantial non-infringing uses of the Gland ANDA Product, and therefore the marketing of the Gland ANDA Product will contribute to infringement of one or more claims of the '105 patent.

38. Upon information and belief, Defendant knows that the Gland ANDA Product is especially made or adapted for use in infringing the '105 patent and is not suitable for substantial non-infringing use.

39. Upon information and belief, Defendant's contentions regarding invalidity of the '105 patent in its "detailed statement of the legal and factual basis" attached to its Notice Letter are without merit and lack a good-faith basis.

40. Plaintiffs are entitled to relief pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Gland ANDA must be a date

which is not earlier than the later of the expiration date of the ’105 patent or the expiration date of any exclusivity to which Plaintiffs are or become entitled.

41. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’105 patent. Plaintiffs do not have an adequate remedy at law. Considering the balance of hardships between Plaintiffs and Defendant, injunctive relief is warranted. The public interest favors entry of an injunction.

42. Plaintiffs reserve the right to assert that this case is exceptional and that Plaintiffs are entitled to an award of reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT II – INFRINGEMENT OF THE ’802 PATENT

43. Plaintiffs repeat and reallege each of the foregoing paragraphs 1-22, as if fully set forth herein.

44. Under 35 U.S.C. § 271(e)(2)(A), Defendant’s submission of ANDA No. 220209 with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, sale, and/or importation of the Gland ANDA Product before the expiration of the ’802 patent was an act of infringement of the ’802 patent.

45. Upon information and belief, Defendant had actual knowledge of the ’802 patent prior to its ANDA submission and was aware that the filing of the Gland ANDA would constitute an act of infringement of the ’802 patent.

46. If the Gland ANDA is approved, upon information and belief, Defendant’s manufacture, use, offer to sell, sale, and/or importation of the Gland ANDA Product before the expiration of the ’802 patent would infringe, either literally and/or under the doctrine of equivalents, one or more claims of the ’802 patent pursuant to 35 U.S.C. § 271(a); would induce infringement of one or more claims of the ’802 patent pursuant to 35 U.S.C. § 271(b); and/or would constitute contributory infringement of one or more claims of the ’802 patent pursuant to 35 U.S.C.

§ 271(c). If the Gland ANDA is approved, upon information and belief, Defendant specifically intends to and will infringe, actively induce infringement of, and/or contribute to infringement of the ’802 patent, and intends to and will do so immediately upon approval.

47. Upon information and belief, the Gland ANDA Product will contain the active ingredient minocycline, which is a 7-dimethylamino-tetracycline antibiotic. Upon information and belief, the Gland ANDA Product will have the same formulation and properties as Minocin®. Pursuant to 21 C.F.R. § 314.94(a)(9)(iii), an ANDA drug product intended for parenteral use “must contain the same inactive ingredients and in the same concentration as the reference listed drug . . . .”

48. Upon information and belief, the Gland ANDA product will be accompanied by a product label, prescribing information, and/or instructions for use that will substantially copy the Minocin® label. Upon information and belief, physicians will follow such instructions for use when administering the Gland ANDA Product. Upon information and belief, the label for the Gland ANDA product will induce physicians to treat bacterial infections in a manner within the scope of one or more claims of the ’802 patent. Upon information and belief, Defendant knows that physicians who act according to the label for the Gland ANDA Product will infringe one or more claims of the ’802 patent, and Defendant has specific intent to actively encourage physicians to infringe one or more claims of the ’802 patent. If the Gland ANDA is approved, upon information and belief, physicians will in fact directly infringe one or more claims of the ’802 patent.

49. Defendant’s Notice Letter does not allege non-infringement of the ’802 patent.

50. Defendant's Notice Letter does not include any allegation that a physician using the Gland ANDA Product following the accompanying label will not directly infringe the '802 patent.

51. By not identifying non-infringement defenses for the '802 patent, Defendant admits that the Gland ANDA Product meets all limitations of its claims.

52. Upon information and belief, Defendant does not have a reasonable basis for believing that the Gland ANDA Product would not infringe the '802 patent.

53. Upon information and belief, Defendant copied the claimed invention of the '802 patent.

54. Upon information and belief, there are no substantial non-infringing uses of the Gland ANDA Product, and therefore the marketing of the Gland ANDA Product will contribute to infringement of one or more claims of the '802 patent.

55. Upon information and belief, Defendant knows that the Gland ANDA Product is especially made or adapted for use in infringing the '802 patent and is not suitable for substantial non-infringing use.

56. Upon information and belief, Defendant's contentions regarding invalidity of the '802 patent in its "detailed statement of the legal and factual basis" attached to its Notice Letter are without merit and lack a good-faith basis.

57. Plaintiffs are entitled to relief pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Gland ANDA must be a date which is not earlier than the later of the expiration date of the '802 patent or the expiration date of any exclusivity to which Plaintiffs are or become entitled.

58. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’802 patent. Plaintiffs do not have an adequate remedy at law. Considering the balance of hardships between Plaintiffs and Defendant, injunctive relief is warranted. The public interest favors entry of an injunction.

59. Plaintiffs reserve the right to assert that this case is exceptional and that Plaintiffs are entitled to an award of reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT III – INFRINGEMENT OF THE ’634 PATENT

60. Plaintiffs repeat and reallege each of the foregoing paragraphs 1-22, as if fully set forth herein.

61. Under 35 U.S.C. § 271(e)(2)(A), Defendant’s submission of ANDA No. 220209 with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, sale, and/or importation of the Gland ANDA Product before the expiration of the ’634 patent was an act of infringement of the ’634 patent.

62. Upon information and belief, Defendant had actual knowledge of the ’634 patent prior to its ANDA submission and was aware that the filing of the Gland ANDA would constitute an act of infringement of the ’634 patent.

63. If the Gland ANDA is approved, upon information and belief, Defendant’s manufacture, use, offer to sell, sale, and/or importation of the Gland ANDA Product before the expiration of the ’634 patent would infringe, either literally and/or under the doctrine of equivalents, one or more claims of the ’634 patent pursuant to 35 U.S.C. § 271(a). If the Gland ANDA is approved, upon information and belief, Defendant specifically intends to and will infringe the ’634 patent, and intends to and will do so immediately upon approval.

64. Upon information and belief, the Gland ANDA Product will contain the active ingredient minocycline, which is a 7-dimethylamino-tetracycline antibiotic. Upon

information and belief, the Gland ANDA Product will have the same formulation and properties as Minocin®. Pursuant to 21 C.F.R. § 314.94(a)(9)(iii), an ANDA drug product intended for parenteral use "must contain the same inactive ingredients and in the same concentration as the reference listed drug . . . ."

65. Defendant's Notice Letter does not allege non-infringement of the '634 patent.

66. By not identifying non-infringement defenses for the '634 patent, Defendant admits that the Gland ANDA Product meets all limitations of its claims.

67. Upon information and belief, Defendant does not have a reasonable basis for believing that the Gland ANDA Product would not infringe the '634 patent.

68. Upon information and belief, Defendant copied the claimed invention of the '634 patent.

69. Upon information and belief, Defendant's contentions regarding invalidity of the '634 patent in its "detailed statement of the legal and factual basis" attached to its Notice Letter are without merit and lack a good-faith basis.

70. Plaintiffs are entitled to relief pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Gland ANDA must be a date which is not earlier than the later of the expiration date of the '634 patent or the expiration date of any exclusivity to which Plaintiffs are or become entitled.

71. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '634 patent. Plaintiffs do not have an adequate remedy at law. Considering the balance of hardships between Plaintiffs and Defendant, injunctive relief is warranted. The public interest favors entry of an injunction.

72. Plaintiffs reserve the right to assert that this case is exceptional and that Plaintiffs are entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV – INFRINGEMENT OF THE '656 PATENT

73. Plaintiffs repeat and reallege each of the foregoing paragraphs 1-22, as if fully set forth herein.

74. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 220209 with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, sale, and/or importation of the Gland ANDA Product before the expiration of the '656 patent was an act of infringement of the '656 patent.

75. Upon information and belief, Defendant had actual knowledge of the '656 patent prior to its ANDA submission and was aware that the filing of the Gland ANDA would constitute an act of infringement of the '656 patent.

76. If the Gland ANDA is approved, upon information and belief, Defendant's manufacture, use, offer to sell, sale, and/or importation of the Gland ANDA Product before the expiration of the '656 patent would infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '656 patent pursuant to 35 U.S.C. § 271(a). If the Gland ANDA is approved, upon information and belief, Defendant specifically intends to and will infringe the '656 patent, and intends to and will do so immediately upon approval.

77. Upon information and belief, the Gland ANDA Product will contain the active ingredient minocycline, which is a 7-dimethylamino-tetracycline antibiotic. Upon information and belief, the Gland ANDA Product will have the same formulation and properties as Minocin®. Pursuant to 21 C.F.R. § 314.94(a)(9)(iii), an ANDA drug product intended for parenteral use "must contain the same inactive ingredients and in the same concentration as the reference listed drug . . . ."

78. Defendant's Notice Letter does not allege non-infringement of the '656 patent.

79. By not identifying non-infringement defenses for the '656 patent, Defendant admits that the Gland ANDA Product meets all limitations of its claims.

80. Upon information and belief, Defendant does not have a reasonable basis for believing that the Gland ANDA Product would not infringe the '656 patent.

81. Upon information and belief, Defendant copied the claimed invention of the '656 patent.

82. Upon information and belief, Defendant's contentions regarding invalidity of the '656 patent in its "detailed statement of the legal and factual basis" attached to its Notice Letter are without merit and lack a good-faith basis.

83. Plaintiffs are entitled to relief pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Gland ANDA must be a date which is not earlier than the later of the expiration date of the '656 patent or the expiration date of any exclusivity to which Plaintiffs are or become entitled.

84. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '656 patent. Plaintiffs do not have an adequate remedy at law. Considering the balance of hardships between Plaintiffs and Defendant, injunctive relief is warranted. The public interest favors entry of an injunction.

85. Plaintiffs reserve the right to assert that this case is exceptional and that Plaintiffs are entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that Defendant's submission of ANDA No. 220209 infringed the '105 patent, '802 patent, '634 patent, and '656 patent pursuant to 35 U.S.C. § 271(e)(2)(A);

C. Judgment that the commercial manufacture, use, offer for sale, and/or sale of the Gland ANDA Product within the United States, and/or the importation of the Gland ANDA Product into the United States, will infringe the '105 patent, '802 patent, '634 patent, and '656 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

D. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4) restraining and enjoining Defendant and its affiliates, subsidiaries, officers, agents, attorneys, employees, and those acting in privity or concert with them, from the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Gland ANDA Product until after the expiration of the '105 patent, '802 patent, '634 patent, and '656 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. An order pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any final FDA approval of the Gland ANDA must be a date that is not earlier than the expiration of the '105 patent, '802 patent, '634 patent, and '656 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

F. An award of money damages and any other appropriate relief if Defendant makes, uses, sells, or offers to sell the Gland ANDA Product within the United States, or imports the Gland ANDA Product into the United States, prior to the expiration of the '105 patent, '802 patent, '634 patent, or '656 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

G. Judgment that the claims of the '105 patent, '802 patent, '634 patent, and '656 patent are valid and enforceable;

H. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

I. Judgment that Plaintiffs are entitled to costs and expenses in this action; and

J. An award of such other and further relief as this Court deems just and proper.

April 4, 2025

POLSINELLI PC

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